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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

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

For The Fiscal Year Ended December 31, 2015

OR

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

COMMISSION FILE NUMBER: 001-34256

HEARTWARE INTERNATIONAL, INC.

(Exact name of registrant as specified in its charter)

Delaware	**26-3636023**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

500 Old Connecticut Path, Building A
Framingham, Massachusetts 01701
+1 508 739 0950

(Address of principal executive offices) (Zip Code)
(Registrant's telephone number, including area code)

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

Title of Each Class	**Name of Each Exchange on which Registered**
Common Stock, $0.001 Par Value Per Share	**The NASDAQ Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act:
None
(Title of class)

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 Section 15(d) of the Exchange 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 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting 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	☐

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

The aggregate market value of the registrant's outstanding common stock held by non-affiliates computed by reference to the closing sale price of the common stock reported on the NASDAQ Stock Market as of June 30, 2015, the last business day of the registrant's second fiscal quarter, was approximately $1.25 billion.

As of February 25, 2016, the registrant had 17,533,606 shares of common stock, par value $0.001, issued and outstanding.

Documents Incorporated By Reference

Portions of the registrant's definitive proxy statement to be delivered to stockholders in connection with the registrant's 2016 Annual Meeting of Stockholders are incorporated herein by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2015.

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Unless the context requires otherwise, references in this Annual Report on Form 10-K to "HeartWare," "the Company," "HeartWare Group," "we," "us" and "our" refer to HeartWare International, Inc. and its consolidated direct and indirect subsidiaries.

Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements are based on our management's beliefs, assumptions and expectations and on information currently available to our management. Generally, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements, which generally are not historical in nature. All statements that address operating or financial performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation:

- our ability to implement systemic improvements necessary to satisfactorily address the observations cited in the June 2, 2014 warning letter we received from the United States Food and Drug Administration ("FDA") as well as other comments from the FDA;
- our expectations with respect to submissions to and approvals from regulatory bodies, such as the FDA;
- our ability to operate our business in compliance with regulatory requirements and to implement appropriate corrective and preventive actions;
- our expectations with respect to our clinical trials, including enrollment in, completion of, or outcomes of our clinical trials as well as approval of new clinical trials and continued access or supplemental protocols with respect to our existing clinical trials;
- our expectations with respect to the integrity or capabilities of our intellectual property position;
- our ability and plans to commercialize our existing products and respond to competitive pressures;
- our ability and plans to develop and commercialize new products and the expected features, functionalities and benefits of these products;
- our estimates regarding our capital requirements and financial performance, including earnings fluctuation and cash availability; and
- our ability to manage the costs and achieve the benefits of our strategic initiatives including acquired companies and technologies.

Our management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on our forward-looking statements because they speak only as of the date when made. We do not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by federal securities laws and the rules and regulations of the Securities and Exchange Commission ("SEC"). We may not actually achieve the plans, projections or expectations disclosed in our forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including without limitation those described in Part I, Item 1A. "Risk Factors" and elsewhere in this report and those described from time to time in our filings with the SEC. Investors should read this entire Annual Report on Form 10-K and consult their respective financial, legal or other professional advisers in relation to the subject matter herein, especially as it pertains to our risks and uncertainties outlined in Part I, Item 1A. "Risk Factors" of this Annual Report on Form 10-K, together with the information provided in our other public filings with the SEC.

Corporate Information

HeartWare International, Inc. was incorporated in Delaware on July 29, 2008 and became the successor to HeartWare Limited, an Australian corporation, on November 13, 2008, as a result of a redomiciliation of HeartWare Limited from Australia to Delaware. Following the redomiciliation, HeartWare International, Inc. became the ultimate parent company of the HeartWare Group. On February 24, 2009, common shares of HeartWare International, Inc. were listed for trading on the NASDAQ Global Market and commenced trading on the following day.

We further discuss our corporate history under "Business—Corporate History."

Our corporate headquarters is located at 500 Old Connecticut Path, Building A, Framingham, Massachusetts. Our telephone number is 1-508-739-0950. Our website address is www.heartware.com. We make available on this website, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports as soon as reasonably practicable after we electronically file or furnish these materials to the Securities and Exchange Commission. We have included our website address in this Annual Report on Form 10-K as an inactive textual reference only. The information on, or that can be accessed through, our website is not part of this Annual Report on Form 10-K.

In addition to our corporate headquarters, our principal facilities include our manufacturing and operations facility in Miami Lakes, Florida, our innovation center in Arden Hills, Minnesota and our distribution and customer service facility in Hannover, Germany. As of December 31, 2015, we had approximately 625 employees worldwide.

Currency

Unless indicated otherwise in this Annual Report on Form 10-K, all references to "$", "U.S.$" or "dollars" refer to United States dollars, the lawful currency of the United States of America. References to "AU$" refer to Australian dollars, the lawful currency of the Commonwealth of Australia. References to "€" or "Euros" means Euros, the single currency of Participating Member States of the European Union. References to "£" or "British Pounds" refer to British pound sterling, the lawful currency of the United Kingdom.

Trademarks

HEARTWARE®, HVAD®, MVAD®, Pal™, CIRCULITE®, SYNERGY® and various company logos are the trademarks of the Company. Other trademarks and trade names mentioned in this Annual Report on Form 10-K are the property of their respective owners.

Part I

Item 1. Business

Overview

HeartWare is a medical device company that develops and manufactures miniaturized implantable heart pumps, or ventricular assist devices, to treat patients suffering from advanced heart failure. We have one operating segment, which designs, manufactures and markets our medical devices. We are headquartered in Framingham, Massachusetts and have facilities in Miami Lakes, Florida, Arden Hills, Minnesota and Hannover, Germany.

The HeartWare Ventricular Assist System (the "HVAD System"), which includes a ventricular assist device ("VAD") or blood pump, patient accessories and surgical tools, is designed to provide circulatory support for patients in the advanced stage of heart failure. The core of the HVAD System is a proprietary continuous flow blood pump, the HVAD pump, which is a full-output device capable of pumping up to 10 liters of blood per minute. The HVAD System is designed to be implanted adjacent to the heart, avoiding abdominal surgery.

Heart failure is a chronic disease that results in the heart's pumping power being weaker than normal. In a healthy person, the left ventricle of the heart pumps oxygenated blood into the aorta and the blood is then circulated throughout the body until it returns through the venous system to the right side of the heart, which then pumps the blood into the lungs where it is re-oxygenated. If the left ventricle is not working properly, the oxygenated blood is not fully cleared from the lungs and the blood is not circulated effectively. If the muscle of the left ventricle is damaged or is not working efficiently, the ventricle will tend to compensate by working harder in an effort to supply adequate blood flow into the aorta. The increased effort generally results in dilation or enlargement of the ventricle, rather than increased blood flow. This dilation then makes it harder for the heart to contract effectively, which results in even lower blood flow and increased effort and further dilation of the ventricle. This progressive, degenerative process generally continues until the patient becomes debilitated and eventually dies from inadequate clearing of the lungs and inadequate flow of oxygenated blood throughout the body. The inadequate lung clearance or lung congestion is why the advanced stages of heart failure are called congestive heart failure, or CHF.

In November 2012, we received approval from the FDA for the HVAD System as a bridge-to-heart-transplantation in patients with end-stage heart failure. The HVAD System has been available in the European Union since receiving CE marking in 2009. In May 2012, we received an expanded European label for long-term use of the HVAD System in all patients at risk of death from refractory, end-stage heart failure. As of December 31, 2015, there have been over 10,000 implants of the HVAD System in patients at over 320 health care sites in 47 countries.

Bridge-to-transplant

FDA approval for a bridge-to-transplant ("BTT") indication was based on the results of our pivotal ADVANCE clinical trial, an FDA-approved Investigational Device Exemption ("IDE") study designed to evaluate the HVAD System as a bridge-to-heart-transplantation for patients with end-stage heart failure, as well as a Continued Access Protocol ("CAP"). Under ADVANCE, 140 patients at 30 hospitals in the U.S. received the HeartWare investigational device between August 2008 and February 2010. The ADVANCE study achieved 94% survival at 6 months and successfully met its primary endpoint of establishing non-inferiority between the investigational device and comparator arm of the study, which was derived from contemporaneous patients from the Interagency Registry for Mechanically Assisted Circulatory Support ("INTERMACS") [$p<0.0001$]. Four supplemental allotments of patients have been granted by the FDA under a CAP, encompassing 242 additional patients.

To help assure the continued safety and effectiveness of an approved device, FDA requires a post-approval study ("PAS") as a condition of approval under 21 CFR 814.82(a)(2) to assess device performance in a real-world setting. HeartWare's PAS is a registry consisting of 600 post-approval patients who received an HVAD and an additional 600 post-approval control patients derived from a contemporaneous group of continuous flow, intracorporeal left VAD ("LVAD") patients entered into the INTERMACS database. The data for both arms of the study will be entered into the INTERMACS registry by the implanting centers. Other post-approval commitments include the transfer of patients from the ADVANCE IDE study into a post-approval trial as well as an obligation to continue training sites in accordance with an approved training program.

Destination Therapy

In May 2012, we completed enrollment in our clinical trial named "ENDURANCE" for a destination therapy indication. Designed to enroll up to 450 patients at 50 U.S. hospitals, the non-inferiority study is a randomized, controlled, unblinded, multicenter clinical trial to evaluate the use of the HVAD System as a destination therapy in advanced heart failure patients. The study population was selected from patients with end-stage heart failure who have not responded to standard medical management and who are ineligible for heart transplantation. Patients in the study were randomly selected to receive either the HVAD System or, as part of a control group, an alternative ventricular assist device approved by the FDA for destination therapy, in a 2:1 ratio.

Each patient receiving the HVAD System or control VAD was followed to the primary endpoint at two years, and will undergo subsequent follow-up for a five-year period post implant. In April 2015 that data from ENDURANCE successfully demonstrated that the trial achieved the primary endpoint.

In August 2015, we completed enrollment of an IDE Supplement which allowed HeartWare an additional patient cohort for the ENDURANCE clinical trial. In this supplemental cohort, HeartWare enrolled 308 patients receiving the HVAD System, as well as 157 control patients using a randomization scheme consistent with the original ENDURANCE protocol. Assessment of primary endpoint is at 1 year post implant. HeartWare intends to incorporate the data from both this supplemental cohort and ENDURANCE into an anticipated PMA Supplement Application seeking approval of the HVAD System for a destination therapy indication.

Other Clinical Activities

In the fourth quarter of 2013, HeartWare received approval from the Japanese Pharmaceuticals and Medical Devices Agency to commence a clinical study in Japan for market authorization for a BTT indication for the HVAD System. Enrollment was completed in August 2014 with 6 patients at 5 clinical sites. All patients reached the primary endpoint and we are currently preparing the submission for market authorization for a BTT indication in Japan.

In addition, in the fourth quarter of 2013, HeartWare received conditional approval from the FDA for a prospective, controlled, unblinded, multicenter clinical trial to evaluate the thoracotomy implant technique for the HVAD System. We began enrollment in this study in January 2015 and expect to finish enrollment in 2016.

MVAD System

Beyond the HVAD System, we are developing our next-generation miniaturized device, known as the MVAD System. The MVAD System is based on the same technology platform as the HVAD System, but adopts an axial flow, rather than a centrifugal flow, configuration and is being developed in multiple designs. The MVAD pump is less than one-half the size of the HVAD pump and can provide partial or full support. The MVAD System is designed to allow for a variety of configurations and surgical placements with the goal of further reducing surgical invasiveness while producing superior clinical results.

In July 2015, we initiated a multicenter, prospective, non-randomized, single-arm CE Mark trial to evaluate the clinical safety and performance of the MVAD System for the treatment of advanced heart failure. In September 2015, we voluntarily paused the MVAD CE Mark clinical trial to address an MVAD controller manufacturing issue. Subsequent to that action, during the fourth quarter of 2015 and in consultation with study investigators, we began evaluating MVAD System performance and reported adverse events in certain clinical trial patients, including events that showed evidence of pump thrombosis. We are currently evaluating various aspects of the MVAD System design to determine whether changes should be made. Should design changes be implemented, initiation of a new trial would likely be required. The timetable for updating affected regulatory filings and restarting clinical implants cannot be reliably projected at this time.

CircuLite

On December 1, 2013, we acquired CircuLite, Inc., the developer of the CircuLite Circulatory Support System, a partial-support system designed to treat less-sick, ambulatory, chronic heart failure patients who are not yet inotrope-dependent. The CircuLite Surgical System is designed for long-term support and is intended to reduce the heart's workload while improving blood flow to vital organs. The CircuLite System experienced issues that arose after its commercial release and caused the loss of its CE marking in the European Union in March 2014. In January 2015, we discontinued development of the CircuLite micro pump and have focused our efforts on a version of our MVAD pump for our partial-assist program. Thus, delays to the development and regulatory approval of the MVAD System, will affect the timing of the development and regulatory approval of

the CircuLite System. The next-generation endovascular system, which is expected to be implanted collaboratively by cardiologists and surgeons in a hybrid catheterization ("cath") lab setting, offers an interventional approach to circulatory support. The CircuLite Circulatory Support System would offer less-invasive, and ultimately interventional, options to patients with earlier-stage heart failure.

Operations

We began generating commercial revenue from sales of the HVAD System in January 2009 and have incurred net losses in each year since our inception. We expect our losses to continue as we expand our pipeline through continued research and development into next-generation products, continue our clinical trials, enhance our infrastructure and expand commercial markets both inside and outside of the United States.

We have funded our operations primarily through product revenue, the issuance of convertible notes and the issuance of shares of our common stock. On December 15, 2010, we issued convertible senior notes due December 15, 2017, unless earlier repurchased or converted (the "2017 Notes") with an aggregate principal amount of $143.75 million pursuant to the terms of an indenture dated as of December 15, 2010. The 2017 Notes are senior unsecured obligations of the Company, and bear interest at a rate of 3.5% per annum, payable semi-annually in arrears on June 15 and December 15 of each year. The 2017 Notes offering was completed pursuant to a prospectus supplement, dated December 9, 2010, to a shelf registration statement on Form S-3 that was previously filed with the SEC and which was declared effective on December 9, 2010. In May 2015, we entered into separate, privately negotiated, exchange agreements (the "Exchange") with certain holders of the 2017 Notes. In this transaction, we exchanged $101.3 million aggregate principal amount of the 2017 Notes, with a carrying value of $83.1 million, for $118.2 million principal amount of convertible senior notes due 2021 unless earlier repurchased, redeemed or converted (the "2021 Notes"). Approximately $42.5 million aggregate principal amount of the 2017 Notes remains outstanding. We did not receive any proceeds related to the Exchange. In conjunction with the Exchange, we also issued an additional $84.2 million principal amount of the 2021 Notes resulting in an aggregate principal amount issued under the 2021 Notes of $202.4 million. Interest on the 2021 Notes is payable semiannually in arrears on June 15 and December 15, at a rate of 1.75% per annum, beginning on December 15, 2015. The 2021 Notes were issued under a base indenture dated as of December 15, 2010 between the Company and Wilmington Trust, National Association, as successor by merger with Wilmington Trust FSB, as trustee, as supplemented by a second supplemental indenture with respect to the 2021 Notes dated May 13, 2015.

In March 2013, we completed a public offering of 1,725,000 shares of our common stock, including the underwriters' exercise of their over-allotment option to purchase 225,000 shares, at an offering price of $86.45 per share for aggregate gross proceeds of approximately $149.1 million. After fees and related expenses, net proceeds from the offering were approximately $141 million. The offering was completed pursuant to a prospectus supplement, dated March 12, 2013, to a shelf registration statement on Form S-3 that was previously filed with the SEC and which was declared effective on December 9, 2010.

On January 30, 2014, we filed a new shelf registration statement with the SEC on Form S-3. This shelf registration statement allows us to offer and sell from time to time, in one or more series or issuances and on terms that we will determine at the time of the offering, any combination and amount of the securities described in the prospectus contained in the registration statement or in the prospectus supplement filed with respect to a particular offering.

Market Opportunity

Heart Failure

Heart failure is one of the leading causes of death in the developed world. The American Heart Association estimates that heart failure affects over 5.5 million people in the United States, while the European Society of

Cardiology reports a prevalence of at least 10 million in European countries. Heart failure is a cardiovascular disease with both an increasing incidence and death rate worldwide. In the United States, over 700,000 new cases are diagnosed with heart failure annually and approximately 58,000 patient deaths are attributed to heart failure annually.

Our Target Markets—Patients With Class III and Class IV Heart Failure

Our technologies target certain classes of patients with advanced heart failure, specifically Class III (less severe) and IV (more severe) patients as defined by the New York Heart Association ("NYHA"). We believe that there is a significant market opportunity for ventricular assist devices, or VADs, that are smaller, easier to implant, easier to use and/or more reliable than other devices that are currently available. We also believe there is a significant market opportunity for any device that, relative to existing therapies, demonstrates superior patient outcomes (*e.g.* reduces adverse events) at a lower cost.

It is estimated that there are approximately one million Class IV patients worldwide, which is the primary market currently served by VADs. In addition to this patient population, there are an estimated five million patients with Class III heart failure worldwide, of which, we estimate that approximately one million patients are severely impacted by heart failure, but are not yet nearing the end stages of the disease. While these patients suffer on a daily basis, they do not need the same full support as the sicker patients diagnosed with later-stage, Class IV heart failure and they may be less willing to undergo the more invasive procedure required for the placement of the typical VAD. We believe that up to one-third of these one million patients could be candidates for a partial-support system, such as the CircuLite Circulatory Support System, placed in a less-invasive surgical approach because of the potential for reduced surgical risk and shorter post-operative recovery periods.

CHF Treatment Options

Although many pharmacological therapies and pacing devices that are designed to stimulate the heart have proven to be effective at prolonging the quality and duration of a patient's life, these treatments and devices do not halt the progression of heart failure. Pharmacologic management of heart failure focuses primarily on improving the overall pump function of the heart while slowing the rate of heart failure progression. For later-stage patients with Class III and Class IV heart failure, some investigations have suggested that the increase in patient survival rates using medical therapy is limited and that optimal medical therapy has not been demonstrated to stop or reverse the effects of heart failure. Other approaches, such as devices that allow physicians to restrict or reduce the size of the heart and cell-based therapy, are either in the early development stages or have not yet achieved outcomes that we believe would lead most physicians to consider these technologies as viable solutions.

Heart transplantation is the current primary therapy for refractory advanced heart failure and ultimately provides the best recovery of cardiac function. Heart transplantation is an effective and accepted surgical procedure that can allow patients with end-stage heart failure to resume relatively normal lives for a period usually expected to be ten years or longer. However, the therapy is significantly constrained by the limited number of available donor hearts. Also, many patients with heart failure are ineligible for heart transplantation because of factors such as age or the presence of other diseases.

VAD Treatment for Advanced Heart Failure

Circulatory assist devices are designed to assume some or all of the pumping function of the heart by mechanically pumping blood into the aorta. Implantation of circulatory assist devices is the only therapy other than transplantation that has been shown to rehabilitate a patient from NYHA Class IV to Class I or II. A November 2001 article in *The New England Journal of Medicine* on a study entitled "Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure," or the REMATCH study, concluded that "the use of a left ventricular assist device in patients with advanced heart failure resulted in a clinically

meaningful survival benefit and an improved quality of life. A left ventricular assist device is an acceptable alternative therapy in selected patients who are not candidates for cardiac transplantation." The conclusions in this study have since been reconfirmed in a number of subsequent similar studies with VADs, including a bridge-to-transplant study and a destination therapy study reported in August 2007 and November 2009 articles, respectively, in *The New England Journal of Medicine*. These conclusions were further echoed in the bridge-to-transplant study for the HVAD System, as described by Aaronson *et al*. in a June 2012 article in *Circulation*. In summary, the HVAD pump was associated with "high rates of 180 day success and survival" with "a favorable adverse event profile" and significantly improved functional capacity and quality of life as not previously reported with any other "drug or device therapy for advanced heart failure."

A large population of patients with end-stage heart failure can benefit from VAD therapy, such as the HVAD System. Currently, the HVAD System is approved for the "bridge-to-transplant" population. Each year, the number of patients with heart failure in need of a heart transplant exceeds the number of donor hearts that become available. According to the Organ Procurement and Transplantation Network, or OPTN, and Scientific Registry of Transplant Recipients, or SRTR, 2,679 heart transplants were conducted in the United States in 2014, and as of December 31, 2014, 3,635 people were listed for heart transplant. The OPTN/SRTR 20143 Annual Data Report reported 44.9% of the patients transplanted were on a VAD as a bridge-to-transplant. In light of the survival benefit of VADs over inotropes, the volume of patients on inotropic therapy at transplant has diminished while the use of VADs has increased. Bridging the patient to transplant with a VAD provides clinicians time to stabilize the patient until a suitable donor heart becomes available.

Our Solution and Products

Proprietary Pump Technology

The HVAD System features the smallest, full-output centrifugal pump designed to be implanted in the chest, directly adjacent to the heart. At the core of our technology platform is our proprietary "hybrid" system for suspending the impeller, which is the only moving part within the pump. The impeller is suspended within the pump housing by the opposing forces of passive magnets and hydrodynamic thrust generated by the pump impeller, which circulates a cushion of blood. Once power is applied to the device and the impeller begins to rotate, there are no points of mechanical contact within the pump, thus providing a wearless pumping system.

We believe the hybrid suspension system has several important advantages over traditional technologies. The elimination of the internal mechanical bearings which are characteristic of second-generation devices removes all points of mechanical friction or contact within the pump. We believe that this removal of contact should lead both to longer-term reliability of the device and to a potential reduced risk of physical damage to blood cells as they pass through the pump. Our hybrid suspension technology also establishes a miniaturization path, which we believe will allow us to significantly downsize our pump technology without compromising clinical performance. We believe competing pump designs which rely on either active magnetic or hydrodynamic forces alone face various physical constraints that may limit their ability to downsize without sacrificing performance.

The HeartWare HVAD System

The first product in our portfolio, the HVAD System, is comprised of the HVAD pump, a small, permanently implantable VAD, patient accessories and surgical tools. The HVAD pump is capable of generating up to 10 liters of blood flow per minute. With a displaced volume of only 50 cubic centimeters and a mass of 140 grams, the HVAD pump is more easily implantable in the pericardial space, directly adjacent to the heart. We believe the implanting in the pericardial space generally leads to shorter surgery time and a less invasive procedure relative to alternative devices, which are normally implanted in the abdomen. In January 2015, we began enrollment in our clinical trial named "LATERAL" related to the thoracotomy implant technique for the HVAD System, which, if successful, will provide an even less invasive procedure. We anticipate completing enrollment in the LATERAL trial in the first half of 2016.

Device reliability of the HVAD System is designed to be enhanced through the use of dual motor stators with independent drive circuitry, allowing a seamless transition between dual and single stator mode if required. The pump's inflow cannula is integrated with the device itself, providing proximity between the heart and the pumping mechanism, facilitating ease of implant and helping to ensure optimal blood flow characteristics. The use of a wide-bladed impeller and the clear flow paths through the pump are designed to help reduce the risk of pump-induced damage to blood cells.

The HVAD System has been approved for sale in Europe since early 2009. In November 2012, we received approval from the FDA for the HVAD System as a bridge-to-heart-transplantation in patients with end-stage heart failure.

The HeartWare MVAD System

The MVAD System is comprised of similar components, surgical tools and peripherals as the HVAD System, but is differentiated significantly by the MVAD pump. The MVAD pump is a miniaturized blood pump intended for patients with chronic heart failure. The device is a full-output axial-flow pump with a fully suspended rotor and a displacement volume of less than one-half of that of the HVAD pump. The MVAD pump is designed for pericardial implantation and initial human clinical trials began in July 2015. We also introduced our next-generation controller, Pal, with the MVAD pump. Pal is a one-piece, wearable controller with a battery designed for an active patient lifestyle. As described in the overview section above, we voluntarily paused enrollment in the MVAD CE Mark trial and are evaluating reported adverse events. Should design changes be implemented, initiation of a new trial would likely be required.

We believe it is likely that more patients will be willing to undergo a shorter, less-invasive surgical procedure that may result in quicker recoveries and hospital discharge. We have taken advantage of the versatility of the MVAD pump design with multiple configurations specific to less-invasive implantation procedures. These devices may expand the potential pool of chronic heart failure patients.

Before the MVAD System will be available for commercial sale, we will need to achieve the following milestones:

- evaluate system design to determine whether additional changes should be made;
- completion of the system development including next-generation peripherals (e.g., controller, batteries, power adapters);
- approval of, and successful completion of, a clinical trial; and
- receipt of regulatory approvals for commercialization.

The CircuLite System

HeartWare acquired CircuLite on December 1, 2013 and with it, the CircuLite Circulatory Support System. The CircuLite Surgical System is designed to be implanted through a right, mini-thoracotomy procedure and does not require a sternotomy or cardiopulmonary bypass. With this approach, the inflow cannula is placed in the left atrium, and the outflow graft is attached to the subclavian artery. A small pump is then placed in a pacemaker-like pocket and attached to the inflow cannula and outflow graft, which connects to a wearable, external controller and battery pack. The CircuLite System experienced issues that arose after its commercial release and caused the loss of its CE marking in the European Union in March 2014. In January 2015, we discontinued development of CircuLite's proprietary micro pump and focused our efforts on a version of our MVAD pump for our partial-assist program. Thus, delays to the development and regulatory approval of the MVAD System will affect the timing of the development and regulatory approval of the CircuLite System. CircuLite pioneered the partial-assist approach and despite challenges, demonstrated that this technique can enhance the quality of life for a less-sick group of heart failure patients, which is believed to be a larger

population than the end-stage heart failure patients that we currently treat with our full-support VADs. The next generation endovascular system, which will be implanted collaboratively by cardiologists and surgeons in a hybrid cath lab setting, offers an interventional approach to circulatory support. The CircuLite System would offer less invasive and ultimately interventional options to earlier-stage heart failure patients.

Enhanced Quality of Life with Implantable Devices

Currently, the HVAD System and all commercially available VADs are powered by a controller, batteries and other power sources carried external to the body. Power is transferred to the implanted pump via a thin electrical cable, called a driveline, which exits the patient's skin in the abdominal area. We are working to develop an implantable system utilizing transcutaneous energy transfer ("TET") or wireless power that will eliminate the need for a percutaneous driveline. A TET system contains a wearable power management system that is inductively coupled to an implanted pump controller and electronics that include a rechargeable battery. The patient can remove the wearable power management system and enjoy a high-quality lifestyle while the system is powered by the implanted battery.

Our Business Strategy

Our primary goal is to focus on optimizing outcomes of patients being treated for advanced heart failure. To this end, we are leading innovation in the VAD sector and are also striving to develop and maintain a proprietary technology platform that enables the development of a pipeline of ever-smaller heart pumps that will reduce procedural invasiveness, and adverse events while simultaneously increasing the number of patients who can benefit from our products. In addition, we intend to explore technologies and therapies for the general treatment of heart failure.

We believe that our technology portfolio provides us with a competitive advantage in the market. To capitalize on that advantage, we are pursuing the following plan:

Expand Market Penetration Outside of the U.S.—We sell to VAD centers and distributors throughout Europe and in other countries outside the U.S. With the receipt of the HVAD System's CE Marking in January 2009, we began to develop the necessary infrastructure to support commercial sales in Europe. Throughout 2015, we continued to expand our infrastructure to support commercial activity and have generated sales through 2015 from customers in over 47 countries. In the future, we intend to build wider distribution channels and ordering systems to deliver our products to the international markets on a wider commercial scale as well as increase the number of countries in which we have approval to sell our device commercially.

Expand U.S. Market Penetration—Our goal is to continue to expand U.S. market penetration for the HVAD System as a bridge-to-transplant system. Our focus is to continue to establish and maintain commercial sites at all of the major U.S. health centers that support VAD implantation. In the U.S., we currently have approximately 132 commercial sites.

We also intend to seek an expanded indication for the HVAD System to include destination therapy. In May 2012, we completed enrollment in our ENDURANCE destination therapy clinical trial. Each test patient has now been followed to the primary endpoint of two years and will be followed for a subsequent five-year period post-implant. In April 2015, we announced that data from ENDURANCE successfully demonstrated that the trial achieved the primary endpoint. In August 2015, we completed enrollment of an IDE Supplement which allowed HeartWare an additional patient cohort for the ENDURANCE clinical trial. Patients have been, or will be, followed for 12 months after implant. HeartWare intends to incorporate the data from both this supplemental cohort and ENDURANCE into an anticipated PMA Application seeking approval of the HVAD System for a destination therapy indication.

***Focus on Continuous Product Development*—**In parallel with continuing to enhance the HVAD System, we plan to advance the development of our next-generation products, such as the MVAD System, the CircuLite System and a TET system, and to enhance our peripheral equipment, such as our HVAD controller and batteries. We expect assessment and development and/or enhancement work for our pipeline products and peripheral equipment to continue throughout 2016. We plan to introduce our next generation controller, Pal, with the MVAD pump in clinical trials and separately for use with the current HVAD pump. Pal is a one-piece wearable controller and battery designed for an active patient lifestyle.

***Partner With Leading Professionals in the Fields of Cardiovascular Surgery Around the World*—**We have established relationships with leading professionals in the field of cardiovascular surgery and at heart centers around the world and will continue to expand this network. We believe these relationships are key to our growth as they help to drive clinical awareness of our products.

***Explore Complementary or Alternative Therapies and Technologies*—**We intend to explore business development opportunities including strategic alliances, joint ventures, and acquisitions that might complement or expand our market opportunities. In mid-2012, we acquired World Heart Corporation primarily to expand our intellectual property portfolio and in late 2013, we acquired CircuLite to develop a partial support system to treat less-sick, patients with chronic heart failure.

On September 1, 2015, we entered into a Business Combination Agreement (the "BCA") by and among the Company, Valtech Cardio, Ltd. ("Valtech"), HW Global, Inc. ("Holdco"), HW Merger Sub, Inc., Valor Merger Sub Ltd. and Valor Shareholder Representative, LLC, pursuant to which we and Valtech proposed to effect a strategic combination of our respective businesses under Holdco, subject to certain closing conditions. Valtech is a privately held company that specializes in the development of innovative surgical and transcatheter valve repair and replacement devices for the treatment of mitral valve regurgitation and tricuspid valve regurgitation. Effective January 28, 2016, we terminated the BCA pursuant to the terms of the BCA by delivering written notice to the other parties. As of December 31, 2015, we had invested approximately $18 million in Valtech in the original form of convertible loans, of which $10 million, together with $0.5 million of accrued interest, was converted into Valtech preferred shares amounting to approximately 3.0% ownership of a fully diluted basis. On February 2, 2016, pursuant to the termination provisions of the BCA, we loaned Valtech an additional $30 million in the form of a convertible loan which per terms of the convertible note may be converted to preferred shares.

Sales and Marketing

Our sales and marketing strategy is to educate and promote the benefits of HeartWare's HVAD System circulatory support systems for the treatment of clinical heart failure among a variety of health care professionals. We market directly to clinicians and medical facilities as well as through medical device distributors in some markets outside of the U.S.

We work with a broad spectrum of health care industry participants to promote the clinical benefits of our device, including hospital administrators, cardiologists, surgeons, nurses, perfusionists, insurers and government payer policy representatives. Enhancing patient outcomes via effective training and clinical end-user support programs and resources is key to the development of our business.

To support our sales and marketing strategy, we have recruited and trained experienced territory managers and clinical specialists. This field team supports customers by supporting implant procedures, providing technical information and training, resolving clinical issues and educating health care professionals on the benefits of HeartWare systems. In addition, we partner with leading physicians in the field to proctor and preceptor new physicians on the use of our devices in their centers and to present clinical and technical data at scientific symposia, congresses, and trade shows, as well as publish in peer-reviewed cardiovascular journals.

Our product management team conducts market research on end-user preferences and unmet needs, identifies areas of improvement in our product offering and services, and works with research and development on new technologies that meet newly identified needs that are not addressed with our current platform of products.

We sell our products primarily to large hospitals and distributors. No customer accounted for more than 10% of total revenue in fiscal years 2015, 2014, and 2013. Approximately 42%, 46% and 49% of our 2015, 2014 and 2013 revenues, respectively, were derived from international sales. Globally, over 10,000 implants have been performed using the HVAD System. The HVAD System has been implanted in patients at over 320 health care sites in 47 countries.

Intellectual Property

We rely on a combination of patents, trade secrets, trademarks and copyrights, together with non-disclosure and confidentiality agreements, to protect our proprietary rights in our technologies.

As of December 31, 2015, we had 106 U.S. patents, 29 Australian and Japanese patents, as well as patents issued in France, Germany, Great Britain, Canada, Italy, the Netherlands, Spain, China, Turkey, Israel, South Korea, Hong Kong, Belgium, Austria and Ireland. We also have 99 pending U.S. non-provisional patent applications, 64 European applications, 25 PCT applications, and a number of international patent applications filed with various national patent offices including Canada, Japan, India, Israel, China, South Korea, Australia and Hong Kong.

Our U.S. and foreign issued patents and patent applications cover fundamental technologies underlying our hemodynamically and physiologically compatible full-output, long-term circulatory assist devices and partial support technologies. The main technologies claimed in patents and patent applications include:

- use of dual stators in a blood pump;
- the combination of passive magnetic bearings and hydrodynamic thrust bearings;
- channels or wide-bladed impellers in a blood pump;
- the use of ceramic between an impeller and motor stator;
- flow estimation based on impeller speed and viscosity;
- use of platinum alloy for blood pump impellers;
- alternative axial flow pump technologies;
- physiological response and pump control algorithms;
- wireless energy transfer systems; and
- blood pump system cannulas.

Major patents and pending patent applications covering technologies for our HVAD System are scheduled to expire at various times between 2016 and 2029. Patents and patent applications covering technologies for our MVAD System are scheduled to expire at various times between 2024 and 2030.

We actively monitor our intellectual property position and periodically review new developments to identify prudent extensions to our patent portfolio. We plan to file additional patent applications on inventions that we believe are patentable and important to our business. We may also license or acquire patents from third parties that may enhance or expand our development activities. Accordingly, we intend to pursue and defend aggressively patent protection on our proprietary technologies. We have also entered into, and may in the future enter into, settlement agreements pursuant to which third parties or their successors or assignees may

commercialize competing technologies or products that would have otherwise been precluded by our patents subject to the agreement.

Despite our efforts, we may be subject to challenges, with or without merit, regarding our patents or other intellectual property. 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, or other persons could allege that our products and technologies infringe, upon 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. 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 a dispute or litigation arises, 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 to design around the patented or otherwise proprietary technology. At this time we are not party to any material legal proceedings that relate to patents or proprietary rights.

Our intellectual property also includes non-patented technology, processes and procedures, and technical knowledge and know-how accumulated or acquired since inception, all of which are significant to our competitive position. It is our policy to enter into confidentiality, non-disclosure and intellectual property assignment agreements with employees and consultants to help ensure that we can protect our rights in developed proprietary technology and prohibit the disclosure of any confidential information or trade secrets.

Government Regulation

United States

Our products are regulated by the FDA as a Class III medical device under the U.S. Food, Drug, and Cosmetic Act. FDA regulations govern:

- product design and development;
- product testing;
- product manufacturing;
- product safety and effectiveness;
- product labeling;
- product storage;
- record keeping;
- product servicing;
- premarket approval (“PMA”);
- advertising and promotion;
- distribution;
- product sales and post-market activities;
- import and export;
- quality systems;
- medical device (adverse event) reporting; and
- field corrective actions (e.g., recalls).

Premarket Approval

Each of our devices are regulated as a Class III medical device. PMA approval from the FDA is required before marketing of a Class III medical device in the United States can commence and the process of obtaining PMA can be costly, lengthy and uncertain. In November 2012, we received approval for the HVAD System as a bridge-to-heart-transplantation in patients with end-stage heart failure.

We completed enrollment of our ENDURANCE trial in May 2012 relating to destination therapy, announced in April 2015 that data from ENDURANCE successfully demonstrated that the trial achieved the primary endpoint and recently completed enrollment of the supplemental cohort to the ENDURANCE trial approved in August 2013. We expect to file a PMA Supplement application to the approved HVAD System PMA for the addition of a "destination therapy" indication with the FDA. This PMA supplement application must be supported by extensive data including, but not limited to, technical, preclinical and both cohorts of the ENDURANCE clinical trial to demonstrate the safety and effectiveness of the device to the FDA's satisfaction. Among other information, the PMA supplement must also contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed device and patient labeling.

If the FDA determines that a PMA supplement is complete, the FDA accepts the application and then begins an in-depth review of the submitted information. The FDA, by statute and regulation, has 180 days to review an accepted PMA application, although the review and response process generally occurs over a significantly longer period of time, often more than a year, and can take up to several years. HeartWare's receipt of an FDA warning letter in June 2014 may further delay an FDA review and an application's approval. During the review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA may conduct a pre-approval inspection of our and our key suppliers' facilities to evaluate compliance with quality system regulations. They may also conduct a Bioresearch Monitoring ("BIMO") inspection of the clinical trial data including audits of clinical sites. To help ensure the continued safety and effectiveness of an approved device, the FDA may also require a post-approval study as a condition of approval. Post-approval studies were required as a condition of approval for the original HVAD System PMA with the indication of bridge-to-heart-transplantation.

Under the FDA Safety and Innovation Act (Public Law 112-144) which included the Medical Device User Fee Amendments of 2012, the fee to submit a PMA application in 2016 is approximately $260,000. User fees are expected to rise over time until the law sunsets in 2017. We qualified for a small business exemption that allowed us to file our first PMA application at no charge, however we presently do not qualify for the exemption. PMA supplements are required for modifications to the manufacturing process, labeling, use and design of a device that is approved through the premarket approval process. PMA supplements often require submission of the same type of information as a PMA application except that the supplement is limited to information needed to support any changes from the device covered by the original PMA. The changes to design may require significant testing, validation and documentation and may be associated with significant review times from 30 days to 180 days and fees ranging from approximately $4,000 up to approximately $39,000 with the exception of the Panel Track Supplement (which includes clinical data) is $196,000.

A post-approval study ("PAS"), which could be clinical or non-clinical, may also be required to gather specific information to address questions about the post-market performance and physician experience with an approved medical device. Concurrent with PMA approval of the HVAD for bridge-to-transplant indication, the FDA has required us to complete a PAS as a condition of approval under 21 CFR 814.82(a)(2) to assess device performance in a real-world setting. HeartWare's PAS is a registry consisting of 600 patients who receive an HVAD and an additional 600 control patients derived from a contemporaneous group of continuous flow, intracorporeal LVAD patients entered into the INTERMACS database. The data for both arms of the study will

be entered into the INTERMACS registry by the implanting centers. Other post-approval commitments include the transfer of patients from the ADVANCE IDE study into a post-approval database as well as an obligation to continue training sites in accordance with an approved training program.

Pervasive and Continuing FDA Regulation

Clinical trials require extensive recordkeeping and reporting requirements. Our clinical trials must be conducted under the oversight of an institutional review board at the relevant clinical trial site and in accordance with applicable regulations and policies including, but not limited to, the FDA's good clinical practice, or GCP, requirements. We, the trial data safety monitoring board, the FDA or the institutional review board at each clinical trial site may suspend a clinical trial at any time for various reasons, including a belief that the risks to study patients outweigh the anticipated benefits.

Both before and after FDA approval, numerous regulatory requirements apply. These include:

- quality system regulation, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures during the design, manufacturing and commercialization phases;
- regulations which govern product labels and labeling, prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling and promotional activities;
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur;
- regulations which govern medical device tracking; and
- notices of correction or removal and recall regulations.

Advertising and promotion of medical devices are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Recently, some promotional activities for FDA-regulated products have resulted in enforcement actions brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act, competitors and others can initiate litigation relating to advertising claims.

Compliance with regulatory requirements is enforced through periodic, unannounced facility inspections by the FDA. At the conclusion of an FDA inspection, the inspector may provide observations identifying areas of potential regulatory concern. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA. Enforcement actions may include any of the following sanctions against us:

- warning letters or untitled letters;
- fines, injunction and civil penalties;
- recall or seizure of our products;
- customer notification, or orders for repair, replacement or refund;
- operating restrictions, partial suspension or total shutdown of production or clinical trials;
- refusing our request for premarket approval of new products;
- withdrawing premarket approvals that are already granted; and
- criminal prosecution.

FDA Warning Letter

We received a warning letter from the FDA, dated June 2, 2014, following an inspection of our Miami Lakes, Florida facility conducted in January 2014. The FDA letter cited four categories for us to address: (1) procedures for validating device design, including device labeling; (2) procedures for implementing corrective and preventive action (CAPA); (3) maintaining records related to investigations; and (4) validation of computer software used as part of production or quality systems. The warning letter did not require any action by physicians or patients and did not restrict the use of our devices.

We sent the FDA our initial response to the warning letter within the required fifteen business days of receipt, and committed to undertaking certain quality system improvements and providing the FDA with periodic updates. During 2014 and continuing in 2015, we implemented systemic changes and organizational enhancements to address the four warning letter items and related quality systems. We have established teams to review and address the items cited by the FDA and have engaged external subject matter experts to assist in assessment and remediation efforts. As we continue to evaluate our quality systems, it is possible that we may need to take additional actions including the possibility of voluntary product recalls when necessary to ensure patient safety and effective performance of the HVAD System.

European Union

The primary regulatory environment in Europe is that of the European Union, or EU, which consists of 28 member states in Europe. In 2014, two EU directives that covered medical devices—Directive 93/42/EEC covering medical devices and Directive 90/385/EEC for active implantable medical devices—became EU regulations, which augmented and clarified earlier directives. The EU also has numerous standards that govern and harmonize the national laws and standards regulating the design, manufacture, clinical trials, labeling, adverse event reporting and post-market surveillance activities for medical devices that are marketed in member states. Medical devices that comply with the requirements of the national law of the member state in which they are first marketed will be entitled to bear CE Marking, indicating that the device conforms to applicable regulatory requirements, and accordingly, can be commercially marketed within EEC states and other countries that recognize this mark for regulatory purposes. We received CE Marking for the HVAD System in January 2009. In May 2012, we received an expanded label for long-term use of the HVAD System in patients at risk of death from refractory, end-stage heart failure.

Other International Regulations

We are also subject to international regulations in other countries where our products are sold and in which HeartWare clinical trials are ongoing. We currently have sales to customers in a variety of countries outside of the U.S. and EU. These regulations relate to product standards, packaging and labeling requirements, import restrictions, tariff regulations, duties and tax requirements. Many of the regulations applicable to our products in these countries are similar to those of the FDA. The national health or social security organizations of certain countries require our products to be qualified before they can be marketed in those countries. In certain countries, doctors may request use of our product under compassionate or emergency use or special access programs prior to approval. These programs tend to be limited and patient-specific and do not replace premarket approval.

In order to be positioned for access to European and other international markets, we sought and obtained certification under the International Standards Organization ("ISO") 13485 standards. ISO 13485 is a set of integrated requirements, which when implemented, form the foundation and framework for an effective quality management system. These standards were developed and published by the ISO, a worldwide federation of national bodies, founded in Geneva, Switzerland in 1947. ISO has more than 90 member countries and ISO certification is widely regarded as essential to enter Western European markets.

Healthcare Regulation

Healthcare policy changes

In response to perceived increases in health care costs in recent years, there have been and continue to be proposals by the federal government, state governments, regulators and third-party payors to control these costs and, more generally, to reform the U.S. healthcare system. For example, on March 23, 2010, the Patient Protection and Affordable Care Act (the "Affordable Care Act") was signed into law. On March 30, 2010, a companion bill, the Health Care and Education Reconciliation Act of 2010 (the "Reconciliation Act") was also signed into law. Among other things, the Affordable Care Act and the Reconciliation Act (collectively, the "Acts"), when taken together, impose a 2.3% excise tax on the sale of certain medical devices, including our devices, which took effect January 1, 2013. However, the Consolidated Appropriations Act, 2016 (Pub. L. 114-113), signed into law on December 18, 2015, includes a two-year moratorium on the 2.3% excise tax and, thus, the tax will not apply during the period beginning on January 1, 2016 and ending on December 31, 2017. Whether this tax, or any other new tax or regulation, may apply to us in the future is uncertain.

Regulations related to prohibiting "kickbacks" and false claims and protecting patient confidentiality

A federal law commonly known as the "Anti-Kickback Law," and several similar state and foreign laws, prohibit payments that are intended to induce physicians or others either to refer patients or to acquire or arrange for or recommend the acquisition of healthcare products or services. These laws constrain our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of medical devices. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent, or for items or services that were not provided as claimed. Because we may provide some coding and billing information to purchasers of the HVAD System and our other products, and because we cannot assure that the government will regard any billing errors that may be made as inadvertent, these laws are potentially applicable to us. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance, which can be substantial.

Data Privacy

There are a number of federal and state and foreign laws protecting the confidentiality of certain patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services promulgated patient privacy rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. These privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. If we are found to be in violation of the privacy rules under HIPAA or similar laws, we could be subject to civil or criminal penalties.

Transparency of payments

A section of the Affordable Care Act known as the Sunshine Act requires applicable manufacturers of drugs and devices to report annually for publication certain payments and other transfers of value to physicians and teaching hospitals as well as certain ownership interests held by physicians. Pursuant to recently issued regulations, applicable manufacturers, including the Company, began to submit reports in 2014 with respect to payments and transfers occurring in 2013. Reports are now due annually. Certain states and foreign countries have similar statutes and regulations requiring reporting of payments to healthcare providers. We are establishing processes and procedures to capture and report payments to physicians and teaching hospitals.

Other Regulation

The Dodd-Frank Wall Street Reform and Consumer Protection Act includes certain disclosure requirements regarding the use of "conflict minerals" originating from the Democratic Republic of Congo and adjoining countries and procedures regarding a manufacturer's efforts to prevent the sourcing of "conflict minerals" whether or not these products are manufactured by third parties. The conflict minerals include tin, tantalum, tungsten and gold, and their derivatives. These new requirements could affect the pricing, sourcing and availability of minerals used in the manufacture of our products. There will be additional costs associated with complying with the disclosure requirements, such as costs related to determining the source of any conflict minerals used in our products. Our supply chain is complex and we may be unable to verify the origins for all metals used in our products. We may also encounter challenges with our customers and stockholders if we are unable to certify that our products are conflict free.

Third-Party Reimbursement

In the United States, hospitals and doctors generally rely on third-party payors, such as Medicare, Medicaid, private health insurance plans and self-funded employers, to pay or reimburse for all or part of the cost of medical devices and the related surgical procedures. In the United States, heart failure represents Medicare's greatest area of spending.

In 2011, the Center for Medicare and Medicaid Services, or CMS, established reimbursement rates for the treatment of patients with LVADs, with major complications and comorbidities ("MS-DRG 1") and without major complications and comorbidities ("MS-DRG 2"). Most patients who receive VADs, and all patients who receive heart transplants, are eligible for MD-DRG 1 reimbursement. Under current payment rates, the national average Medicare payment to CMS-certified centers for MS-DRG 1 procedures is approximately $150,000. Actual payments are subject to other variables such as an application of a wage index, indirect medical education costs, cost outliers, and disproportionate share payments for each institution. In addition, when VAD patients are discharged from the hospital and then readmitted for transplantation, hospitals may qualify for two separate MS-DRG 1 or 2 payments.

We believe that our products are Medicare-eligible and therefore that they should be entitled to reimbursement. On October 30, 2013, CMS issued a Decision Memo for Ventricular Assist Devices for Bridge-to-Transplant and Destination Therapy (CAG-00432R), which updated the national coverage determination ("NCD") for bridge-to-transplant and destination therapy VADs. The updated NCD, among other things, attempts to clarify BTT and DT patient selection criteria. The updated NCD clarified that BTT patients, without an exemption, must be active on the Organ Procurement and Transplantation Network's waitlist for a heart in order to be eligible for Medicare or Medicaid reimbursement. Since the HVAD System is currently only approved in the U.S. for BTT patients, this update to the NCD creates a subset of potential HeartWare BTT patients who may no longer be eligible for Medicare and Medicaid reimbursement and could impact patient selection.

Most private insurance providers have implemented U.S. policies for circulatory assist devices, including Blue Cross and Blue Shield Plans, Aetna, Cigna, United Healthcare and others, and these private insurance providers have their own reimbursement criteria for their members, which can be found in their VAD medical policies. Generally, these third-party payors do not impose the active listing requirements contained in the NCD. However, they may not cover medical devices during an ongoing clinical trial; even though a trial may be categorized as a Medicare-approved IDE Category B2 clinical trial. All of our sites in the U.S. bridge-to-transplant and destination therapy clinical trials received Medicare and third-party reimbursement to some extent. Our staff includes reimbursement and government policy professionals whose objectives include improving insurance reimbursement outcomes for the HVAD System.

International reimbursement varies from country to country and often hospital to hospital. The European system is more effective at focusing resource-intensive procedures in a small number of centers within each

country and LVADs fall into that category of resource-intensive procedures. In those hospitals that perform VAD implantation, we believe that there are adequate budgets to purchase circulatory assist devices although governmental austerity programs could impact available funding. As in the United States, we believe that in Europe physicians and patients drive the decision as to which VAD to purchase. In many jurisdictions, a favorable health technology assessment is required prior to obtaining reimbursement for a medical device. These assessments are often difficult to conduct and can be time-consuming and expensive.

Competition

Competition in the VAD industry is expected to increase as better devices become available. We believe that our products compete primarily on their safety and efficacy as a treatment for congestive heart failure as compared to other devices and other treatments. Other factors that affect our ability to effectively compete in the VAD market is our ability to obtain necessary regulatory approvals to market the device in the U.S., the price of our device and the ability of healthcare providers to secure reasonable reimbursement rates. We believe that over time, smaller, less-invasive, reliable and durable devices will emerge as the preferred alternatives for the treatment of congestive heart failure. In the long run, we believe our continued competitive success will depend on our ability to enhance patient outcomes, reduce adverse events and develop innovative products.

Our principal competitors in the implantable cardiac assist space include St. Jude Medical, Inc. (which acquired Thoratec Corporation in October 2015), Jarvik Heart, Inc., ReliantHeart Inc., Berlin Heart GmbH, and Sunshine Heart, Inc., and a range of other smaller, specialized medical device companies with devices at varying stages of development.

Research and Development

Research and development costs include activities related to the research, development, design, testing, and manufacturing of prototypes of our products as well as costs associated with certain clinical and regulatory activities. We expect our research and development expenses to continue to increase as we implement enhancements to the HVAD System, continue to develop our MVAD System and CircuLite System, enhance our peripheral product offerings, conduct additional pre-approval and post-approval clinical trials and hire additional employees. For the years ended December 31, 2013, 2014 and 2015 we incurred research and development expenses of $98.8 million, $119.8 million, and $120.8 million, respectively.

Manufacturing and Assembly

Our manufacturing activities to date**,** and for the foreseeable future, will continue to consist primarily of process development, component assembly, quality control testing and sustaining engineering. Most of the components of the HVAD System are manufactured by third parties, including the center post, pump housing and impeller. Some critical components, including the controller and monitor, are manufactured solely by an outside supplier, and except for final testing and assembly, are essentially provided to us as a finished good ready-for-sale as part of our HVAD System.

In order to sell our product commercially in the European Union, we are required to meet certain regulatory standards. In October 2008, we received a Certificate of Registration from British Standard Institution (BSI) certifying that the Company's Quality Management System complies with the requirements of ISO 13485:2003. It signifies that HeartWare has established a comprehensive quality system that conforms to the International Organization for Standardization ("ISO") 13485:2003 requirements. The ISO 13485:2003 standard is fully recognized in many countries as a measure of quality. In January 2009, we received a Full Quality Assurance Certificate, CE 540273 from BSI. It signifies that the HVAD System designed and manufactured by HeartWare conforms with the provisions of Council Directive for Active Implantable Medical Devices, 90/385/EEC, Annex 2, Section 3.2 at every stage, from design to final controls. In order to maintain these certifications, we must show that HeartWare's Quality System remains compliant with the requirements of ISO 13485 and applicable standards.

We do not presently have supply agreements with many of our key suppliers and we have not secured second source suppliers for all of our supplies.

Employees

As of December 31, 2015, we had 625 employees, of whom 390 are engaged in operations activities including research and development, quality assurance and manufacturing, 161 are engaged in marketing, sales, clinical and regulatory activities and 74 are engaged in finance, legal and other administrative functions. None of our employees are represented by a labor union or covered by a collective bargaining agreement other than employees in France who are subject to national collective bargaining agreements. We consider our relations with our employees to be good.

Corporate History

HeartWare International, Inc. was incorporated in Delaware on July 29, 2008 as a wholly-owned subsidiary of HeartWare Limited, a corporation incorporated in Australia on November 26, 2004. On November 13, 2008, HeartWare Limited completed its redomiciliation from Australia to Delaware pursuant to certain schemes of arrangement approved by an Australian court. In connection with this redomiciliation, each holder of HeartWare Limited ordinary shares was issued one share of HeartWare International, Inc. common stock in exchange for every 35 ordinary shares of HeartWare Limited. As a result, HeartWare Limited became a wholly-owned subsidiary of HeartWare International, Inc., and HeartWare International, Inc. became the parent company of the HeartWare Group. The ordinary shares of HeartWare Limited traded on the on the ASX from January 31, 2005 until November 13, 2008 when the interests in HeartWare International, Inc. started trading on the ASX in the form of CHESS Depositary Interests, or CDIs. On February 24, 2009, common shares of HeartWare International, Inc. were listed for trading on the NASDAQ Global Market and commenced trading on the following day. On September 17, 2013, HeartWare was officially delisted from the ASX, meaning that interests in HeartWare are no longer publicly traded on the ASX.

HeartWare Limited became the parent of our operating subsidiary, HeartWare, Inc., on January 24, 2005. HeartWare, Inc. is a Delaware corporation which was incorporated on April 8, 2003 under the name Perpetual Medical, Inc., and which changed its name to HeartWare, Inc. on July 10, 2003. Since July 10, 2003, HeartWare, Inc. has operated the business formerly owned and operated by Kriton Medical, Inc., which had been developing the HeartWare System since approximately 1995. In May 2003, Kriton filed for protection from creditors under Chapter 11 of the United States Bankruptcy Code. On July 10, 2003, HeartWare, Inc. purchased substantially all of the assets of Kriton free and clear of any and all liens, security interests, encumbrances and claims.

Item 1A. Risk Factors

Our business faces many risks. We believe the risks described below are material risks facing the Company. However, these risks may not be the only risks we face. Additional unknown risks, or risks that we currently consider immaterial, may also impair our business operations. If any of the events or circumstances described below actually occurs, our business, financial condition or results of operations could suffer, and the trading price of our shares could decline significantly. Investors should consider the specific risk factors discussed below, together with the cautionary statements under the caption "Forward-Looking Statements" and the other information and documents that we file from time to time with the SEC.

Risks Related to Our Financial Standing

We have incurred operating losses since our inception and anticipate that we will continue to incur operating losses for the foreseeable future. Our ability to achieve profitability from a current net loss level will depend on our ability to increase gross revenue, manage our expenditures and reduce the per-unit cost of producing the HVAD System by increasing our customer orders and manufacturing volume.

We have incurred net losses since our inception, including net losses of $72.8 million, $19.4 million and $59.3 million for the fiscal years ended December 31, 2015, 2014 and 2013, respectively. As of December 31, 2015, our accumulated deficit was $421.5 million. Currently, we have only one product, the HVAD System, approved for sale. We continue to incur substantial clinical trial expenditures, significant research and development costs and costs related to our operations. We expect to continue to incur significant operating losses for the foreseeable future as we incur costs associated with:

- conducting multiple clinical trials, including preapproval trials for new products, such as the MVAD System, and new indications for existing products, such as destination therapy, as well as post-approval trials for existing products;
- researching and developing next-generation products and peripherals, such as the MVAD System, the Pal controller and the CircuLite System, as well as incremental improvements to and sustaining engineering for existing products and peripherals;
- integrating and developing acquired and licensed technology;
- building our service capabilities to meet growing customer demand;
- growing, maintaining and protecting our intellectual property;
- seeking and maintaining regulatory approvals and operating our quality systems, including warning letter remediation;
- expanding our sales and marketing capabilities both internationally and in the U.S.;
- manufacturing product and increasing our manufacturing capabilities to meet rising demand;
- broadening our infrastructure in order to meet the needs of our growing operations; and
- complying with the requirements related to being a public company in the United States.

To become and remain profitable, we must succeed in a range of challenging activities, including all of the activities listed above. We also must, among other things, continue to reduce the per-unit cost of our products. If we are unable to increase sales and simultaneously reduce assembly, raw material, component and manufacturing overhead costs, our ability to achieve profitability will continue to be constrained. If we do achieve profitability, we may not be able to sustain it.

We have a significant amount of indebtedness consisting primarily of our convertible senior notes. We may not be able to generate enough cash flow from our operations to service or pay principal and interest on our indebtedness, which could adversely affect our business, financial condition or results of operations. Furthermore, we may incur additional indebtedness or refinance our current indebtedness in the future, which could also adversely affect our business, financial condition or results of operations. The conversion of our convertible senior notes at the election of the holders, to the extent we settle the conversion in cash, could impact our liquidity, and to the extent we settle in stock, could dilute our existing stockholders.

As of December 31, 2015, our indebtedness under our convertible senior notes in the principal amount of $244.8 million totaled $191.1 million, net of discounts. The indebtedness consisted of Convertible Senior Notes due December 15, 2017 in the principal amount of $42.5 million totaling $36.5 million, net of discounts, and Convertible Senior Notes due December 15, 2021 in the principal amount of $202.4 million totaling $154.6 million, net of discounts. Generally, holders may convert their Convertible Notes at their option only upon satisfaction of one or more of the conditions relating to the sale price of our common stock, the trading price per $1,000 principal amount of Convertible Notes or specified corporate events. Upon conversion, we will pay or deliver, as the case may be, cash, shares of our common stock or a combination thereof, at our election. Our ability to make payments on, or to refinance, our Convertible Notes, to incur future indebtedness, and to fund planned capital expenditures, research and development efforts, working capital, acquisitions and other general corporate purposes, depends on our ability to generate or access cash in the future. This, to a certain extent, is subject to general economic, financial, competitive, legislative, regulatory, clinical and other factors, some of which are beyond our control. If we do not generate sufficient cash flow from operations, or if future borrowings are not available to us in an amount sufficient to pay our indebtedness, including payments of principal upon conversion of the Convertible Notes or upon their maturity, or to fund our liquidity needs, we may be forced to refinance all or a portion of our indebtedness, including the Convertible Notes, on or before their maturity, sell assets, reduce or delay capital expenditures, seek to raise additional capital or take other similar actions. We may not be able to affect any of these actions on a timely basis at commercially reasonable terms or at all. Our ability to refinance our indebtedness will depend on our financial condition at the time, the restrictions in the instruments governing our indebtedness and other factors, including market conditions. In addition, in the event of a default with respect to the Convertible Notes, the holders of the Convertible Notes and/or the trustee under the indenture governing the notes may accelerate the payment of our obligations under the notes, which could have a material adverse effect on our business, financial condition or results of operations. Our inability to generate sufficient cash flow to satisfy our debt service obligations, or to refinance or restructure our obligations on commercially reasonable terms or at all, would likely have an adverse effect, which could be material, on our business, financial condition and results of operations.

In addition, our significant indebtedness combined with our other financial obligations and contractual commitments could have other important consequences. For example, it could:

- make us more vulnerable to adverse changes in general U.S. and worldwide economic, industry and competitive conditions;
- make us more vulnerable to adverse changes in government regulation and reimbursement;
- limit our flexibility in planning for, or reacting to, changes in our business and our industry;
- place us at a competitive disadvantage compared to our competitors who have less debt; and
- limit our ability to borrow additional amounts for working capital, capital expenditures, acquisitions, debt service requirements, execution of our business strategy or other purposes.

Any of these factors could materially and adversely affect our business, financial condition or results of operations. In addition, if we incur additional indebtedness, which we are not prohibited from doing under the terms of the indenture governing the convertible senior notes, the risks related to our business and our ability to service our indebtedness would increase.

In the event the conditional conversion feature of the notes is triggered, holders of the Convertible Notes will be entitled to convert the Convertible Notes at any time during specified periods at their option. If one or more holders elect to convert their Convertible Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than cash in lieu of any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the notes as a current rather than long-term liability, which would result in a material reduction of our net working capital. The terms of our convertible senior notes permit us to settle them, upon conversion by the holders thereof, in cash, stock or a combination thereof. To the extent we use stock for settlement, our existing stockholders may be diluted.

We may need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We currently spend more cash than we generate from operating revenue. Depending on a range of outcomes, especially our achievement and continuation of regulatory approval of our products and the growth of revenue, we may need to seek additional funding in the future. Additional funding may not be available when we desire on terms favorable to us, or at all. If we raise additional funding through the issuance of equity or convertible debt securities, our shares may suffer dilution. If we are unable to secure additional funding, our product development programs and our commercialization efforts would be delayed or reduced or may cease entirely.

We currently rely entirely on sales of our sole product, the HVAD System, to generate revenue. Our existing and future products may not achieve or sustain market acceptance. In addition, any factors that negatively impact sales of this product will adversely affect our business, financial condition and results of operations.

Our sole marketed product is the HVAD System, which we introduced to the European market in January 2009 and which received regulatory approval for sale in the U.S. in late 2012. We expect to continue to derive substantially all of our revenue for the next few years from the sale of this product and its related devices. Accordingly, our ability to generate revenue is entirely reliant on our ability to market and sell this product. We expect to begin to derive limited revenue as a result of MVAD systems purchased by participating clinical trial sites pursuant to a qualified U.S. IDE study; however, clinical trials of the next generation MVAD System may adversely impact revenue derived from the current generation HVAD System. In September 2015, we voluntarily paused our MVAD System CE Mark clinical trial and the timing for restarting clinical implants, if ever, cannot be reliably projected at this time.

Even if we are able to obtain and maintain the necessary regulatory approvals in all jurisdictions to commercialize the HVAD System or other products that we may develop, our products may not gain or sustain market acceptance among physicians, patients, health care payors or the medical community.

The degree of market acceptance of any of the devices that we may develop and commercialize will depend on a number of factors, including: the prevalence and severity of any adverse events or side effects especially as it relates to survival, quality of life, and patient management; potential advantages over alternative treatments or competitive products; the strength and perceived advantages of our peripherals such as the monitor, controller and batteries; and sufficient third party coverage or reimbursement.

If we fail to obtain and maintain adequate level of reimbursement for our products by third-party payors, there may be no commercially viable markets for our products or the markets may be much smaller than expected.

Although our customers have generally achieved reimbursement for the purchase of our products to date, the availability and levels of reimbursement by governmental and other third-party payors affect the market for

our products. Reimbursement and health care payment systems vary significantly by country, and include both government-sponsored health care and private insurance. Payors may attempt to limit coverage and the level of reimbursement of new therapeutic products or investigational devices. Government and other third-party payors also continually attempt to contain or reduce the costs of health care by challenging prices charged for health care products and services. Often, reimbursement is determined independently of, and only following, product approval, and may need to be renewed on a regular basis.

To obtain reimbursement or pricing approval in some countries, we may be required to produce clinical and economic data, which may involve one or more clinical trials, that compares the cost-effectiveness of our products to other available therapies. In addition, the efficacy, safety, performance and cost-effectiveness of our products in comparison to competing products may determine the availability and level of reimbursement for our products.

We believe that future reimbursement may be subject to increased restrictions both in the United States and in international markets. Future legislation, regulation or reimbursement policies of third-party payors may adversely affect the demand for our existing products as well as products currently under development and limit our ability to sell our products on a profitable basis. We cannot predict how pending or future legislative and regulatory proposals would influence the manner in which medical devices, including ours, are purchased or covered and reimbursed.

On October 30, 2013, CMS issued a Decision Memo for Ventricular Assist Devices for bridge-to-transplant ("BTT") and destination therapy ("DT") (CAG-00432R), which updated the national coverage determination ("NCD") for bridge-to-transplant and destination therapy VADs. The updated NCD, among other things, attempts to clarify BTT and DT patient selection criteria. The updated NCD clarified that BTT patients, without an exemption, must be active on the Organ Procurement and Transplantation Network's waitlist for a heart in order to be eligible for Medicare or Medicaid reimbursement. Since the HVAD System is currently approved in the U.S. for BTT patients only, the update to the NCD creates a subset of potential HeartWare BTT patients who may no longer be eligible for Medicare and Medicaid reimbursement. The update also mandates affiliations with heart transplant centers, which limits VAD implantation at alternate care facilities. Therefore, the update may adversely affect our revenue, earnings, business or results of operation.

If reimbursement for our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, market acceptance of our products would be impaired and our future revenue would be materially adversely affected. Often, reimbursement is not available for products used in clinical trials as the relevant insurance providers may refuse to provide reimbursement for trial products on the basis that the products are "experimental" or "investigational" and do not have the requisite regulatory approvals. As we develop next-generation products, this requirement may materially adversely affect our revenue, earnings, business and stock price.

Investors could lose confidence in our financial reports, and the value of our shares may be adversely affected, if our internal controls over financial reporting are found not to be effective by management or by our independent registered public accounting firm or if we make disclosure of existing or potential significant deficiencies or material weaknesses in those controls.

Management's assessment of our internal controls over financial reporting is discussed in Item 9A of this Annual Report on Form 10-K for the year ended December 31, 2015. The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures, and internal control over financial reporting as of December 31, 2015. Based on that evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures, and internal control over financial reporting are effective as of December 31, 2015. Our independent registered public accounting firm has issued their attestation report on our internal control over financial reporting, which is included in Item 8 of this Annual Report on Form 10-K for the year ended December 31, 2015.

We continue to evaluate our existing internal controls over financial reporting against the standards adopted by the Public Company Accounting Oversight Board, or PCAOB. During the course of our ongoing evaluation of the internal controls, we may identify areas requiring improvement and will design enhanced processes and controls to address any issues identified through this review. As we continue to commercialize our products, we may need to enhance our accounting and financial controls functions, particularly as they relate to accounting for revenue and inventory, and we may need to add more personnel to our financial reporting group. Remediating any deficiencies, significant deficiencies or material weaknesses that have been or could be identified by us or our independent registered public accounting firm may require us to incur significant costs and expend significant time and management resources. We cannot assure you that any of the measures we implement to remedy any deficiencies will effectively mitigate or remedy deficiencies. The existence of one or more deficiencies or weaknesses could affect the accuracy and timing of our financial reporting. Investors could lose confidence in our financial reports, and the value of our shares may be adversely affected if our internal controls over financial reporting are found not to be effective by management or by our independent registered public accounting firm or if we make disclosure of existing or potential significant deficiencies or material weaknesses in those controls.

Business development activities are inherently risky, and integrating our operations with businesses we may acquire may be difficult and, if unsuccessfully executed, may have a material adverse effect on our business.

We may, selectively, from time to time engage in business development activities, such as strategic acquisitions, minority investments or strategic alliances in order to complement or expand our current business or enter into a new product area. These transactions can involve significant challenges and risks, including the risk that the transaction does not advance our business strategy, results in a loss or fails to produce a satisfactory return on our investment. For example, as disclosed, we continue to be a minority investor in Valtech Cardio Ltd., an Israeli company, and, in connection with the termination of our Business Combination Agreement with Valtech, we made a loan to Valtech in the principal amount of $30 million pursuant to a Convertible Promissory Note. There can be no assurance that we will recognize an acceptable rate of return or other benefit from our investment in Valtech or our loan to it, or that the loan will be repaid in accordance with its terms. While our evaluation of any potential acquisition or investment includes business, clinical, legal and financial due diligence with the goal of identifying and evaluating the material risks involved, we may be unsuccessful in ascertaining or evaluating all risks. These plans are also subject to the availability of appropriate opportunities and competition from other companies seeking similar opportunities. Moreover, the success of any strategic effort may be affected by a number of factors, including our ability to properly assess and value the potential business opportunity to finalize the development of the acquired technology and to commercialize successfully the final product.

Risks Related to Regulatory Approval

In November 2012, we received approval to market the HVAD System in the U.S. as a bridge-to-heart-transplantation. Our future success depends heavily on our ability to maintain FDA approval to market our existing product for our initial indication, obtain FDA approval for additional indications, and to market our pipeline products in the U.S. and around the world.

The process of obtaining and maintaining marketing approval or clearance from the FDA and other regulatory authorities for our existing and future products, or enhancements or modifications to these products, could:

- take a significant period of time;
- require the expenditure of substantial resources;
- involve rigorous pre-clinical and clinical testing as well as post-approval studies;
- require changes to our products;

- require corrective action, including recalls, with respect to products already distributed; and
- result in limitations on the indicated uses of the products.

Assuming we are able to file the required regulatory premarket approval applications for additional indications for our HVAD System as well as the initial indication of for our MVAD System and other pipeline products, there can be no assurance that we will receive the required approvals, or, if we do receive the required approvals, that we will receive them on a timely basis or for the full scope of the indication(s) requested or that we will otherwise be able to satisfy the conditions of approval, if any. In particular, because of the FDA warning letter received by HeartWare in June 2014, we are under additional regulatory scrutiny, which could increase the risk of delay in product approvals. The failure to receive product approval by the FDA, or any significant delay in receipt of approval, will have a material adverse effect on our business, financial condition or results of operations.

If we are unable to commence or complete successfully our clinical trials, or if we experience significant delays in the successful commencement or completion of our clinical trials, our ability to obtain regulatory approval to commercialize our products, and our ability to generate revenue, will be materially adversely affected.

Regulatory approvals to sell our existing and future products both in and outside of the U.S. typically require clinical trials, which can be time consuming, unpredictable and expensive. Significant technical, bench and preclinical testing may be required prior to submitting for regulatory authorization to commence a clinical trial. The cost, timing and outcome of any of these trials or testing may be unfavorable or may be insufficient to obtain the required approvals.

Completion of any of our clinical trials, including our ongoing destination therapy trial, our thoracotomy trial, and particularly our MVAD System CE mark trial, and initiation of new clinical trials, including for the CircuLite System, could be delayed or adverse events during a trial could cause us to amend, repeat or terminate the trial. If this was to happen, our costs associated with the trial will increase, and it will take us longer to obtain regulatory approvals and to commercialize the product, or we may never obtain regulatory approvals. Like with our current MVAD System CE Mark clinical trial, our clinical trials may be voluntarily suspended or terminated by us at any time, including during the closing stages of enrollment and the subsequent patient follow-up period in the event that, for example, there should be an unacceptable level of adverse clinical events such as stroke, thrombus, bleeding or pump exchanges. Also, regulatory authorities, the data safety and monitoring board, or site investigational review boards could suspend or terminate a trial at any time. Any failure or significant delay in completing clinical trials for our products may materially harm our financial results and the commercial prospects for our products.

The completion of any of our clinical trials could be substantially delayed or prevented by several factors, including: slower than expected rates of patient recruitment and enrollment, including as a result of study inclusion and exclusion criteria; our competitors undertaking similar clinical trials at the same time as us, or having functionally comparable products that have received approval for sale; physicians or patients preferring to use approved devices or other treatments or devices rather than our devices; prevalence and severity of adverse events, such as thrombosis or stroke, and other unforeseen safety issues; and governmental and regulatory delays or changes in regulatory requirements, policies or guidelines.

Our manufacturing facilities and the manufacturing facilities of our suppliers must comply with applicable regulatory requirements. If we or our suppliers fail to achieve and maintain regulatory approval for these or additional manufacturing facilities, our business and our results of operations would be harmed.

Completion of our clinical trials and commercialization of our products require access to, or the development of, manufacturing facilities that meet and maintain applicable U.S. and international regulatory

standards to manufacture a sufficient supply of our products. In addition, the FDA must approve facilities that manufacture our products for U.S. commercial purposes, as well as the manufacturing processes and specifications for the product, with similar, additional approvals required in order to achieve and maintain CE marking in Europe or regulatory approvals in other jurisdictions. Suppliers of components and products used to manufacture our products must also comply with FDA and foreign regulatory requirements, which often require significant time, money, resources, record-keeping and quality assurance efforts and subject us and our suppliers to potential regulatory inspections and stoppages. If we or our suppliers, particularly our single-source suppliers, fail to comply with the regulatory requirements for our manufacturing operations, our commercialization efforts could be delayed or suspended, which would harm our business and our results of operations. Our receipt of an FDA warning letter increases this risk as we are subject to a higher level of regulatory scrutiny as we work to update and improve our quality system.

We may not meet regulatory quality standards applicable to our manufacturing and quality processes, which could have an adverse effect on our business, financial condition or results of operations.

Even after products have received marketing approval or clearance from the FDA or other regulatory bodies, those product approvals and clearances can be withdrawn due to failure to comply with regulatory standards or the occurrence of problems following initial approval whether identified through a required post-approval study or through medical device reporting. As a device manufacturer, we are required to demonstrate and maintain compliance with a variety of regulatory requirements, including the FDA's Quality System Regulation, or "QSR." The QSR is a complex regulatory scheme that covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products, including trend analysis and corrective and preventive actions. In addition, the U.S. federal medical device reporting regulations require us to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, is likely to cause or contribute to a death or serious injury. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA. Our failure to comply with the QSR or to take satisfactory corrective action in response to an adverse QSR inspection or complaint information could result in enforcement actions, including a public warning letter, a shutdown of, or restrictions on, our manufacturing operations, delays in approving or clearing a product, refusal to permit the import or export of our products, a recall or seizure of our products, fines, injunctions, civil or criminal penalties, or other sanctions, any of which could cause our business and operating results to materially suffer. The FDA has issued, and could issue in the future, warning letters or other communications to the Company. If we fail to satisfy or remediate the matters discussed in warning letters or communications, the FDA could take further enforcement actions as described above. Further, related remediation could require a substantial amount of money and time and could precipitate field actions, all of which could harm our business, customer confidence and our results of operations.

In the European Union, we are required to maintain certain ISO certifications in order to sell our products and must undergo periodic inspections by notified bodies to obtain and maintain these certifications. If we fail to continue to comply with ISO regulations, European Union organizations may withdraw clearance to market, require a product recall or take other enforcement action.

Product deficiencies could result in field actions, recalls, substantial costs and write-downs; this could also lead to delay or termination of ongoing trials.

Our products are subject to various regulatory guidelines, involve complex technologies and are approved for a specified life. Identified quality problems, such as failure of critical components including batteries, controllers or driveline connectors, or the failure of third parties to supply us with sufficient conforming quantities of these products or components, could lead to adverse clinical events that could cause us to amend, repeat or terminate clinical trials, or impact the availability of our product in the marketplace. In addition, product improvements, product redundancies or failure to sell product before it expires could result in scrapping

or expensive rework of product and our business, financial or results of operations could suffer. Product complaints, quality issues and necessary corrective and preventive actions could result in communications to customers or patients, field actions, the scrapping, rework, recall or replacement of product, substantial costs and write-offs, and harm to our business reputation and financial results. Further these activities could adversely affect our relationships with our customers or their confidence in our products which could materially adversely affect our earnings, results and financial viability.

We operate in multiple regulatory environments that require costly and time consuming approvals.

Even if we obtain regulatory approvals in specific jurisdictions to commercialize the HVAD System or other products that we may develop, sales of our products in other jurisdictions will be subject to regulatory requirements that vary from country to country. The time and cost required to obtain approvals from these countries may be longer or shorter than that required for FDA approval, and requirements for registration may differ from those of the FDA. Some jurisdictions, such as Japan, may even require that we conduct additional trials. Laws and regulations regarding the manufacture and sale of our products are subject to future changes, as are administrative interpretations and policies of regulatory agencies. If we fail to comply with applicable foreign, federal, state or local market laws or regulations, we could be subject to enforcement actions. Enforcement actions could include product seizures, recalls, withdrawal of clearances or approvals, and civil and criminal penalties, which in each case would harm our business and financial condition.

Risks Related to Operations

We have limited manufacturing capabilities and personnel, and if our manufacturing facilities are unable to provide an adequate supply of products, our growth could be limited and our business could be harmed.

We currently manufacture our HVAD System at our facilities in Miami Lakes, Florida. If there were a disruption to our manufacturing facilities or the surrounding area, for example, due to a hurricane, we would have no other means of manufacturing our HVAD System until we were able to restore the manufacturing capability at our facility or develop alternative manufacturing facilities.

If we are unable to ship or produce sufficient quantities of our HVAD System for sale or for use in our current and planned clinical trials, or if our manufacturing process yields substandard product, our development and commercialization efforts would be delayed. Further, if regulations restrict the way we ship our products, such as new regulations that may restrict the way we ship our lithium ion batteries, we may incur additional expense or experience distribution delays. In addition, if a regulatory authority approves or clears a new product or a new indication for the HVAD System, we may not be able to ship or manufacture additional product in the quantities needed to meet the increased commercial demand on a timely basis. Even if we are able to produce and ship sufficient quantities of our products, we may not be able to attain sufficient profitability on that production or any resultant sales.

We currently have limited resources, facilities and experience to commercially manufacture our products. In order to produce our products in the quantities that we anticipate will be required to meet anticipated market demand, we will need to increase the production process and efficiency over the current level of production. There are significant technical and regulatory challenges to increasing manufacturing capacity and efficiency, and continuing to develop commercial-scale manufacturing facilities will require the investment of additional funds and hiring and retaining additional management and technical personnel who have the necessary manufacturing and operational experience. We may not successfully complete any required increase in a timely or economically viable manner, or at all. If we are unable to do so, we may not be able to produce the HVAD System or other products that we may develop, in sufficient quantities to meet future demand.

If we are unable to manufacture a sufficient or consistent supply of the HVAD System or other products we are developing, or if we cannot do so efficiently or pursuant to regulatory standards, our revenue, business and financial prospects would be adversely affected.

We rely on specialized suppliers for certain components and materials, and we do not have second-source suppliers for all of our components.

We depend on a number of suppliers to successfully manufacture sufficient quantities of the components we use in our products, both our existing commercial products and our products in development. We rely on suppliers for various critical components including the center post, housing and impeller that are assembled into our primary product, the HVAD System, as well as finished products that comprise our peripheral and external equipment included in the HVAD System. Similar relationships exist in relation to our MVAD System. Lead times for our components are significant and can be as long as sixteen weeks or longer and many of our components are manufactured to very tight tolerances and specifications. We do not presently have supply agreements with the majority of our key suppliers but have extensive purchase orders in place with these vendors.

We have second-source suppliers for some, but not all, of our components. In particular, we do not have second-source suppliers for our controllers, battery chargers and monitors. Our reliance on third-party suppliers also subjects us to other risks that could harm our business, including:

- we do not believe that we are a major customer of some of our suppliers, in terms of the volume of components and materials that we purchase, and these suppliers may therefore give other customers' needs higher priority than ours or discontinue or modify components based on demand or lack of demand from other customers;
- we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;
- some of our components are extraordinarily complex and must be manufactured to extremely tight tolerances and specifications with the result that our suppliers, especially new suppliers, may make errors in manufacturing that could negatively affect the efficacy or safety of our products or cause our components not to be delivered on time or at all or to be delivered outside of our specifications;
- the availability of second-source suppliers may be extremely limited or their implementation as a supplier may be lengthy due to the tight tolerances and specifications in which we typically operate as well as regulatory requirements;
- switching components or changes to our components, specifications or designs may require product redesign and regulatory submissions, which can lead to production interruptions; and
- our suppliers and their sub-suppliers may encounter financial hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements.

Any interruption or delay in obtaining products from our third-party suppliers, or our inability to obtain products from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competing products.

While we have identified second-source suppliers for other key components, we have not entered into written agreements with these suppliers and we cannot be certain that we will be able to maintain our manufacturing schedule without undue delay or substantial cost if any of these arrangements is terminated.

Additionally, we may experience problems or delays in our own manufacturing and assembly processes, which may be harmful to our financial status or reputation and, therefore, make it more difficult or expensive for us to continue with, or enter into relationships with, specialized suppliers. Our business plan is predicated on maintaining strong relationships and favorable supply arrangements with a series of external parties to manufacture components of our HVAD System and other products we may develop, such as the MVAD System. If we are unsuccessful in this regard or are unable to secure or maintain agreements with these manufacturers on favorable terms or at all, then our ability to commercialize our technology and expand our operations will be dramatically impaired.

We use external consultants and engineers to help us develop new products and peripherals as well as components for our current products and peripherals. Many of these external projects anticipate innovation or technology development that does not currently exist and are funded on a time and materials basis. As a result,

the ability of third-party contractors to develop the necessary technology in accordance with established budgets and timelines is uncertain. Failure to timely execute a development program could result in the delay or abandonment of a new product or component or increase the cost of the activity. These outcomes could adversely impact our business, prospects and financial condition.

Risks Related to Future Growth

If we are unable to manage our expected growth, we may not be able to meet market demand, generate expected benefits from the opportunities available to us, satisfy quality regulations or commercialize our products.

We expect to continue to expand our operations and grow our research and development, product development, quality, regulatory, manufacturing, sales, marketing and administrative operations. This expansion has placed, and is expected to continue to place, a significant strain on our management, infrastructure, information technology, operational and financial resources. To manage continued growth and to commercialize our products, we will be required to improve existing operational, quality and financial systems, procedures and controls and expand, train and manage our employee base. In addition, we will need to manage relationships with various third parties and external entities participating in our research and development efforts, clinical trials, quality systems, manufacturers, suppliers and other organizations, including various regulatory bodies in the U.S. and other jurisdictions. We have begun to implement systemic changes and organizational improvements to address the items raised by the FDA in our warning letter. We may not be able to implement needed improvements in an efficient and timely manner and may discover deficiencies in existing systems and controls, which may require remediation such as process enhancements and field actions. Our failure to accomplish any of these tasks could materially harm our business and prospects.

Further, we have aggressively expanded, and expect to continue to expand, into foreign markets. Expansion into additional foreign markets imposes additional burdens on our executive and administrative personnel, research, regulatory and sales departments and generally limited managerial resources. Our efforts to introduce our current or future products into additional foreign markets may not be successful, in which case we may have expended significant resources without realizing the expected benefit. Ultimately, the investments required for expansion into additional foreign markets could exceed the returns, if any, generated from this expansion. The taxation and customs requirements, together with other applicable laws and regulations of foreign jurisdictions, can be inherently complex and subject to differing interpretation by local authorities. We are subject to the risk that either we have misinterpreted applicable laws and regulations or that foreign authorities may take inconsistent, unclear or changing positions on local law, customs practices or rules. In the event that we have misinterpreted local requirements, or that foreign authorities take positions contrary to ours, we may incur liabilities that may differ materially from the amounts accrued in our financial statements.

Destination therapy procedures represent an increasing share of ventricular assist device implants. Although we are currently conducting destination therapy trials and plan to submit an application for PMA approval to the FDA, we may be unable to obtain destination therapy approval for several years.

Hospitals must meet specific regulatory or reimbursement requirements in order to perform destination therapy procedures. These requirements and national coverage determinations may change from time to time. We are currently conducting clinical trials to study the use of the HVAD System for destination therapy. If reimbursement is reduced, or if the requirements are modified, or if physicians decline to use our products for destination therapy in the future, our market opportunities will be diminished and our business and stock price may be adversely impacted. The number of destination therapy procedures actually performed depends on many factors, most of which are out of our direct control, including:

- the number of sites approved for destination therapy by relevant regulatory agencies;
- the clinical outcomes, and physician presentations of clinical outcomes, of our destination therapy trials and destination therapy procedures, in general;

- implanting surgeons' and referring cardiologists' commitment to destination therapy;
- the economics of VADs for destination therapy at individual hospitals, which includes the costs of the VAD and related pre- and post-operative procedures and treatment and their reimbursement; and
- the economics of hospitals not conducting a destination therapy procedure, including the costs and related reimbursements of long-term hospitalization of patients with advanced heart failure and alternative therapies.

The different outcomes of these and other factors, and their timing, may have a material and adverse effect on our future results.

In addition, our primary competitor has received a destination therapy indication for its current product and is seeking a destination therapy indication for its new product. If physicians grow accustomed to those devices for destination therapy and become unwilling to use our device for this indication, our ability to participate in and benefit from this opportunity may suffer.

If we fail to successfully introduce next-generation products and improvements to our existing product, our future growth may suffer.

As part of our strategy, we intend to develop and introduce a number of next-generation products and make enhancements to our existing products. We also intend to develop new indications for our existing products. If we are slow in bringing new products to market or otherwise fail to successfully develop, manufacture, design clinical trials for, introduce or commercialize any of these new products, product improvements or new indications on a timely basis, or if they are not well-accepted by the market or third party payors, our future growth may suffer. For example, we are developing a next-generation system based on our MVAD pump technology, designing a new and improved controller and conducting a clinical trial for a thoracotomy placement, among others. If we are not successful in these efforts, among others, our future business opportunities and growth potential will suffer.

Business development activities are inherently risky, and integrating our operations with businesses we may acquire may be difficult and, if unsuccessfully executed, may have a material adverse effect on our business.

We may, selectively, from time to time engage in business development activities, such as strategic acquisitions, like our acquisitions of World Heart Corporation and CircuLite, Inc., our contemplated acquisition of Valtech Cardio, Ltd., and other investments and alliances in order to complement or expand our current business or enter into a new market. These transactions can involve significant costs, challenges and risks, including that the transaction does not advance our business strategy, requires significant ongoing investment, or fails to produce a satisfactory return on our investment. While our evaluation of any potential acquisition or investment includes business, clinical, legal and financial due diligence with the goal of identifying and evaluating the material risks involved, we may be unsuccessful in ascertaining or evaluating all risks. These plans are also subject to the availability of appropriate opportunities and competition from other companies seeking similar opportunities. Moreover, the success of any strategic effort may be affected by a number of factors, including our ability to properly assess and value the potential business opportunity, to finalize the development of the acquired technology and to commercialize successfully the final product.

Each acquisition involves the integration of a separate company that was previously operated independently and has different systems, processes, policies and cultures. The process of combining companies may be disruptive to our businesses and may cause an interruption of, or a loss of momentum in, both of the businesses. Further, these challenges could materially harm our stock price, business, financial condition or results of operations. If we are unable to successfully integrate strategic acquisitions in a timely manner, our business and our growth strategies could be negatively affected. Even if we are able to successfully complete the integration of

the operations of other companies or businesses we may acquire in the future, we may not be able to realize all or any of the benefits that we expect to result from the integration, either in monetary terms or in a timely manner.

We may choose to license or acquire products or technologies, in addition to, or instead of, developing them ourselves. We cannot be certain that these efforts will be successful or that we will realize any revenue from them.

We license or acquire products and technologies under licensing, purchasing and other agreements. In addition to active internal and external research and development efforts, we may seek, from time to time, to license or acquire new products or technologies to supplement or replace products or technologies. License and acquisition of technology involves numerous risks, including the inability to successfully license or acquire the desired product or technology on terms favorable to us or at all, the incurrence of significant financial commitments to third parties, and the risks associated with third parties terminating licenses arrangements if we do not perform as required under the agreements.

In addition, third parties may breach or terminate their license agreements with us or fail to conduct their activities in connection with our relationships in a timely manner. If we or our counterparties terminate or breach any of our licenses we may:

- lose our right to develop and market certain intellectual property;
- experience delays in the development or commercialization of our product;
- litigate or arbitrate disputes, both of which are time-consuming and expensive and have uncertain outcomes;
- incur liability for damages; and
- be unable to obtain any other similar licenses on acceptable terms, if at all.

Any of these factors could materially harm our stock price, business, financial condition or results of operations.

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

Our VAD systems have lengthy sales cycles and we may incur substantial sales and marketing expenses and expend significant effort without making a sale. Even after making the decision to purchase our VAD systems, our customers often deploy our products slowly, and this time period may be extended if our products are acquired on a consignment basis, as is the case for some of our customers. In addition, cardiac centers that buy the majority of our products are usually led by physicians who are heavily recruited by competing centers or by centers looking to increase their profiles. When one of these physicians moves to a new center we sometimes experience a temporary but significant reduction in purchases by the center from which the surgeon has departed while it replaces its lead surgeon. As a result, it is difficult for us to predict the quarter in which customers may purchase our VAD systems and our product sales and operating results may vary significantly from quarter to quarter. In addition, product purchases often lag initial expressions of interest in our product by new centers as training of the VAD team and internal hospital administrative procedures is typically required prior to the initial implant procedures.

Risks Related to Competition

We compete against companies that have longer operating histories, more established or approved products and greater resources than we do, which may prevent us from achieving further market penetration or improving operating results.

Competition in the medical device industry is intense. Our products will compete against products offered by public companies, such as St. Jude Medical, Inc. (which acquired Thoratec Corporation in October 2015) and Sunshine Heart, Inc., as well as several private companies, such as Jarvik Heart, Inc. and ReliantHeart Inc. Some of these competitors, particularly St. Jude Medical, Inc., have significantly greater financial and human resources than we do, have established reputations or approved products or significantly greater name recognition than we do, and have significantly larger and more established distribution channels and sales and marketing capabilities than we do. For example, St. Jude Medical, Inc. has received a CE Mark for its next-generation HeartMate III device, has commenced a U.S. clinical trial for its HeartMate III device and has marketing approval in the U.S. for its HeartMate II device for both destination and bridge-to-transplant indications. Our HVAD System, which is our only commercial product, is currently approved in the U.S. for the bridge-to-transplant indication only. We are likely to compete with new companies in the future as additional competitors enter the market. We also face competition from other medical therapies, which may focus on our target markets as well as competition from manufacturers of pharmaceutical treatments and other devices that are currently in development.

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, such as heart transplants and pharmaceuticals;
- product performance and design;
- product safety;
- sales, marketing and distribution capabilities;
- comparable clinical outcomes;
- physician acceptance of our products;
- success and timing of new product development and introductions;
- penetration into existing and new geographic markets; and
- intellectual property protection.

The competition for qualified personnel is particularly intense in our industry. In addition, we have added or made changes to executive personnel during 2015 and may continue to do so as our needs evolve. If we are unable to retain or hire executive and other key personnel, we may not be able to sustain or grow our business.

Our ability to operate successfully and manage our potential future growth depends significantly upon our ability to attract, retain and motivate highly skilled and qualified research, technical, clinical, regulatory, sales, marketing, managerial, legal and financial personnel. We have hired, and expect to continue to hire, a substantial number of employees in these areas and others in order to support U.S. commercialization and the expected growth in our global business. However, we face intense competition for qualified personnel, and we may not be able to attract, retain and motivate these individuals. We compete for talent with numerous companies, as well as hospitals, universities and non-profit research organizations. Our future success also depends on the personal efforts and abilities of the principal members of our senior management and scientific staff to provide strategic direction, management of our operations and maintenance of a cohesive and stable working environment. Although we have employment and incentive compensation agreements with all of our executive officers and incentive and compensation plans for our other personnel providing them with various economic incentives to

remain employed with us, these incentives may not be sufficient to retain them. We do not maintain key-man life insurance on the lives of any of the members of our senior management. The loss of key personnel for any reason or our inability to hire, retain and motivate additional qualified personnel in the future could prevent us from sustaining or growing our business.

Risks Related to Product Liability

We manufacture a complex medical device implanted in the heart that subjects us to numerous risks. Product liability claims could damage our reputation or adversely affect our business.

There are risks associated with implanting our device in patients with end-stage heart failure, including, but not limited to, death, bleeding, stroke, device malfunction and other adverse events. Should our customers experience an increase in adverse events, they may reduce their usage or purchase of our device. In addition, should our patients experience injury due to these events, they or regulatory authorities may pursue legal or administrative action against us. Any of these occurrences could have a materially adverse impact on our operations and financial results and conditions as well as customer confidence in us or our products. Specifically, product liability and similar claims may be expensive to defend and may result in large judgments against us. A product liability or other damages claim, product recall or product misuse, regardless of the ultimate outcome, could require us to spend significant time and money in litigation or to pay significant damages and could seriously harm our business. We maintain limited clinical trial insurance and product liability insurance. We cannot be certain that insurance will be sufficient to cover all claims that may be made against us. Our insurance policies generally must be renewed on an annual basis. We may not be able to maintain or increase insurance on acceptable terms or at reasonable costs. Claims against us, regardless of their merit, could result in significant awards against us that could materially adversely harm our business, financial condition, results of operations or prospects. A product liability or other damages claim, product recall or product misuse involving any type of VAD, but especially involving one of ours, could also materially and adversely damage our reputation and the perception of VADs generally and affect our ability to attract and retain customers, irrespective of whether or not the claim or action was meritorious.

Risks Related to the Economy and Public Policy Relevant to our Business

Adverse changes in general economic conditions in the United States and overseas could adversely affect us.

We are subject to the risks arising from adverse changes in general economic market conditions. Many global economies remain sluggish as they recover from a severe recession and unprecedented turmoil. The U.S. and other developed economies continue to suffer from market volatility, rising healthcare costs, difficulties in the financial services sector, tight credit markets, concerns of inflation, reduced corporate profits and capital spending, significant job losses or slower than expected job creation, reduced consumer spending, and continuing economic uncertainties. The turmoil and the uncertainty about future economic conditions could negatively impact our current and prospective customers, adversely affect the financial ability of governments and health insurers to pay claims, adversely impact our expenses and ability to obtain financing of our operations, cause delays or other problems with key suppliers and increase the risk of counterparty failures. Since the use of the HVAD System in a patient is generally dependent on the availability of third-party reimbursement and normally requires the patient to make a significant co-payment, the pace of the global recovery will continue to influence our potential customers and may negatively affect customer orders. Similarly, the impacts of the challenging economy on our existing customers may cause some of them to cease purchasing, or lower or delay reimbursement for HVAD Systems and this will reduce our revenue, which in turn will make it more difficult to achieve the per-unit cost savings, which are expected to be attained through increases in our manufacturing volume.

The severe recession impacted the financial stability of many public and private health insurers. As a result, insurers continue to scrutinize claims more rigorously and delay or deny reimbursement more often. Although

VAD procedures occur in relatively limited numbers, the per-procedure reimbursement levels may draw the attention of third-party payors. Since the sale of the HVAD System is generally dependent on the availability of third-party reimbursement, any delay or decline in reimbursement will adversely affect our revenue.

Global market and economic conditions may exacerbate certain risks affecting our business.

International markets, especially Europe and the Middle East, represent a major part of our present business. Approximately 42% of our 2015 revenues were derived from international sales and a significant amount of our marketing efforts are focused on European and Middle Eastern countries. Although not materially impacted to date, our accounts receivable in certain European countries may be subject to significant payment delays due to government funding and reimbursement practices or limited financial flexibility of our distributors. Some foreign governments have announced or implemented austerity measures to constrain the overall level of government expenditures, which may include reforming health care coverage and reducing health care costs. These measures will continue to exert pressure on our customers and may impact their ability to pay for product on a timely basis or to maintain their current purchasing patterns. These adverse market and economic conditions could reduce our product sales and revenue, result in additional allowances, or reduce credit sales to our distribution network. In addition, some European and other payors require health technology assessments or economic cost-benefit analyses to be conducted by a manufacturer or third-party analysis group in order to obtain or maintain reimbursement of medical devices. These analyses can be expensive and time consuming, and may not produce outcomes favorable to us. Adverse or delayed outcomes will adversely affect our revenue. Similar obstacles may delay our expansion into new markets or reduce the expected benefits of entry into new markets.

Fluctuations in foreign currency exchange rates could adversely affect our financial results.

Changes in foreign currency exchange rates can affect the value of our assets, liabilities, costs and revenue. For example, strengthening of the U.S. dollar had an unfavorable year-over-year impact of approximately 7%, or $19.2 million, on our reported revenue in 2015. In 2015, approximately 37% of our revenue was sourced from international sales denominated in foreign currencies, mainly in Europe and principally in Euros, while most of our expenditures are incurred in U.S. dollars.

With limited exceptions, our international sales are denominated in Euros or in local currencies, not U.S. dollars, and fluctuations in foreign currency exchange rates, especially an appreciation of the U.S. dollar against major international currencies, will materially impact our revenue and earnings. Due to the size and stage of development of our operations and revenue, we do not presently mitigate our exposure to exchange risk to a significant extent other than by holding the majority of our funds in U.S. dollars or U.S. dollar-denominated investments.

Healthcare policy changes, including the Patient Protection and Affordable Care Act, may have a material adverse effect on us.

In response to perceived increases in health care costs in recent years, there have been, and continue to be, proposals by the federal government, state governments, regulators and third-party payors to control these costs and, more generally, to reform the U.S. healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the amounts of reimbursement available for our products and could limit the acceptance and availability of our products. Moreover, as discussed in the paragraph below, the Affordable Care Act imposes significant taxes on medical device makers such as us. The Affordable Care Act and other proposals could have a material adverse effect on our financial position and results of operations.

On March 23, 2010, the Affordable Care Act was signed into law by President Obama. On March 30, 2010, a companion bill, the Health Care and Education Reconciliation Act of 2010 (the “Reconciliation Act”) was also signed into law by President Obama. Among other things, the Affordable Care Act and the Reconciliation Act (collectively, the “Acts”), when taken together, impose a 2.3% excise tax on the sale of certain medical devices.

Although the Consolidated Appropriations Act, 2016 (Pub. L. 114-113), signed into law on December 18, 2015, includes a two year moratorium on the 2.3% excise tax, whether this tax, or any other new tax or regulation, may apply to us in the future is uncertain.

Other elements of the Acts such as comparative effectiveness research, an independent payment advisory board, transparency requirements, payment system reforms, including shared savings pilots and other provisions could meaningfully change the way healthcare is developed and delivered, and may materially impact numerous aspects of our business.

We are subject to federal and state laws prohibiting "kickbacks" and false or fraudulent claims, which, if violated, could subject us to substantial penalties. Foreign jurisdictions in which we operate may have similar laws. Other laws such as the Foreign Corrupt Practices Act (the "FCPA") and the U.K. Bribery Act prohibit improper payments to government officials to induce the purchase of products or similar actions. Any challenge to, or investigation into, our practices under these laws are costly to defend, might result in fines and penalties and could cause adverse publicity, thus causing harm to our business and operations. In addition, we can be held liable for our distributors' failure to comply with these laws.

A federal law commonly known as the Anti-Kickback Law, and several similar state and foreign laws, prohibit payments that are intended to induce physicians or others either to refer patients or to acquire or arrange for or recommend the acquisition of healthcare products or services. These laws constrain our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of medical devices. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent, or for items or services that were not provided as claimed. Because we may provide some coding and billing information to purchasers of the HVAD System and our other products, and because we cannot assure that the government will regard any billing errors that may be made as inadvertent, these laws are potentially applicable to us. In addition, these laws are potentially applicable to us because we may provide training reimbursement and other payments to healthcare professionals and institutions. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance, which can be substantial.

The FCPA and the United Kingdom's Bribery Act prohibit improper payments to government officials to induce inappropriate behavior. In many jurisdictions, hospitals are owned or operated by governmental authorities, and physicians and administrators who are employed by the hospital may be considered to be a government official. As a result, certain relationships with our customers could expose us to liability under these statutes. Corrupt practices and anti-bribery laws prescribe civil and criminal penalties for noncompliance, which can be substantial. Even an unsuccessful challenge or investigation into our practices is costly to defend, and could cause adverse publicity, and thus could have a material adverse effect on our business, financial condition or results of operations.

In addition, under certain circumstances, we may be liable for the actions of our distributors to the extent they do not comply with these laws.

Risks Related to Intellectual Property and Confidential Information

We may not be able to effectively protect our intellectual property rights, which could have an adverse effect on our business, financial condition or results of operations.

Our success depends in part on our ability to obtain and maintain protection in the United States and other countries of the intellectual property relating to or incorporated into our technology and products. Our patent portfolio consists of internally developed technology as well as patents and patent applications which we licensed or acquired from others. In addition, from time to time, we also acquire or license technology from third parties.

As a result, we may have less complete knowledge and records with respect to the development and ownership of acquired and third-party technology, patents and intellectual property than we would otherwise have for technology, patents and intellectual property developed internally by us.

Our pending and future patent applications may not issue as patents or, if issued, may not issue in a form that will provide us with any meaningful protection or any competitive advantage. Even if issued, existing or future patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from developing and marketing similar products or limit the length of terms of patent protection we may have for our products. Further, other companies may design around technologies we have patented, licensed or developed. Moreover, changes in patent laws or their interpretation in the United States and other countries could also diminish the value of our intellectual property or narrow the scope of our patent protection. In addition, the legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar to ours.

We may need to initiate lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive and, if we lose, could cause us to lose some of our intellectual property rights, which would harm our ability to compete in the market.

We rely on patents to protect a portion of our intellectual property and our competitive position. Patent law relating to the scope of claims in the technology fields in which we operate is still evolving and, consequently, patent positions in the medical device industry are generally uncertain. In order to protect or enforce our patent rights, we may initiate patent litigation against third parties, such as infringement suits or interference proceedings. Litigation may be necessary to:

- assert claims of infringement;
- enforce our patents;
- protect our trade secrets or know-how; or
- determine the enforceability, scope and validity of the proprietary rights of others.

Any lawsuits that we initiate could be expensive, take significant time and divert management's attention from other business concerns. Litigation also puts our patents at risk of being invalidated or interpreted narrowly. Additionally, we may provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially valuable. The occurrence of any of these events may have a material adverse effect on our business, financial condition and results of operations.

Claims that our current or future products infringe or misappropriate the proprietary rights of others could adversely affect our ability to sell those products and cause us to incur additional costs.

Substantial litigation over intellectual property rights exists in the medical device industry. We expect that we could be increasingly subject to third-party infringement claims as our revenue increases, the number of technology holders grows, competition expands and the functionality of products and technology in different industry segments overlaps. Third parties may currently have, or may eventually be issued, patents on which our current or future products or technologies may allegedly infringe.

There can be no certainty that litigation will not arise in relation to third-party intellectual property or, if it does arise, whether or not it will be determined in a manner which is favorable to us. Any litigation, regardless of its outcome, would likely result in the expenditure of significant financial resources and the diversion of management's time and resources. In addition, litigation in which we are accused of infringement may cause

negative publicity, adversely impact prospective customers, cause product shipment delays, prohibit us from manufacturing, marketing or selling our current or future products, require us to develop non-infringing technology, make substantial payments to third parties or enter into royalty or license agreements, which may not be available on acceptable terms or at all. If a successful claim of infringement was made against us and we could not develop non-infringing technology or license the infringed or similar technology on a timely and cost-effective basis, our revenue may decrease substantially and we could be exposed to significant liability. A court could enter orders that temporarily, preliminarily or permanently enjoin us or our customers from making, using, selling, offering to sell or importing our current or future products, or could enter an order mandating that we undertake certain remedial activities. Claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our reputation, business, financial condition or results of operations.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patented technology, we rely on a combination of non-patented proprietary technology, trade secrets, processes and procedures, technical knowledge and know-how accumulated or acquired since inception. Despite these measures, any of our intellectual property rights could be challenged, invalidated, circumvented or misappropriated. We generally seek to protect this information by confidentiality, non-disclosure and assignment of invention agreements with our employees, consultants, scientific advisors and third parties. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may be disclosed to or otherwise become known or be independently developed by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. If our intellectual property is disclosed or misappropriated, it would harm our ability to protect our rights and have a material adverse effect on our business, financial condition and results of operations.

We may be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers of our employees.

We employ individuals who were previously employed at other medical device companies, including our competitors or potential competitors. To the extent that our employees are involved in research areas that are similar to those in which they were involved with their former employers, we may be subject to claims that such employees have inadvertently or otherwise used or disclosed the alleged trade secrets or other proprietary information of the former employers. Litigation may be necessary to defend against such claims.

Security breaches and other disruptions could compromise our information and expose us to liability, which could cause our business and reputation to suffer.

In the ordinary course of our business and as required by regulatory authorities, we collect and store sensitive data, including certain patient tracking information and information related to our clinical sites. We also maintain in confidence intellectual property, proprietary business information and personally identifiable information of our employees, on our networks. The secure processing, maintenance and transmission of this information is critical to our operations and business strategy. Further, the FDA has recently issued additional cyber-security guidance that encourages medical device manufactures to conduct risk assessment and monitoring, routine device cyber maintenance and necessary actions to mitigate device functionality and patient safety risks. Despite our security measures, such as limiting access to information, reviewing and updating device software and utilizing password protection, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any access, disclosure or other loss of information could result in legal claims or proceedings, remediation costs, regulatory penalties, liability under laws that protect the privacy of personal information, disruption of our operations and the services we provide to

customers, damage to our reputation, and a loss of confidence in our products and services, which could adversely affect our business/operating margins, revenues and competitive position.

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

There are a number of federal and state and foreign laws protecting the confidentiality of certain patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services promulgated patient privacy rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. These privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. If we are found to be in violation of the privacy rules under HIPAA or similar laws (to the extent applicable to us), we could be subject to civil or criminal penalties, which could increase our liabilities, harm our reputation and have a material adverse effect on our business, financial condition or results of operations. European privacy laws are generally more stringent than similar laws in the U.S. Since a significant amount of our revenue and business relationships arise in Europe, we may be at risk should we fail to comply with local requirements even if we have complied with U.S. regulations.

Risks Related to Our Common Stock

The price of our common stock may fluctuate significantly.

Shares of our common stock were listed for trading on The NASDAQ Stock Market LLC on February 24, 2009. Trading commenced the following day. Prior to that time, there had been no public market for our common stock in the United States. The closing price of our shares of common stock traded on The NASDAQ Stock Market LLC has ranged from U.S. $35.21 to U.S. $94.47 in the period from January 1, 2015 to December 31, 2015. The price of our common stock could fluctuate significantly for many reasons, including future announcements or new information concerning us or our competitors, reimbursement or the potential market for our products.

In addition, stock markets in general and the market for shares of healthcare stocks in particular, have experienced extreme price and volume fluctuations in recent years, fluctuations that frequently have been unrelated to the operating performance of the affected companies. These broad market fluctuations may adversely affect the market price of our shares. The market price of our shares could decline below its current price and the market price of our shares may fluctuate significantly in the future. These fluctuations may be unrelated to our performance.

We are subject to litigation risks, including securities class action and product liability litigation, which may be costly to defend and the outcome of which is uncertain.

All industries, including the medical device industry, are subject to legal claims, with and without merit. We are subject to various legal claims in the ordinary course of our business. In addition, on January 22, 2016, the St. Paul Teachers' Retirement Fund Association filed a putative class action complaint in the United States District Court for the Southern District of New York on behalf of all persons and entities who purchased or otherwise acquired shares of the Company from June 10, 2014 through January 11, 2016. We can provide no assurance as to the outcome of this litigation or any other litigation matter in which we are a party. In particular, securities class action lawsuits are typically costly to defend and, accordingly, even if resolved in our favor, could have a material adverse effect on our business, financial condition, results of operations and cash flow. This litigation could also substantially divert the attention of our management and our resources in general.

Uncertainties resulting from the initiation and continuation of securities class action litigation or other litigation also could harm our ability to obtain credit, insurance and financing for our operations, maintain investor and customer confidence and compete in the marketplace. We can provide no assurance that additional litigation, including securities class action litigation, will not be filed against us in the future. See Part I, Item 3 "Legal Proceedings" for more information on our legal proceedings.

We do not intend to pay cash dividends on our common stock in the foreseeable future.

We have never declared or paid any cash dividends on our shares, and we currently do not anticipate paying any cash dividends in the foreseeable future. We intend to retain any earnings to finance the development and expansion of our products and business. Accordingly, our stockholders will not realize a return on their investment unless the trading price of our shares appreciates.

Anti-takeover provisions in our charter documents and Delaware law may discourage a third party from acquiring us, which could limit our stockholders' opportunities to sell their shares at a premium.

Certain provisions of our Certificate of Incorporation and By-laws may be considered as having an anti-takeover effect, such as those provisions establishing a classified board of directors, consisting of three classes of directors, and requiring that directors be removed only for cause, authorizing the board of directors to issue from time to time any series of preferred stock and fix the designation, powers, preferences and rights of the shares of such series of preferred stock, prohibiting stockholders from acting by written consent in lieu of a meeting, requiring advance notice of stockholder intention to put forth director nominees or bring up other business at a stockholders' meeting, and prohibiting stockholders from calling a special meeting of stockholders. We are also subject to Section 203 of the Delaware General Corporation Law, which in general prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder, unless certain conditions specified therein are satisfied. These provisions could have the effect of depriving our stockholders of an opportunity to sell their shares at a premium over prevailing market prices by discouraging third parties from seeking to obtain control of us in a tender offer or similar transaction.

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.

For U.S. federal income tax purposes, we have incurred net losses since our inception. 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 operation of 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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our corporate headquarters are located at 500 Old Connecticut Path, Building A, Framingham, Massachusetts. Our principal other facilities include our manufacturing and operations facility in Miami Lakes, Florida, our innovation center in Arden Hills, Minnesota and our distribution and customer service facility in Hannover, Germany. We also continue to rent space in Teaneck, New Jersey as a result of our 2013 acquisition of CircuLite.

Our corporate headquarters in Framingham, Massachusetts consists of approximately 74,000 square feet of company space and is primarily used for administrative and ancillary laboratory purposes, including development testing. The initial lease term is seven years with an option to renew for a period of fifty-seven months, but in no event beyond September 30, 2025.

On December 9, 2010, we entered into a lease for a facility in Miami Lakes, Florida as part of our planned expansion to support our efforts to prepare for U.S. commercialization. The facility is used primarily for manufacturing, research and development and administrative functions. Under the lease, which was amended in November 2012 to add a small amount of additional space, we rent approximately 132,000 square feet for a period ending February 28, 2022, with an option to renew for two five-year terms.

Our facility in Hannover, Germany is approximately 9,400 square feet. The lease commenced on October 1, 2015 with an initial term of three years with an option to renew for two two-year terms.

On August 19, 2014, we entered into a lease for a facility in Arden Hills, Minnesota consisting of approximately 2,400 square feet to support certain research and development activities. The Minnesota lease has a two-year term with an option to extend for an additional two years. We anticipate doubling the size of this facility in the coming months.

Through our acquisition of CircuLite in December 2013, we assumed a lease for a facility in Teaneck, New Jersey used primarily for research and development and administrative functions. The lease, which covers approximately 22,000 square feet, was entered into in December 2012 and expires in October 2020. We also assumed a collection of leases that CircuLite entered into between September 2007 and February 2013 for office space, research and development functions and manufacturing purposes in two adjacent properties in Aachen, Germany. A separate facility in Aachen, Germany, which was originally intended to be used as office and research and development space and which is approximately 8,300 square feet, was covered under an operating lease that expired on October 31, 2017. We entered into a termination agreement with the landlord and exited all facilities in Aachen, Germany as of March 31, 2015.

We believe that the facilities noted above are suitable and adequate for our current needs.

Item 3. Legal Proceedings

Except for the matter discussed below, the Company is not a party to any material pending legal proceedings at the date of filing of this Annual Report on Form 10-K.

On January 22, 2016, the St. Paul Teachers' Retirement Fund Association filed a putative class action complaint (the "Complaint") in the United States District Court for the Southern District of New York on behalf of all persons and entities who purchased or otherwise acquired shares of the company from June 10, 2014 through January 11, 2016 (the "Class Period"). The Complaint claims that the company and two of our executives violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by making false and misleading statements about, among other things, the company's response to the June 2014 FDA Warning Letter, the development of the MVAD System and the acquisition of Valtech. The Complaint claims that the disclosure of the purportedly false and misleading statements caused the price of the company's stock to drop, and seeks to recover damages on behalf of all purchasers or acquirers of the company's stock during the Class Period. The company intends to vigorously defend itself against these claims. Because of the many questions of fact and law that may arise, the outcome of this legal proceeding is uncertain at this point.

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

Our shares of common stock trade on the NASDAQ Stock Market under the symbol "HTWR".

The following table sets forth, for the periods indicated, the high and low closing prices for our common stock on NASDAQ.

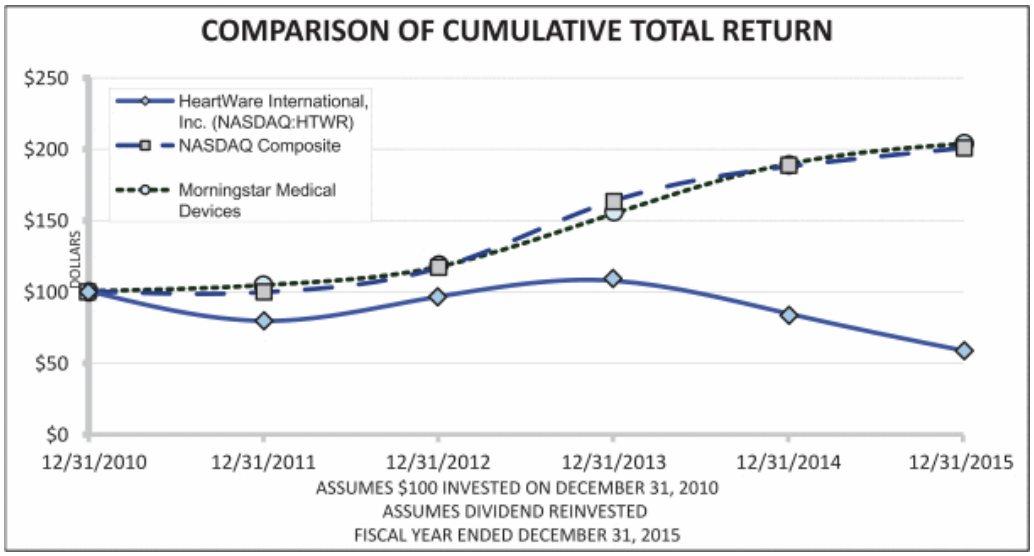
Period	High	Low
Fiscal Year 2015:		
First Quarter	$ 90.29	$72.51
Second Quarter	94.47	72.69
Third Quarter	90.71	50.51
Fourth Quarter	55.94	35.21
Fiscal Year 2014:		
First Quarter	$104.66	$90.83
Second Quarter	95.42	81.26
Third Quarter	93.44	76.89
Fourth Quarter	86.03	69.43

As of February 25, 2016, we had 17,533,606 shares of common stock issued and outstanding and there were 74 holders of record of our common stock.

We have not declared or paid any cash dividends on our shares, and we currently do not anticipate paying any cash dividends in the foreseeable future. Our convertible notes were issued pursuant to the terms of an Indenture dated December 15, 2010 and a prospectus supplement, dated May 13, 2015. The Indenture does not contain any covenants or restrictions on the payments of dividends. We intend to retain any earnings to finance the development and expansion of our products and business.

Stock Price Performance Graph

The graph presents the cumulative total stockholder return on an investment in our common stock, the NASDAQ Composite Index (U.S. companies only) and the Morningstar Medical Devices Index for the period from December 31, 2010 to December 31, 2015. The graph assumes the value of an investment in our common stock was $100 on December 31, 2010, and the reinvestment of all dividends, if any.



Company/Market/Peer Group	12/31/2010	12/31/2011	12/31/2012	12/31/2013	12/31/2014	12/31/2015
HeartWare International, Inc. (NASDAQ: HTWR)	$ 100.00	$ 78.79	$ 95.87	$ 107.23	$ 83.85	$ 57.55
NASDAQ Composite-Total Returns	$ 100.00	$ 99.17	$ 116.48	$ 163.21	$ 187.27	$ 200.31
Morningstar Medical Devices	$ 100.00	$ 103.58	$ 116.77	$ 154.03	$ 189.21	$ 202.56

Equity Compensation Plans

The following table sets forth information regarding the Company's Equity Compensation Plans as of December 31, 2015:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (b) (1)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders:			
HeartWare International, Inc. Employee Stock Option Plan	52,342	$ 24.80(2)	— (3)
HeartWare International, Inc. 2008 Stock Incentive Plan (4)	38,062	$ 60.59	— (3)
HeartWare International, Inc. 2012 Incentive Award Plan (5)	640,896	$ 2.85	1,556,729(6)
Equity compensation plans not approved by security holders:			
Non-Plan options	2,857	$ 19.16(2)	N/A

(1) The weighted average exercise price of all outstanding options is $49.20 and the weighted average remaining term of all outstanding options is 3.78 years.

(2) The exercise price has been converted to U.S. dollars using the spot rate at December 31, 2015.

(3) Upon stockholder approval of the 2012 Incentive Award Plan in May 2012, no additional grants may be made under these Plans.

(4) Outstanding awards under the 2008 Stock Incentive Plan include 2,812 restricted stock units with exercise prices of $0 and 35,250 options with exercise prices equal to the fair value of our common stock on the date of grant. The weighted average exercise price of the outstanding options was $65.43 at December 31, 2015.

(5) Outstanding awards under the 2012 Incentive Award Plan consist of 619,896 restricted stock units with exercise prices of $0 and 21,000 options with exercise prices equal to the fair value of our common stock on the date of grant. The weighted average exercise price of the outstanding options was $86.83 at December 31, 2015.

(6) Under the terms of the 2012 Incentive Award Plan, the total number of shares of our common stock initially reserved for issuance is 1,375,000, provided that the total number of shares of our common stock that may be issued pursuant to awards other than options, stock appreciation rights or other awards for which the holder pays the intrinsic value existing as of the date of grant whether directly or by forgoing a right to receive a payment from the Company, is 1,275,000. An amendment to the Plan was approved on June 4, 2015 which increased the number of shares reserved for issuance by 1,100,000.

Item 6. Selected Financial Data

The following selected consolidated statement of operations data for the years ended December 31, 2015, 2014 and 2013, and the selected consolidated balance sheet data as of December 31, 2015 and 2014, have been derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The following selected consolidated statement of operations data for the years ended December 31, 2012 and 2011, and balance sheet data as of December 31, 2013, 2012 and 2011, have been derived from our audited consolidated financial statements which are not included in this Annual Report on Form 10-K. The selected consolidated financial data set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" below and our audited consolidated financial statements and notes thereto appearing elsewhere in this Annual Report on Form 10-K.

	Years Ended December 31,				
(In thousands, except per share data)	2015	2014	2013	2012	2011
Consolidated Statement of Operations Data:					
Revenue, net	$276,843	$278,420	$207,929	$110,922	$ 82,764
Cost of revenue	103,287	92,195	76,468	51,023	32,932
Selling, general and administrative expenses	94,594	87,177	76,524	53,945	42,314
Research and development expenses	120,769	119,782	98,757	83,548	50,149
Impairment of intangible assets	26,849	2,650	3,726	—	—
Change in fair value of contingent consideration	(31,410)	(23,260)	—	—	—
Other expense, net (a)	34,520	18,682	11,298	10,124	12,424
Net loss	(72,780)	(19,366)	(59,311)	(87,718)	(55,055)
Basic and diluted net loss per share	(4.21)	(1.14)	(3.69)	(6.15)	(3.94)

	As of December 31,				
(In thousands)	2015	2014	2013	2012	2011
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$243,578	$178,481	$200,476	$ 102,808	$ 163,182
Total assets	457,576	423,813	429,827	206,499	240,732
Convertible senior notes, net of discounts (b)	191,062	114,803	107,125	100,315	94,277
Contingent liabilities (c)	12,330	43,740	67,000	—	—
Total stockholders' equity	188,492	208,534	198,607	68,211	126,784

(a) In the years ended December 31, 2015, 2014, 2013 and 2012, other expense includes approximately $14.3 million, $13.1 million, $12.2 million and $11.4 million, respectively, of interest expense associated with our convertible senior notes due December 15, 2017 and convertible senior notes due December 15, 2021 and 2015 includes loss on debt extinguishment of $16.6 million.

(b) At December 31, 2015, the aggregate principal amount of our convertible senior notes due December 15, 2017 was $42.47 million and as at December 31, 2014, 2013, 2012, and 2011, the aggregate principal amount of our convertible senior notes due December 15, 2017 was $143.75 million. At December 31, 2015, the aggregate principal amount of our convertible senior notes due December 15, 2021 was $202.37 million.

(c) On December 1, 2013, we acquired CircuLite, Inc. using a combination of cash and stock. In addition to the initial consideration paid at closing, the former CircuLite security holders may be entitled to receive up to an additional $300 million in shares of HeartWare common stock (or cash, in certain cases, at our discretion) upon the achievement of five specified performance milestones and royalty payments. This liability is carried at its estimated fair value at the reporting dates.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. This discussion and analysis contains forward-looking statements that involve risks, uncertainties, judgments and assumptions. You should review the "Risk Factors" section of this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Certain abbreviated key terms have the meanings defined elsewhere in this Annual Report on Form 10-K.

Overview

HeartWare is a medical device company that develops and manufactures miniaturized implantable heart pumps, or ventricular assist devices, to treat patients suffering from advanced heart failure.

The HeartWare Ventricular Assist System (the "HVAD System"), which includes a ventricular assist device ("VAD") or blood pump, patient accessories and surgical tools, is designed to provide circulatory support for patients in the advanced stage of heart failure. The core of the HVAD System is a proprietary continuous flow blood pump, the HVAD pump, which is a full-output device capable of pumping up to 10 liters of blood per minute. The HVAD System is designed to be implanted adjacent to the heart, avoiding abdominal surgery, which is generally required to implant similar devices.

In November 2012, we received approval from the United States Food and Drug Administration ("FDA") for the HVAD System as a bridge-to-heart-transplantation in patients with end-stage heart failure. The HVAD System has been available in the European Union since receiving CE marking in 2009. In May 2012, we received an expanded European label for long-term use of the HVAD System in all patients at risk of death from refractory, end-stage heart failure. As of December 31, 2015, there have been over 10,000 implants of the HVAD System in patients at over 320 health care sites in 47 countries.

In August 2015, we completed enrollment of an Investigational Device Exemption ("IDE") Supplement, which allowed HeartWare an additional patient cohort for the ENDURANCE clinical trial. In this supplemental cohort, HeartWare enrolled 308 patients receiving the HVAD System, as well as 157 control patients using a randomization scheme consistent with the original ENDURANCE protocol. Assessment of primary endpoint is at 1 year post implant. In April 2015, we announced that data from ENDURANCE successfully demonstrated that the trial achieved the primary endpoint. HeartWare intends to incorporate the data from both this supplemental cohort and ENDURANCE into an anticipated PMA Supplement Application seeking approval of the HVAD System for a destination therapy indication.

MVAD System

Beyond the HVAD System, we are developing our next-generation miniaturized device, known as the MVAD System. The MVAD System is based on the same technology platform as the HVAD System, but adopts an axial flow, rather than a centrifugal flow, configuration and is being developed in multiple designs. The MVAD pump is less than one-half the size of the HVAD pump and can provide partial or full support. The MVAD System is designed to allow for a variety of configurations and surgical placements with the goal of further reducing surgical invasiveness while producing superior clinical results.

In July 2015, we initiated a multicenter, prospective, non-randomized, single-arm CE Mark trial that evaluates the clinical safety and performance of the MVAD System for the treatment of advanced heart failure. We also submitted an IDE to the FDA and a submission to Health Canada seeking approval to commence MVAD System clinical trials in the United States and Canada, respectively.

In September 2015, we voluntarily paused the MVAD CE Mark clinical trial to address an MVAD controller manufacturing issue. Subsequent to that action, during the fourth quarter of 2015 and in consultation

with study investigators, we began evaluating MVAD System performance and reported adverse events in certain clinical trial patients, including events that showed evidence of pump thrombosis. We are currently evaluating various aspects of the MVAD System design to determine whether changes should be made. Should design changes be implemented, initiation of a new trial would likely be required. The timetable for updating affected regulatory filings and restarting clinical implants cannot be reliably projected at this time.

CircuLite

On December 1, 2013, we acquired CircuLite, Inc. CircuLite is the developer of the CircuLite Circulatory Support System, a partial support system designed to treat less sick, ambulatory, chronic heart failure patients who are not yet inotrope-dependent. The CircuLite Surgical System is designed for long-term support and is intended to reduce the heart's workload while improving blood flow to vital organs. The CircuLite System experienced issues that arose after its commercial release and caused the loss of its CE marking in the European Union in March 2014. In January 2015, we discontinued development of the CircuLite micro pump and have focused our efforts on a version of our MVAD pump for our partial-assist program. Thus, delays to the development and regulatory approval of the MVAD System, will affect the timing of the development and regulatory approval of the CircuLite system and resulted in the impairment of intangible assets during the fourth quarter of 2015 (*see* note 8 for additional information). The next generation endovascular system, which is expected to be implanted collaboratively by cardiologists and surgeons in a hybrid catheterization ("cath") lab setting, offers an interventional approach to circulatory support. The CircuLite Circulatory Support System offers less invasive and ultimately interventional options to earlier-stage heart failure patients.

Valtech

On September 1, 2015, we entered into a Business Combination Agreement (the "BCA") by and among the Company, Valtech Cardio, Ltd. ("Valtech"), HW Global, Inc. ("Holdco"), HW Merger Sub, Inc., Valor Merger Sub Ltd. and Valor Shareholder Representative, LLC, pursuant to which we and Valtech proposed to effect a strategic combination of our respective businesses under Holdco subject to certain closing conditions. Valtech is a privately held company that specializes in the development of innovative surgical and transcatheter valve repair and replacement devices for the treatment of mitral valve regurgitation and tricuspid valve regurgitation. Effective January 28, 2016, we terminated the BCA pursuant to the terms of the BCA by delivering written notice to the other parties. As of December 31, 2015, we had invested approximately $17 million in Valtech in the original form of convertible loans, of which $10 million together with $0.5 million of accrued interest was converted into Valtech preferred shares amounting to approximately 3.0% ownership on a fully diluted basis. Pursuant to the BCA we loaned Valtech $1 million on January 7, 2016 and $30 million following termination of the BCA per provisions of the BCA, in the form of convertible loans.

FDA Warning Letter

We received a warning letter from the FDA, dated June 2, 2014, following an inspection of our Miami Lakes, Florida facility conducted in January 2014. The FDA letter cited four categories for us to address: (1) procedures for validating device design, including device labeling; (2) procedures for implementing corrective and preventive action (CAPA); (3) maintaining records related to investigations; and (4) validation of computer software used as part of production or quality systems. The warning letter did not require any action by physicians or patients and did not restrict the use of our devices.

We sent the FDA our initial response to the warning letter within the required fifteen business days of receipt, and committed to undertaking certain quality system improvements and providing the FDA with periodic updates. During 2014 and continuing in 2015, we implemented systemic changes and organizational enhancements to address the four warning letter items and related quality systems. We have established teams to review and address the items cited by the FDA and have engaged external subject matter experts to assist in assessment and remediation efforts. As we continue to evaluate our quality systems, it is possible that we may

need to take additional actions including the possibility of voluntary product recalls when necessary to ensure patient safety and effective performance of the HVAD System. We anticipate a follow-up inspection by the FDA of our Miami Lakes, Florida facility in 2016.

Field Actions

On April 30, 2014, we implemented a corrective action to notify clinicians and patients of an observed increase in complaints related to earlier-than-expected battery depletion and routine battery handling. This notification provided information to assist patients and clinicians with monitoring battery performance, recognizing abnormal behaviors and reinforcing proper power management of the HVAD System. On July 30, 2014, we extended this field action to include a voluntary recall of certain older batteries. The recall instructed sites to replace certain older batteries in the field upon patients' routine visits in order to further mitigate the potential risks associated with premature battery depletion. Subsequently, during the period ended September 30, 2015, we extended this field action to replace certain older batteries for newer batteries containing improved cells from a new supplier. This corrective action was ongoing as of December 31, 2015.

In February 2015, we expanded a 2013 voluntary Field Safety Corrective Action, by initiating a voluntary medical device recall of certain older controllers distributed in the U.S. during the ADVANCE and ENDURANCE clinical trial periods. The affected controllers exhibit a higher susceptibility to electrostatic discharge than newer, commercial controllers. This recall was completed as of December 31, 2015.

On January 7, 2016, as part of our ongoing Warning Letter remediation efforts and quality systems enhancements, we initiated field actions related to certain older AC Adapters, batteries and software updates. The AC Adapter field action was implemented to mitigate potential risks for AC Adapters designed for use outside the United States which have a higher risk of failing in event of a power surge compared to other HeartWare AC Adapters, the replacement of certain older batteries is to further mitigate residual battery reliability concerns, and the software updates are intended to, among other things, reduce the risk of premature "battery switching" and the occurrence of false battery alarms.

During 2015, we recorded charges aggregating $8.5 million for estimated costs associated with the field actions discussed above.

Convertible Notes

In May 2015, we issued $84.2 million principal amount of 1.75% convertible senior notes due December 15, 2021 (the "2021 Notes"), unless earlier repurchased, redeemed or converted. Combined with the 2021 Notes issued in connection with the Exchange described in note 8 of the accompanying financial statements, the aggregate principal amount issued under the 2021 Notes was $202.4 million. The Exchange resulted in the retirement of outstanding 2017 Notes with a carrying value of $83.1 million, the write-off of unamortized debt issuance costs of $1.0 million and settlement of $10.7 million related to the conversion feature embedded in the 2017 Notes. The 2021 Notes offered in the Exchange had a fair value of $88.0 million, which resulted in a loss on extinguishment of debt of $16.6 million in the three months ended June 30, 2015. The net proceeds from the issuance of the 2021 Notes amounted to $74.7 million, net of deferred issuance costs paid as of December 31, 2015. In connection with the issuance of the 2021 Notes, we incurred costs of approximately $5.2 million. Interest on the 2021 Notes is payable semiannually in arrears on June 15 and December 15, at a rate of 1.75% per annum, beginning on December 15, 2015.

Class Action Claim

On January 22, 2016, the St. Paul Teachers' Retirement Fund Association filed a putative class action complaint (the "Complaint") in the United States District Court for the Southern District of New York on behalf of all persons and entities who purchased or otherwise acquired shares of the company from June 10, 2014

through January 11, 2016 (the "Class Period"). The Complaint claims that the company and two of our executives violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by making false and misleading statements about, among other things, the company's response to the June 2014 FDA Warning Letter, the development of the MVAD System and the acquisition of Valtech. The Complaint claims that the disclosure of the purportedly false and misleading statements caused the price of the company's stock to drop, and seeks to recover damages on behalf of all purchasers or acquirers of the company's stock during the Class Period. The company intends to vigorously defend itself against these claims.

Summary of Recent Financial Performance

Revenue was $276.8 million in 2015 compared to $278.4 million in 2014. This decrease reflected 6.9% revenue growth in the United States, where our HVAD System is labeled for a bridge-to-transplant indication, offset by a 9.5% decrease internationally where the HVAD System is more broadly indicated for general long-term heart failure patients. In the United States, revenue growth reflected continued market penetration within existing customer accounts and revenue contributed from newly added customers. Internationally, the decrease was primarily a result of unfavorable foreign exchange impact. As of December 31, 2015, the Company had approximately 132 customers in the United States and approximately 192 customers internationally.

We experienced a decrease in gross margin percentage to 63% in 2015 compared to 67% in 2014, which was primarily a result of charges aggregating $8.5 million for field actions discussed above.

Combined selling, general, administrative, research and development expenses (excluding the impairment of intangible assets and the change in fair value of contingent consideration) in 2015 increased to $215.4 million, compared to $207.0 million in 2014. The net increase includes expansion of sales and marketing activities, external warning-letter remediation costs, research and development pipeline activities and increased clinical activity related to MVAD as well as expanded indications for the HVAD System.

Our financial results are more fully described in *Results of Operations* below.

Critical Accounting Policies and Estimates

We prepare our financial statements in accordance with accounting principles generally accepted in the United States. We are required to adopt various accounting policies and to make estimates and assumptions in preparing our financial statements that affect the reported amounts of our assets, liabilities, revenue and expenses. On an ongoing basis, we evaluate our estimates and assumptions. We base our estimates on our historical experience to the extent practicable and on various other assumptions that we believe are reasonable under the circumstances and at the time they are made. If our assumptions prove inaccurate or if our future results are not consistent with our historical experience, we may be required to make adjustments in our policies that affect our reported results. Our significant accounting policies are disclosed in Note 3 to the financial statements included in this report.

Our most critical accounting policies and estimates include: revenue recognition, inventory capitalization and valuation, accounting for share-based compensation, measurement of fair value, valuation of tax assets and liabilities, reserves, long-lived assets, intangible assets and goodwill, and contingent consideration. We also have other key accounting policies that are less subjective and, therefore, their application is less subject to variations that would have a material impact on our reported results of operations. The following is a discussion of our most critical policies, as well as the estimates and judgments involved.

Revenue recognition

We recognize revenue from product sales in accordance with FASB ASC 605—*Revenue Recognition*. Revenue from product sales is recognized when persuasive evidence of an arrangement exists, substantially all

the risks and rewards of ownership have transferred to our customers, the selling price is fixed and collection is reasonably assured and there are no further obligations to customers. Sales from products are not subject to rights of return and, historically, actual sales returns have not been significant. We sell products through our direct sales force and through distributors. Sales through distributors are recognized as revenue upon sale to the distributor as these sales are considered to be final and no right of return or price protection exists. Sales to customers, when not made on consignment, are recognized upon shipment. A significant portion of our revenue is generated on a consignment basis. Revenue from products sold on a consignment basis is recognized on the date the consigned product is implanted or otherwise consumed. In limited circumstances, we rent peripheral equipment to patients. We recognize revenue from this arrangement when a contract is entered into with the patient's insurer over the term the equipment is rented.

Inventory

We expense costs relating to the production of inventories as research and development ("R&D") expense in the period incurred until such time as we believe future commercialization is considered probable and future economic benefit is expected to be recognized, which generally is reliant upon receipt of regulatory approval. We then begin to capitalize subsequent inventory costs relating to that product. Inventories are stated at the lower of cost or market. Cost is determined on a first-in, first out, or FIFO, method. Work-in-process and finished goods include direct and indirect labor and manufacturing overhead. Finished goods include product which is ready-for-use and which is held by us or by our customers on a consignment basis.

We review our inventory for excess or obsolete items and write-down obsolete or otherwise unmarketable inventory to its estimated net realizable value. Obsolescence may occur due to product expiring or product improvements rendering previous versions obsolete. The extent to which product improvements will cause obsolescence of existing inventory is difficult to determine as the rate of customer acceptance is dependent on many factors. We make judgments and estimates on matters, including forecasted sales volume. Our estimates and judgments in this area are subject to uncertainty and may differ from our actual experience in the future, which could have a material effect on recorded inventory values.

We include in inventory materials and finished goods that are held for sale. Certain materials and finished goods held in inventory may be used in research and development activities and are expensed as part of research and development costs when consumed.

Share-Based Compensation

We recognize share-based compensation expense in connection with our share-based awards based on the estimated fair value of the awards on the date of grant, net of estimated forfeitures, using an accelerated accrual method over the vesting period. Therefore, we only recognize compensation cost for those awards expected to vest over the service period of the award. We estimate the forfeiture rate based on our historical experience of forfeitures. If our actual forfeiture rate is materially different from our estimate, share-based compensation expense could be significantly different from what we have recorded in the current period.

Calculating share-based compensation expense requires the input of highly subjective judgment and assumptions, including forfeiture rates, estimates of expected life of the share-based award, stock price volatility and risk-free interest rates. The assumptions used in estimating the fair value of our share-based awards represent our best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our share-based compensation expense could be materially different in the future.

We value restricted stock units, or RSUs, at their intrinsic value on the date of grant. We estimate the fair value of our stock options using a Black-Scholes option pricing model. When appropriate, we estimate the expected life of a stock option by averaging the contractual term of the stock option (up to 10 years) with the

associated vesting term (typically 4 years). We estimate the volatility of our shares on the date of grant utilizing the historical volatility of our publicly-traded shares. We estimate the risk-free interest rate based on rates in effect for United States government bonds with terms similar to the expected lives of the stock options, at the time of grant.

We have issued share-based awards with performance-based vesting criteria. Achievement of the milestones must be probable before we begin recording share-based compensation expense. At each reporting date, we review the likelihood that these awards will vest and if the vesting is deemed probable, we begin to recognize compensation expense at that time. In the period that achievement of the performance-based criteria is deemed probable, U.S. GAAP requires the immediate recognition of all previously unrecognized compensation since the original grant date. As a result, compensation expense recorded in the period that achievement is deemed probable could include a substantial amount of previously unrecorded compensation expense related to the prior periods. If ultimately performance goals are not met, for any share-based awards where vesting was previously deemed probable, previously recognized compensation cost will be reversed.

Fair Value Measurements

FASB ASC 820—*Fair Value Measurements and Disclosures* defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. FASB ASC 820 requires disclosures about the fair value of all financial instruments, whether or not recognized, for financial statement purposes. Disclosures about the fair value of financial instruments are based on pertinent information available to us as of the reporting dates. Accordingly, the estimates presented in our financial statements are not necessarily indicative of the amounts that could be realized on disposition of the financial instruments.

FASB ASC 820 specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

The three levels of the fair value hierarchy are as follows:

Level 1—Quoted prices for identical instruments in active markets.

Level 2—Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3—Instruments with primarily unobservable value drivers.

The assumptions used in calculating the fair value of financial instruments represent our best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, the use of different estimates or assumptions would result in a higher or lower fair value and different amounts being recorded in our financial statements. Calculating fair value utilizing Level 3 inputs requires the input of highly subjective judgment and assumptions. See Note 6 to the accompanying financial statements.

Income Taxes

We account for income taxes in accordance with the liability method presented by FASB ASC 740—*Income Taxes*. Under this method, deferred income taxes are determined based on the estimated future tax effects of differences between the financial statement and tax basis of assets and liabilities given the provisions of enacted tax laws. Deferred income tax provisions and benefits are based on changes to the assets or liabilities from year

to year. In providing for deferred taxes, we consider tax regulations of the jurisdictions in which we operate, estimates of future taxable income, and available tax planning strategies. If tax regulations, operating results or the ability to implement tax-planning strategies vary, adjustments to the carrying value of deferred tax assets and liabilities may be required. Valuation allowances are recorded related to deferred tax assets based on the "more likely than not" criteria of FASB ASC 740. Through December 31, 2015, we have historically concluded that a full valuation allowance is required to offset our net deferred tax assets other than certain foreign net operating losses which are deemed realizable. We operate within multiple taxing jurisdictions and are subject to audit in those jurisdictions. Because of the complex issues involved, any claims could require an extended period to resolve.

FASB ASC 740 requires that we recognize the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the "more likely than not" threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority.

Reserves

Management must make estimates and assumptions to determine the amount of reserves to record in the financial statements. If any of these decisions proves incorrect, our consolidated financial statements could be materially and adversely affected.

We maintain allowances for doubtful accounts for estimated losses that may result from an inability to collect payments owed to us for product sales. We regularly review the allowance by considering factors such as historical experience, the age of the accounts receivable balances and current economic conditions that may affect a customer's ability to pay.

Certain patient accessories sold with the HVAD System are covered by a limited warranty ranging from one to two years. Estimated contractual warranty obligations are recorded as an expense when the related revenue is recognized and are included in cost of revenue on our consolidated statements of operations. Factors that affect estimated warranty liability include the number of units sold, historical and anticipated rates of warranty claims, cost per claim and vendor-supported warranty programs. We periodically assess the adequacy of our recorded warranty liabilities and adjust the amounts as necessary. The costs to repair or replace products associated with product recalls and voluntary service campaigns are recorded when they are determined to be probable and reasonably estimable as a cost of revenue and are not included in our warranty liability.

Long-Lived Assets, Purchased Intangible Assets and Goodwill

We evaluate the carrying value of our long-lived assets, including purchased intangible assets, whenever events, changes in business circumstances or our planned use of long-lived assets indicate that their carrying amounts may not be fully recoverable or that their useful lives are no longer appropriate. If these facts and circumstances exist, we assess for recovery by comparing the carrying values of long-lived assets with their future undiscounted net cash flows. If the comparison indicates that impairment exists, impairment losses are recorded for the excess of the carrying value over the fair value of the long-lived assets based on discounted cash flows. Significant management judgment is required in the forecast of future operating results that are used in the preparation of expected undiscounted cash flows. See Note 8 to the accompanying financial statements.

We also evaluate the carrying value of intangible assets (not subject to amortization) related to in-process research and development ("IPR&D") assets which are considered to be indefinite-lived until the completion or abandonment of the associated research and development projects. Accordingly, amortization of the IPR&D assets does not occur until the product reaches commercialization. During the period the assets are considered indefinite-lived, they are tested for impairment on an annual basis, as well as between annual tests if we become

aware of any events occurring or changes in circumstances that indicate that the fair values of the IPR&D assets are less than their carrying amounts. If and when development is complete, which generally occurs when regulatory approval to market the product is obtained, the associated IPR&D assets are deemed definite-lived and are then amortized based on their estimated useful lives at that point in time. If the related project is terminated or abandoned, we may have a full or partial impairment related to the IPR&D assets, calculated as the excess of their carrying value over fair value. See Note 8 to the accompanying financial statements.

We test goodwill for impairment on an annual basis in the fourth quarter of each fiscal year or more frequently if we believe indicators of impairment exist. The performance of the test involves a two-step process. The first step requires comparing the fair value of the reporting unit to its net book value, including goodwill. A potential impairment exists if the fair value of the reporting unit is lower than its net book value. The second step of the process is only performed if a potential impairment exists, and it involves comparing the aggregate fair value of the reporting unit's net assets other than goodwill to the fair value of the reporting unit as a whole. Goodwill is considered impaired, and an impairment charge is recorded, if the excess of the fair value of the reporting unit over the fair value of the net assets is less than the carrying value of goodwill.

Contingent Consideration

On December 1, 2013, we acquired CircuLite, Inc. In addition to initial consideration paid at closing, the former CircuLite security holders may be entitled to receive additional shares of HeartWare common stock (or cash, in certain cases, at our discretion) upon the achievement of specified regulatory and commercial milestones, not to exceed $300 million in the aggregate over a ten-year period. The estimated fair value of the contingent payments is recorded as a liability and is remeasured at each reporting period. The estimated fair value is calculated using a discounted cash flow model utilizing significant unobservable inputs including future revenue projections, the probability of achieving each of the potential milestones and an estimated discount rate commensurate with the risks of the expected cash flows attributable to the various milestones. Material changes in any of these inputs could result in a significantly higher or lower fair value measurement and commensurate changes to this liability. Changes in the fair value of the contingent payments are recorded on a separate line item on our consolidated statements of operations. *See* Note 6 to the accompanying financial statements.

Results of Operations

The following is a description of significant components of our operations, including significant trends and uncertainties that we believe are important to an understanding of our business and results of operations.

The results of operations for CircuLite are included in our consolidated statements of operations subsequent to the December 1, 2013 date of acquisition.

Fiscal Years 2015 and 2014

Revenue, net

In 2015 and 2014, we generated revenue through commercial sales and clinical trials. Net revenue for the years ended December 31, 2015 and 2014 was as follows:

	2015	2014	Change
	(in thousands)		
Revenue, net	$276,843	$278,420	-1%

Revenue in 2015 reflected 6.9% revenue growth in the United States, where our HVAD System is labeled for a bridge-to-transplant indication, offset by a 9.5% decrease internationally where the HVAD System is more broadly indicated for general long-term heart failure patients. In the United States, revenue growth reflected continued market penetration within existing customer accounts and revenue contributed from newly added customers. Internationally, the decrease was the result of unfavorable foreign exchange impact.

Our U.S. revenue was $161.8 million in 2015 compared to $151.3 million in 2014. We recognized revenue on a total of 1,475 HVAD systems in the U.S. in 2015 compared to 1,394 systems in 2014. U.S. revenue in 2015 and 2014 included 108 and 191 HVAD Systems, respectively, as part of our supplemental patient cohort for the ENDURANCE clinical trial.

Our international revenue was $115.0 million in 2015 compared to $127.1 million in 2014. A total of 1,428 HVAD pumps were sold internationally in 2015 compared to 1,357 pumps sold in 2014.

Changes in foreign currency exchange rates unfavorably impacted net revenue by approximately $19.2 million, or 6.9%, in 2015 compared to 2014. In 2015, approximately 37% of our net revenue was denominated in foreign currencies including principally the Euro and British Pound compared to 43% in 2014. Movements in foreign currency exchange rates have had an effect on our reported revenue amounts in the past and could have a significant favorable or unfavorable impact on our reported revenue amounts in the future.

We expect to continue to generate and grow commercial revenue from product sales as we further expand our sales and marketing efforts on a global basis. Future product sales are dependent on many factors, including perception of product performance, competitive offerings, and market acceptance among physicians, patients, health care payors and the medical community as well as our capacity to meet customer demand by manufacturing sufficient quantities of our products.

Cost of Revenue

Cost of revenue includes costs associated with manufacturing and distributing our products and consists of direct materials, labor and overhead expenses allocated to the manufacturing process, provisions for excess or obsolete inventory, and shipping costs. Cost of revenue totaled approximately $103.3 million and $92.2 million in 2015 and 2014, respectively.

Gross profit and gross margin percentage for the years ended December 31, 2015 and 2014 were as follows:

	2015	2014
	(in thousands)	
Gross profit	$173,556	$186,225
Gross margin %	63%	67%

The decrease in gross margin percentage in 2015 was primarily a result of approximately $8.5 million of reserves established for field actions announced in the third quarter of 2015.

Selling, General and Administrative

Selling, general and administrative expenses include costs associated with selling and marketing our products and the general corporate administration of the Company. These costs are primarily related to salaries and wages and related employee costs, travel, marketing, external consultants and contractors, legal and accounting fees and general infrastructure costs, and include all operating costs not associated with or otherwise classified as research and development costs or cost of revenue.

	2015	2014	Change
	(in thousands)		
Selling, general and administrative expenses	$94,594	$87,177	9%
% of operating expenses, excluding impairment of intangible assets and changes in fair value of contingent consideration	44%	42%	

The net increase of $7.4 million included approximately $5.6 million of transaction expenses associated with the contemplated acquisition of Valtech, $3.6 million of salaries and related costs associated with personnel growth and $1.8 million of increased professional fees. We also experienced an increase in medical device excise taxes of $0.1 million as a result of the Affordable Care Act (discussed below). These increases were partially offset by a net decrease of $1.5 million of restructuring charges compared to 2014, which included lease exit costs associated with our former Massachusetts headquarters and CircuLite's New Jersey headquarters, severance costs and asset impairment charges. All other spending, including information technology and facilities costs, amounted to a net decrease of $2.2 million.

In 2010, the Affordable Care Act and the Health Care and Education Reconciliation Act were signed into law. Among other things, these Acts, when taken together, impose a 2.3% excise tax on the U.S. sales of certain medical devices, including our devices, which became effective January 1, 2013. We have included this tax expense in selling, general and administrative expenses on our consolidated statements of operations. We have not invoiced our customers for this tax as a separate charge, and the tax is not included as an element of revenue. The statutory rate of the medical device excise tax is 2.3% of revenue on initial sales of finished medical products sold in the United States. Recent legislation imposes a two year moratorium on the 2.3% excise tax and, thus, the tax will not apply during the period beginning on January 1, 2016 and ending on December 31, 2017.

We expect our selling, general and administrative expenses to continue to increase in 2016 compared to 2015 as we continue to expand our sales and distribution capabilities in an effort to increase market penetration on a global basis as well as enhance our administrative capabilities to support our overall corporate growth.

Research and Development

Research and development expenses are the direct and indirect costs associated with developing our products prior to commercialization, including the costs of operating clinical trials, and are expensed as incurred. These expenses fluctuate based on project-level activity and consist primarily of salaries and wages and related employee costs of our research and development, clinical and regulatory staffs, external research and development costs, and materials and expenses associated with clinical trials. Research and development expenses also include costs associated with our compliance with FDA regulations. Additional costs include travel, facilities and overhead allocations.

	2015	2014	Change
	(in thousands)		
Research and development expenses	$120,769	$119,782	1%
% of operating expenses, excluding impairment of intangible assets and changes in fair value of contingent consideration	56%	58%	

The $1.0 million increase in research and development expenses included $2.4 million in increased salaries and related costs associated with personnel growth, an increase in non-cash share-based compensation of $0.3 million, $2.2 million of infrastructure-related costs, $1.7 million in grant and honorarium expense, $0.4 million in regulatory fees and increased restructuring charges aggregating $1.2 million, including contract termination fees and severance costs. These increases were partially offset by $7.1 million related to decreases in project spending.

Included in the amounts above for 2015 and 2014 are expenses of $7.3 million and $5.4 million, respectively, incurred in connection with the warning letter we received from the FDA in June 2014. We expect our warning letter-related expenses, on an annualized basis, to increase during the first half of 2016 compared to 2015, but should decrease thereafter as we complete resource intensive activities for which we have contracted external consultants and advisors.

We expect that research and development expenses will continue to represent a significant portion of our operating expenses for the foreseeable future as we continue to incur substantial development costs related to our

next-generation products, including the Pal controller, the MVAD System, the CircuLite System and certain early research initiatives. We also expect to incur substantial costs for clinical trials for the HVAD System in new markets and expanded indications and for the MVAD System both in Europe and the United States, as well as ongoing clinical trial expenses associated with bridge-to-transplant post-approval study requirements and ongoing patient follow-up related to the ENDURANCE clinical trial.

Impairment of Intangible Assets

During the fourth quarter of 2015, we recorded impairment charges of $22.1 million related to IPR&D and $4.8 million related to tradenames and customer lists associated with our acquisition of CircuLite in December 2013. The charges were primarily the result of program delays which impact the certainty of development and eventual regulatory approval of a CircuLite System. See Note 8 in the accompanying consolidated financial statements for additional information.

During the fourth quarter of 2014, we recorded an impairment charge of $2.6 million related to IPR&D acquired from CircuLite in December 2013. The charge resulted from a decision to discontinue development of the acquired CircuLite micro pump in favor of replacing it with a version of our MVAD pump. See Note 8 in the accompanying consolidated financial statements for additional information.

Change in Fair Value of Contingent Consideration

On December 1, 2013, we acquired CircuLite, Inc. using a combination of cash and stock. In addition to initial consideration paid at closing, the former CircuLite security holders may be entitled to receive additional shares of HeartWare common stock (or cash, in certain cases, at our discretion) upon the achievement of five specified performance milestones and royalty payments. We calculate the estimated fair value of the contingent consideration on a quarterly basis.

In 2015, adjustments aggregating $31.4 million were recorded for the net decrease in the estimated fair value of the contingent consideration since December 31, 2014. The change in fair value of the contingent consideration in 2015 was due to a $38.1 million reduction associated with the likelihood of not achieving performance milestones related to the re-launch of the CircuLite system, which was partially offset by an increase of $6.7 million related to accretion of the liability due to passage of time. This change was a result of longer than anticipated timelines to develop and receive approval for the CircuLite System.

In 2014, adjustments aggregating $23.3 million were recorded for the net decrease in the estimated fair value of the contingent consideration since December 31, 2013. The change in fair value of the contingent consideration in 2014 was due to several factors, including a $16.6 million reduction due to the likelihood of not achieving the performance milestone conditions related to the re-launch of the acquired form of the CircuLite System following its loss of CE marking in the European Union in March 2014. In addition, we discontinued development of the CircuLite micro pump and have focused our efforts on a version of our MVAD pump for our partial-assist program. As a result of this shift, we updated our future projections for the CircuLite System and reassessed the probabilities of attaining certain contingent milestone payments under the terms of the merger agreement. Our updated analysis resulted in an aggregate $17.5 million decrease in the fair value of the contingent consideration related to certain milestones and royalty payments. This overall decrease in fair value was partially offset by an increase of $10.8 million related to accretion of the liability due to the passage of time.

Determining the estimated fair value of the contingent consideration requires significant management judgment or estimation. The estimated fair value is calculated using the income approach, with significant inputs that include various revenue assumptions, discount rates and applying a probability to each outcome. Material changes in any of these inputs could result in a significantly higher or lower fair value measurement. Potential valuation adjustments will be made in future accounting periods as additional information becomes available, including, among other items, progress toward developing the CircuLite System, as well as revenue and milestone targets as compared to our current projections. Adjustments associated with changes in the estimated

fair value of the contingent consideration are presented on a separate line item on our consolidated statements of operations and will be similarly presented in future accounting periods.

Foreign Exchange

We generate a substantial portion of our revenue and collect receivables in foreign currencies. Fluctuations in the exchange rate of the U.S. dollar against the Euro, British Pound and Australian dollar can result in foreign currency exchange gains and losses that may significantly affect our financial results. Continued fluctuation of these exchange rates could result in financial results that are not comparable from quarter to quarter.

In 2015, our net foreign exchange losses totaled approximately $4.4 million compared to net losses of approximately $5.0 million in 2014. During the second half of 2014 and first half of 2015, the Euro weakened significantly relative to the U.S. dollar. This was the primary contributor to the net foreign exchange losses experienced in 2015 and 2014.

In 2015 and 2014, the majority of our realized and unrealized foreign exchange gains and losses resulted from the settlement of certain balance sheet accounts, primarily accounts receivable that were denominated in foreign currencies, and the remeasurement to U.S. dollars at period end of certain balance sheet accounts, denominated in foreign currencies, primarily the Euro. We expect to continue to realize foreign exchange gains and losses for the foreseeable future as a significant portion of our sales is denominated in foreign currencies. We do not currently utilize foreign currency contracts to manage foreign exchange risks.

Interest Expense

Interest expense in 2015 and 2014 primarily consisted of interest incurred on the principal amount of our convertible senior notes issued in December 2010 and May 2015, amortization of the related discounts and amortization of the portions of the deferred financing costs allocated to the debt component. The convertible senior notes issued in December 2010 bear interest at a rate of 3.5% per annum and those issued in May 2015 bear interest at a rate of 1.75% per annum. The discount on the convertible senior notes and the deferred financing costs are being amortized to interest expense through the December 15, 2017 maturity date of the convertible senior notes issued in December 2010 and through the December 15, 2021 maturity date of the convertible senior notes issued in May 2015 using the effective interest method.

Interest expense was approximately $14.3 million and $13.1 million in 2015 and 2014, respectively. Interest paid and incurred on the principal amount of the convertible senior notes at the 3.5% and 1.75% coupon rates was approximately $5.1 million and $5.0 million in 2015 and 2014, respectively. Non-cash amortization of the discount and deferred financing costs totaled approximately $9.2 million and $8.1 million in 2015 and 2014, respectively.

Investment Income, net

Investment income is primarily derived from investments and cash and short-term deposit accounts held in the U.S. as well as note receivable interest on a strategic investment in an early-stage, privately-held company. The amortization of premium on our investments is also included in investment income, net. Investment income, net was approximately $0.8 million and $0.7 million in 2015 and 2014, respectively. The increase was primarily due to interest earned on the aforementioned note receivable and higher cash balances in 2015. We continue to experience low interest rates on our deposits and available-for-sale investments.

Other, net

Other expense was approximately $16.6 million and $1.3 million in 2015 and 2014, respectively. The increase was primarily due a $16.6 million loss on extinguishment of debt related to an exchange of convertible notes. *See* Note 10 for additional information.

Income Taxes

We are subject to taxation in the United States and jurisdictions outside of the United States. These jurisdictions have different marginal tax rates. Foreign earnings are considered to be permanently reinvested in operations outside the U.S. and therefore are not subject to U.S. income taxes until repatriated. As of December 31, 2015, we had no unrepatriated foreign earnings. We have incurred significant U.S. losses since inception, however, changes in issued capital and share ownership, as well as other factors, may limit our ability to utilize any net operating loss carry-forwards, and therefore a 100% valuation allowance has been recorded against our net deferred tax assets in the United States and Australia. In 2015 and 2014, our tax provision includes estimated foreign taxes in jurisdictions where wholly-owned subsidiaries may be subject to current taxes.

In accordance with ASC 740 we continue to record and evaluate tax positions for recognition using a more-likely-than-not threshold, and those tax positions eligible for recognition are measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon the effective settlement with a taxing authority that has full knowledge of all relevant information.

Fiscal Years 2014 and 2013

Revenue, net

In November 2012, we received approval from the FDA for the HVAD System as a bridge to heart transplant in patients with end-stage heart failure. This approval resulted in substantially increased sales in the United States through 2014. 2014 sales derived from a mix of clinical trial activities in the United States and ongoing commercial sales of our HVAD System internationally, while 2013 sales primarily reflected commercial sales of our HVAD System both in the United States and internationally. In 2014, domestic revenue comprised approximately 54% of our net revenue compared to approximately 51% in 2013.

In 2014 and 2013, we generated revenue through commercial sales and clinical trials. Net revenue for the years ended December 31, 2014 and 2013 was as follows:

	2014	2013	Change
	(in thousands)		
Revenue, net	$278,420	$207,929	34%

In 2014, our U.S. revenue increased approximately $46.0 million, or 44%, to $151.3 million compared to U.S. revenue of approximately $105.3 million in 2013. A total of 1,394 HVAD systems were sold in the U.S. in 2014 compared to 978 systems sold in 2013. U.S. revenue in 2014 included 191 HVAD systems as part of our supplemental patient cohort for the ENDURANCE clinical trial compared to clinical trial unit sales in 2013. International revenue increased in 2014 by approximately $24.5 million, or 24%, to $127.1 million compared to international revenue of approximately $102.6 million in 2013. A total of 1,357 HVAD pumps were sold internationally in 2014 compared to 1,101 pumps sold internationally in 2013.

Changes in foreign currency exchange rates favorably impacted net revenue by approximately $0.9 million, or 0.4%, in 2014 compared to 2013. In 2014, approximately 43% of our net revenue was denominated in foreign currencies including principally the Euro and British pound.

Cost of Revenue

Cost of revenue totaled approximately $92.2 million and $76.5 million in 2014 and 2013, respectively.

Gross profit and gross margin percentage for the years ended December 31, 2014 and 2013 were as follows:

	2014	2013
	(in thousands)	
Gross profit	$186,225	$131,461
Gross margin %	67%	63%

The increase in gross margin percentage for 2014 compared to 2013 was primarily a result of production efficiencies driven by increased revenue and manufacturing throughput resulting in 5.0 percentage points of improvement, partially offset by 1.3 percentage points resulting from increases in reserve allowances including battery and controller recalls.

Selling, General and Administrative

Selling, general and administrative expenses for the years ended December 31, 2014 and 2013 were as follows:

	2014	2013	Change
	(in thousands)		
Total selling, general and administrative expenses	$87,177	$76,524	14%
% of operating expenses, excluding impairment of intangible assets and changes in fair value of contingent consideration	42%	44%	

During 2014, we continued to experience significant growth as we expanded our sales and distribution capabilities, especially in the U.S. in connection with the commercial launch of the HVAD System subsequent to receiving FDA approval in November 2012. We also experienced increased administrative costs as we expanded our administrative capabilities to support overall corporate growth.

The increase of $10.7 million resulted primarily from commercial expansion and included $8.5 million of salaries and related costs associated with headcount growth, $2.7 million of increased travel, conferences, tradeshows and other marketing expenditures, $1.3 million of professional fees and $1.4 million of non-cash share-based compensation expense. In addition, we incurred increased excise taxes of $1.4 million as a result of the Reconciliation Act (discussed above) and $2.3 million in restructuring costs in connection with the acquisition of CircuLite. All other spending decreased by approximately $6.9 million.

Research and Development

Research and development expenses for the years ended December 31, 2014 and 2013 were as follows:

	2014	2013	Change
	(in thousands)		
Total research and development expenses	$119,782	$98,757	21%
% of operating expenses, excluding impairment of intangible assets and changes in fair value of contingent consideration	58%	56%	

The $21.0 million increase in research and development expenses was primarily due to a $7.1 million increase in salaries and related costs associated with headcount growth, a $5.9 million increase in clinical trial costs, a $1.4 million increase in development project costs, including consumables, outside engineering, consultants and contractors and an increase in non-cash share-based compensation of $0.8 million. All other research and development costs increased by approximately $5.8 million.

Impairment of Intangible Assets

During the fourth quarter of 2014, we recorded an impairment charge of $2.6 million related to IPR&D acquired from CircuLite in December 2013. The charge resulted from a decision to discontinue development of the acquired CircuLite micro pump in favor of replacing it with a version of our MVAD pump. *See* Note 8 for additional information.

During the fourth quarter of 2013, we recorded an impairment charge totaling $3.7 million to write-off goodwill and IPR&D that was recorded in 2012 in connection with our acquisition of World Heart. Subsequent to an evaluation of the ongoing research and development efforts surrounding the technology, we determined we would discontinue further development efforts needed to commercialize the MiFlow technology, other than with respect to certain know-how which has been incorporated into our development of the MVAD System.

Change in Fair Value of Contingent Consideration

In 2014, adjustments aggregating $23.3 million were recorded for the net decrease in the estimated fair value of the contingent consideration since December 31, 2013. The change in fair value of the contingent consideration in 2014 was due to several factors, including a $16.6 million reduction due to the likelihood of not achieving the performance milestone conditions related to the re-launch of the acquired form of the CircuLite System following its loss of CE marking in the European Union in March 2014. In addition, we discontinued development of the CircuLite micro pump and have focused our efforts on a version of our MVAD pump for our partial-assist program. As a result of this shift, we updated our future projections for the CircuLite System and reassessed the probabilities of attaining certain contingent milestone payments under the terms of the merger agreement. Our updated analysis resulted in an aggregate $17.5 million decrease in the fair value of the contingent consideration related to certain milestones and royalty payments. This overall decrease in fair value was partially offset by an increase of $10.8 million due to accretion of the liability due to the passage of time. *See* Note 6 for additional information.

Foreign Exchange

In 2014, our net foreign exchange losses totaled approximately $5.0 million compared to net losses of approximately $0.1 million in 2013. In 2014 and 2013, the majority of our realized and unrealized foreign exchange gains and losses resulted from the settlement of certain balance sheet accounts, primarily accounts receivable that were denominated in foreign currencies, and the remeasurement to U.S. dollars at period end of certain balance sheet accounts, denominated in foreign currencies, primarily the Euro. We expect to continue to realize foreign exchange gains and losses for the foreseeable future as a significant portion of our sales is denominated in foreign currencies. We do not currently utilize foreign currency contracts to manage foreign exchange risks.

Interest Expense

Interest expense in 2014 and 2013 primarily consisted of interest incurred on the principal amount of our convertible senior notes issued in December 2010, amortization of the related discount and amortization of the portion of the deferred financing costs allocated to the debt component. The convertible senior notes bear interest at a rate of 3.5% per annum. The discount on the convertible senior notes and the deferred financing costs are being amortized to interest expense through the December 15, 2017 maturity date of the convertible senior notes using the effective interest method.

Interest expense was approximately $13.1 million and $12.2 million in 2014 and 2013, respectively. Interest paid and incurred on the principal amount of the convertible senior notes at the 3.5% coupon rate was approximately $5.0 million in 2014 and 2013. Non-cash amortization of the discount and deferred financing costs totaled approximately $8.1 million and $7.2 million in 2014 and 2013, respectively.

Investment Income, net

Investment income was primarily derived from investments and cash and short-term deposit accounts held in the U.S. The amortization of premium on our investments is also included in investment income, net. Investment income, net was approximately $0.7 million and $0.4 million in 2014 and 2013, respectively. This increase in 2014 was related to approximately $0.3 million of net interest receivable from Valtech.

Income Taxes

In 2014 and 2013, income tax expense related primarily to income earned by a foreign subsidiary. Foreign earnings were considered to be permanently reinvested in operations outside the U.S. and therefore we did not provide for U.S. income taxes on these unrepatriated foreign earnings.

Liquidity and Capital Resources

As of December 31, 2015, our cash and cash equivalents combined with short term investments were approximately $243.6 million, compared to $178.5 million at December 31, 2014.

Following is a summary of our cash flow activities for the years ended December 31, 2015, 2014 and 2013:

	2015	2014	2013
		(in thousands)	
Net cash used in operating activities	$ (498)	$(17,174)	$ (22,223)
Net cash used in investing activities	(5,546)	(46,556)	(46,321)
Net cash provided by financing activities	74,808	721	145,649
Effect of exchange rate changes on cash and cash equivalents	3,337	3,075	(146)
Net increase (decrease) in cash and cash equivalents	$72,101	$(59,934)	$ 76,959

Cash Used in Operating Activities

Cash used in operating activities for the year ended December 31, 2015 included a net loss of approximately $72.8 million, adjustments for non-cash items of $56.1 million and cash provided by working capital of $16.2 million. The net loss was driven by normal operating activities including the sale of the HVAD System in the United States and abroad, increased expenditures on research and development and administrative costs, as well as $5.6 million of transaction expenses associated with the contemplated acquisition of Valtech. Adjustments for non-cash items primarily consisted of $26.8 million of impairments to intangible assets associated with the CircuLite acquisition, $23.8 million of share-based compensation, $16.6 million for the loss on extinguishment of debt, $8.7 million of depreciation and amortization on long-lived assets, $8.7 million for the amortization of the discount on our convertible senior notes and $1.1 million related to impairment of fixed assets. These increases were partially offset by a $31.4 million decrease in fair value of contingent consideration related to the CircuLite acquisition. The increase in cash from changes in working capital included $3.5 million for the change in inventory, $9.4 million for the increase in accrued liabilities, $0.9 million in decreased trade accounts receivable, $2.0 million for the change in trade accounts payable and $0.4 million for the increase in other assets.

Cash used in operating activities for the year ended December 31, 2014 included a net loss of approximately $19.4 million, adjustments for non-cash items of $22.3 million and cash used in working capital of $20.1 million.

The net loss was driven by normal operating activities, including the sale of the HVAD System in the United States and abroad, increased expenditures on research and development as well as increased administrative costs. Adjustments for non-cash items primarily consisted of $23.5 million of share-based compensation, $8.4 million of depreciation and amortization on long-lived assets, $7.7 million for the amortization of the discount on our convertible senior notes, $3.3 million related to impairment of intangible assets and fixed assets and $1.0 million loss on an equity investment. The above non-cash adjustments were partially offset by a $23.3 million decrease in fair value of contingent consideration related to the CircuLite acquisition. The decrease in cash from changes in working capital included $16.3 million for the purchase and manufacture of inventories, $11.8 million in increased trade accounts receivable, and $4.3 million for the payment of trade accounts payable. These amounts were partially offset by a decrease in prepaid expenses and other assets of $4.0 million and an increase in accrued liabilities of $7.3 million.

Cash used in operating activities for the year ended December 31, 2013 included a net loss of approximately $59.3 million and non-cash adjustments to net loss totaling approximately $40.9 million, which primarily consisted of $21.9 million of share-based compensation, $6.8 million for the amortization of the discount on our convertible senior notes, $7.0 million of depreciation and amortization on long-lived assets, and $3.7 million related to impairment of goodwill and intangible assets. Also included in cash used in operating activities in 2013 are approximately $4.9 million in increased prepaid expenses, $4.3 million for the purchase and manufacture of inventories and $2.4 million in increased trade accounts receivables. These amounts were partially offset by an increase in other accrued liabilities of $4.0 million and an increase in trade accounts payable of $3.6 million.

Cash Used in Investing Activities

In 2015, net cash used by investing activities included $7.0 million for convertible loans made to Valtech, $3.0 million used to acquire property, plant and equipment and $2.1 million for intellectual property. These cash uses were partially offset by $6.3 million in net sales and maturities of available-for sale securities.

In 2014, net cash used by investing activities included $39.0 million for the purchase (net of maturities) of available-for sale securities, $6.7 million used to acquire property, plant and equipment and $1.6 million for intellectual property. In 2014, we received approximately $0.7 million upon the release of a portion of the security deposit on one of our facility leases.

In 2013, net cash used by investing activities included $22.6 million for the purchase (net of maturities) of available-for sale securities, $20.0 million used for our acquisition of CircuLite and other strategic investments, $3.4 million used to acquire property, plant and equipment and $0.7 million received upon the sale of certain property, plant and equipment in connection with the closure of our Australian facility. Other investing activities in 2013 used cash of approximately $1.1 million.

Cash Provided by Financing Activities

On December 15, 2010, we issued 3.5% convertible senior notes due December 15, 2017, unless earlier repurchased or converted (the “2017 Notes”) with an aggregate principal amount of $143.75 million pursuant to the terms of an indenture dated as of December 15, 2010. The 2017 Notes are senior unsecured obligations of the Company, and bear interest at a rate of 3.5% per annum, payable semi-annually in arrears on June 15 and December 15 of each year. The 2017 Notes offering was completed pursuant to a prospectus supplement, dated December 9, 2010, to a shelf registration statement on Form S-3 that was previously filed with the SEC and which was declared effective on December 9, 2010. In May 2015, we entered into separate, privately negotiated, exchange agreements (the “Exchange”) with certain holders of the 2017 Notes. In this transaction, we exchanged $101.3 million aggregate principal amount of the 2017 Notes, with a carrying value of $83.1 million, for $118.2 million principal amount of 1.75% convertible senior notes due 2021 unless earlier repurchased, redeemed or converted (the “2021 Notes”). Approximately $42.5 million aggregate principal amount of the 2017 Notes remains outstanding. We did not receive any proceeds related to the Exchange. In conjunction with the

Exchange, we also issued an additional $84.2 million principal amount of the 2021 Notes resulting in an aggregate principal amount issued under the 2021 Notes of $202.4 million. Interest on the 2021 Notes is payable semiannually in arrears on June 15 and December 15, at a rate of 1.75% per annum, beginning on December 15, 2015. The 2021 Notes were issued under a base indenture dated as of December 15, 2010 between the Company and Wilmington Trust, National Association, as successor by merger with Wilmington Trust FSB, as trustee, as supplemented by a second supplemental indenture with respect to the 2021 Notes to dated May 13, 2015.

In May 2015, we issued $84.2 million principal amount of 1.75% convertible senior notes due December 15, 2021 (the "2021 Notes"), unless earlier repurchased, redeemed or converted. Combined with the 2021 Notes issued in connection with the Exchange described above, the aggregate principal amount issued under the 2021 Notes was $202.4 million. The Exchange resulted in the retirement of outstanding 2017 Notes with a carrying value of $83.1 million, the write-off of unamortized debt issuance costs of $1.0 million and settlement of $10.7 million related to the conversion feature embedded in the 2017 Notes. The 2021 Notes offered in the Exchange had a fair value of $88.0 million, which resulted in a loss on extinguishment of debt of $16.6 million in the three months ended June 30, 2015. The net proceeds from the issuance of the 2021 Notes amounted to $74.7 million, net of deferred issuance costs paid as of December 31, 2015. In connection with the issuance of the 2021 Notes, we incurred costs of approximately $5.2 million. Interest on the 2021 Notes is payable semiannually in arrears on June 15 and December 15, at a rate of 1.75% per annum, beginning on December 15, 2015.

On March 12, 2013, we entered into an Underwriting Agreement (the "Underwriting Agreement") with J.P. Morgan Securities LLC, as representative of the several underwriters named in the Underwriting Agreement (the "Underwriters"), pursuant to which we agreed to sell and the Underwriters agreed to purchase, subject to and upon terms and conditions set forth therein, an aggregate of 1,500,000 shares of our common stock at a net sales price of $81.9114 per share (the public offering price of $86.45 per share minus the underwriting discount). We also granted the Underwriters an option to purchase 225,000 additional shares of our common stock at the public offering price less the underwriting discount, which the Underwriters exercised in full on March 13, 2013. The closing of the offering occurred on March 18, 2013. After fees and related expenses, net proceeds from the offering were approximately $141.0 million. The offering was completed pursuant to a prospectus supplement, dated March 12, 2013, to a shelf registration statement on Form S-3 that was previously filed with the SEC and which was declared effective on December 9, 2010.

In 2015, 2014 and 2013, we received approximately $0.1 million, $0.9 million and $4.9 million, respectively, from the exercise of stock options.

Operating Capital and Capital Expenditure Requirements

We have incurred substantial operating losses to date and anticipate that we will continue to consume cash and incur substantial net losses as we expand our sales and marketing capabilities, develop new products including the MVAD System and the Pal controller, and seek regulatory approvals for expanded indications of the HVAD System in the U.S. In 2016, cash on hand is expected to primarily be used to fund our ongoing operations, including:

- expanding our sales and marketing capabilities on a global basis;
- growing market penetration particularly in the U.S.;
- continued product development, including development of the MVAD pump and Pal controller;
- pre-clinical and clinical costs relating to the MVAD pump, and clinical trials related to expanded indications of the HVAD System;
- post-approval monitoring related to the HVAD System;

- regulatory and other compliance functions, including activities to enhance our quality systems in response to the warning letter we received from the FDA in June 2014;
- replacement of product in the field as a result of ongoing and potential future field actions;
- responding to litigation claims;
- expand work-in-process and finished goods inventory to support ongoing operations;
- strategic activities intended to expand our access to new technologies;
- planned investments in infrastructure to support our growth; and
- general working capital.

Our convertible notes bear interest at a rate of 1.75% or 3.5% per annum, payable semi-annually in arrears on June 15 and December 15 of each year. To date, all interest payments have been paid on a timely basis. Based on the outstanding principal amount of our convertible senior notes at December 31, 2015, the semi-annual interest payments due on June 15 and December 15, 2016 will be approximately $2.5 million each. These amounts are expected to be paid from cash on hand.

We believe cash on hand and investment balances as of December 31, 2015 are sufficient to support our planned operations for at least the next twelve months. At December 31, 2015, approximately $6.1 million of our cash on hand was held in foreign locations, including Australia, Germany and the United Kingdom. To date, the Company has not had unremitted foreign earnings and has not incurred U.S. federal and state income taxes related to repatriated earnings. As our operations in our foreign subsidiaries grow, we may generate foreign earnings. Any repatriation of those earnings to the United States would likely result in us incurring federal and state income taxes. We currently plan to permanently reinvest any earnings of our foreign subsidiaries.

Because of the numerous risks and uncertainties associated with the development of medical devices, we are unable to estimate the exact amounts of capital outlays and operating expenditures necessary to maintain regulatory approvals, fund commercial expansion, and develop and obtain regulatory approvals for new products. Our future capital requirements will depend on many factors, including but not limited to the following:

- implementation of systemic improvements necessary to satisfactorily address the observations cited in the June 2, 2014 warning letter we received from the FDA;
- commercial acceptance of our products;
- reimbursement of our products by governmental agencies and third-party payors;
- costs to manufacture and ensure regulatory compliance of our products;
- expenses required to operate multiple clinical trials;
- further product research and development for next generation products and expanding indications for our products as well as efforts to sustain and implement incremental improvements to existing products;
- expanding our sales and marketing capabilities on a global basis;
- broadening our infrastructure in order to meet the needs of our growing operations, including regulatory compliance;
- replacement of product in the field as a result of ongoing and potential future field actions;
- expenses related to funding and integrating strategic investments, acquisitions and collaborative arrangements;
- payment, if moratorium lifted, of the 2.3% excise tax on gross revenue from the sale of our medical devices in the United States imposed by the Patient Protection and Affordable Care Act;

- payment of our convertible notes on maturity if not converted or refinanced; and
- complying with the requirements related to being a public company in the U.S.

Contractual Obligations

At December 31, 2015, our contractual financial obligations and commitments by due dates were as follows:

	Total	Less than 1 year	1-3 years	3-5 years	Thereafter
			(in thousands)		
Convertible senior notes	$275,005	$ 5,028	$52,527	$ —	$217,450
Operating lease obligations	22,079	3,853	7,949	7,907	2,370
Purchase obligations	43,813	43,185	628	—	—
Other	867	100	172	148	447
Total	$341,764	$52,166	$61,276	$ 8,055	$220,267

From time to time we invest in certain development-stage entities in connection with research activities. The above table does not reflect certain contingent milestone payments in connection with these arrangements as the amounts and timing of payment are indeterminate at this time.

On December 1, 2013, we acquired CircuLite, Inc. using a combination of cash and stock. In addition to initial consideration paid at closing, the former CircuLite security holders may be entitled to receive additional shares of HeartWare common stock (or cash, in certain cases, at our discretion) upon the achievement of five specified performance milestones and royalty payments. The above table does not reflect these milestone payments, which may be payable over a 10 year period from the time of acquisition and the timing and amount of the milestone payments are indeterminate at this time. The maximum amount of the aggregate milestone payments could be $300 million. As of December 31, 2015, the fair value of the contingent payments was approximately $12.3 million and is reflected on our consolidated balance sheet.

As of December 31, 2015, our potential liability for uncertain tax positions was approximately $2.1 million, including interest. Due to the degree of uncertainty regarding these liabilities, we are unable to make a reasonably reliable estimate of the amount and period in which these liabilities might be realized.

Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Market risk represents the risk of changes in the value of market risk sensitive instruments caused by fluctuations in interest rates, foreign exchange rates and commodity prices. Changes in these factors could cause fluctuations in our results of operations and cash flows.

Interest Rate Risk

Our exposure to interest rate risk is currently confined to interest earnings on our cash and cash equivalents that are invested in highly liquid money market funds, short-term time deposits, short-term bank notes and short-term commercial paper. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to generate reasonable income from our investments without assuming significant risk. We do not presently use derivative financial instruments in our investment portfolio. Our cash and investments policy emphasizes liquidity and preservation of principal over other portfolio considerations.

If interest rates rise, the market value of our investment portfolio may decline, which could result in a loss if we choose or are forced to sell an investment before its scheduled maturity. We do not utilize derivative financial instruments to manage interest rate risks.

Our convertible senior notes do not bear interest rate risk as the notes were issued with a fixed interest rate of 1.75% or 3.5% per annum.

Foreign Currency Rate Fluctuations

We conduct business in foreign countries. For U.S. reporting purposes, we translate all assets and liabilities of our non-U.S. entities at the period-end exchange rate and revenue and expenses at the average exchange rates in effect during the periods. The net effect of these translation adjustments is shown in the accompanying consolidated financial statements as a component of stockholders' equity.

We generate a significant portion of our revenue and collect receivables in foreign currencies. Fluctuations in the exchange rate of the U.S. dollar against major foreign currencies, including the Euro, British Pound and Australian dollar, can result in foreign currency exchange gains and losses that may significantly impact our financial results. These foreign currency transaction and translation gains and losses are presented as a separate line item on our consolidated statements of operations. Continued fluctuation of these exchange rates could result in financial results that are not comparable from quarter to quarter. We do not currently utilize foreign currency contracts to mitigate the gains and losses generated by the remeasurement of non-functional currency assets and liabilities but do hold cash reserves in currencies in which those reserves are anticipated to be expended.

Item 8. Financial Statements and Supplementary Data

HEARTWARE INTERNATIONAL, INC.

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Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
HeartWare International, Inc.

We have audited the accompanying consolidated balance sheets of HeartWare International, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2015. We also have audited the Company's internal control over financial reporting as of December 31, 2015, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, 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 Annual Report. Our responsibility is to express an opinion on these financial statements and an opinion on the Company's internal control over financial reporting based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of HeartWare International, Inc. and subsidiaries as of December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by COSO.

/s/ GRANT THORNTON LLP
Fort Lauderdale, Florida
February 26, 2016

HEARTWARE INTERNATIONAL, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except per share data)

	December 31, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 175,047	$ 102,946
Short-term investments	68,531	75,535
Accounts receivable, net	35,570	38,041
Inventories	47,686	54,046
Prepaid expenses and other current assets	2,868	5,975
Total current assets	329,702	276,543
Property, plant and equipment, net	15,098	19,036
Goodwill	61,233	61,390
In-process research and development	10,800	32,850
Other intangible assets, net	13,045	17,807
Deferred financing costs, net	3,973	1,552
Long-term investments and other assets	23,725	14,635
Total assets	$ 457,576	$ 423,813
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 15,249	$ 13,322
Other accrued liabilities	45,889	36,589
Total current liabilities	61,138	49,911
Convertible senior notes, net	191,062	114,803
Contingent liabilities (*See* Notes 4 and 6)	12,330	43,740
Other long-term liabilities	4,554	6,825
Commitments and contingencies—*See* Note 17		
Stockholders' equity:		
Preferred stock—$.001 par value; 5,000 shares authorized; no shares issued and outstanding at December 31, 2015 and 2014, respectively	—	—
Common stock—$.001 par value; 50,000 and 25,000 shares authorized at December 31, 2015 and 2014, respectively; 17,405 and 17,156 shares issued and outstanding at December 31, 2015 and 2014, respectively	17	17
Additional paid-in capital	618,219	565,609
Accumulated deficit	(421,499)	(348,719)
Accumulated other comprehensive loss:		
Cumulative translation adjustments	(8,085)	(8,112)
Unrealized loss on investments	(160)	(261)
Total accumulated other comprehensive loss	(8,245)	(8,373)
Total stockholders' equity	188,492	208,534
Total liabilities and stockholders' equity	$ 457,576	$ 423,813

HEARTWARE INTERNATIONAL, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)

	Years Ended December 31,		
	2015	2014	2013
Revenue, net	$276,843	$278,420	$207,929
Cost of revenue	103,287	92,195	76,468
Gross profit	173,556	186,225	131,461
Operating expenses:			
Selling, general and administrative	94,594	87,177	76,524
Research and development	120,769	119,782	98,757
Impairment of intangible assets	26,849	2,650	3,726
Change in fair value of contingent consideration	(31,410)	(23,260)	—
Total operating expenses	210,802	186,349	179,007
Loss from operations	(37,246)	(124)	(47,546)
Other income (expense):			
Foreign exchange loss	(4,417)	(4,952)	(70)
Interest expense	(14,305)	(13,133)	(12,224)
Investment income, net	790	666	370
Other, net	(16,588)	(1,263)	626
Loss before taxes	(71,766)	(18,806)	(58,844)
Income tax expense	1,014	560	467
Net loss	$ (72,780)	$ (19,366)	$ (59,311)
Net loss per common share—basic and diluted	$ (4.21)	$ (1.14)	$ (3.69)
Weighted average shares outstanding—basic and diluted	17,274	16,992	16,066

HEARTWARE INTERNATIONAL, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)

	Years Ended December 31,		
	2015	2014	2013
Net loss	$(72,780)	$(19,366)	$(59,311)
Other comprehensive income (loss)			
Foreign currency translation adjustments	27	(253)	180
Unrealized (loss) gain on investments	101	(246)	9
Comprehensive loss	$(72,652)	$(19,865)	$(59,122)

HEARTWARE INTERNATIONAL, INC.
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
(In thousands, except per share data)

	Common Shares, $.001 Par Value Per Share		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares Issued	Amount				
Balance, December 31, 2012	14,582	15	346,301	(270,042)	(8,063)	68,211
Issuance of common stock pursuant to public offering, net of offering costs	1,725	2	140,977	—	—	140,979
Issuance of common stock in connection with acquisition of CircuLite	226	—	21,794	—	—	21,794
Issuance of common stock pursuant to share-based awards	345	—	4,871	—	—	4,871
Share-based compensation	—	—	21,874	—	—	21,874
Net loss	—	—	—	(59,311)	—	(59,311)
Other comprehensive loss	—	—	—	—	189	189
Balance, December 31, 2013	16,878	17	535,817	(329,353)	(7,874)	198,607
Issuance of common stock in connection with an intellectual property agreement						
Issuance of common stock pursuant to public offering, net of offering costs	50	—	5,000	—	—	5,000
Issuance of common stock in connection with acquisition of CircuLite	3	—	329	—	—	329
Issuance of common stock pursuant to share-based awards	225	—	921	—	—	921
Share-based compensation	—	—	23,542	—	—	23,542
Net loss	—	—	—	(19,366)	—	(19,366)
Other comprehensive loss	—	—	—	—	(499)	(499)
Balance, December 31, 2014	17,156	$ 17	$ 565,609	$ (348,719)	$ (8,373)	$208,534
Issuance of common stock in connection with an intellectual property agreement	26	—	2,000	—	—	2,000
Issuance of common stock pursuant to share-based awards	223	—	81	—	—	81
Settlement of conversion feature on 3.5% Notes exchanged	—	—	(19,467)	—	—	(19,467)
Allocation of fair value of equity component of 1.75% Notes	—	—	47,400	—	—	47,400
Allocation of pro-rata portion of offering costs to equity component of 1.75% Notes	—	—	(1,209)	—	—	(1,209)
Share-based compensation	—	—	23,805	—	—	23,805
Net loss	—	—	—	(72,780)	—	(72,780)
Other comprehensive income	—	—	—	—	128	128
Balance, December 31, 2015	17,405	$ 17	$ 618,219	$ (421,499)	$ (8,245)	$188,492

HEARTWARE INTERNATIONAL, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Years Ended December 31,		
	2015	2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$ (72,780)	$ (19,366)	$ (59,311)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation of property, plant and equipment	6,667	6,674	6,451
Amortization of intangible assets	2,078	1,724	598
Impairment of fixed assets	1,118	607	—
Impairment of goodwill and intangible assets	26,849	2,650	3,726
Share-based compensation expense	23,805	23,542	21,874
Amortization of premium on investments	1,074	810	635
Amortization of discount on convertible senior notes	8,691	7,678	6,809
Amortization of deferred financing costs	556	412	365
Change in fair value of contingent consideration	(31,410)	(23,260)	—
Other	16,654	1,498	467
Change in operating assets and liabilities:			
Accounts receivable	894	(11,786)	(2,372)
Inventories	3,546	(16,284)	(4,331)
Prepaid expenses and other current assets	2,953	3,985	(4,850)
Other non-current assets	(2,539)	—	—
Accounts payable	1,950	(4,300)	3,564
Other accrued liabilities	9,663	7,324	3,975
Other long-term liabilities	(267)	918	177
Net cash used in operating activities	(498)	(17,174)	(22,223)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of investments	(28,105)	(58,864)	(28,905)
Maturities of investments	34,415	19,870	6,346
Acquisition of CircuLite, net of cash acquired	—	—	(9,985)
Investment in unconsolidated investee	(7,000)	—	(10,000)
Additions to property, plant and equipment, net	(3,035)	(6,721)	(2,692)
Additions to patents	(2,115)	(1,555)	(814)
Cash received from (paid for) security deposits	294	714	(271)
Net cash used in investing activities	(5,546)	(46,556)	(46,321)
CASH FLOWS FROM FINANCING ACTIVITIES			
Borrowings on convertible senior notes	79,889	—	—
Payment of convertible notes issuance costs	(5,161)	—	—
Proceeds from issuance of common stock	—	—	149,126
Payment of common stock issuance costs	—	—	(8,148)
Repayment of promissory note	—	(200)	(200)
Proceeds from exercise of stock options	80	921	4,871
Net cash provided by financing activities	74,808	721	145,649
Effect of exchange rate changes on cash and cash equivalents	3,337	3,075	(146)
CHANGE IN CASH AND CASH EQUIVALENTS	72,101	(59,934)	76,959
CASH AND CASH EQUIVALENTS—BEGINNING OF PERIOD	102,946	162,880	85,921
CASH AND CASH EQUIVALENTS—END OF PERIOD	$175,047	$102,946	$162,880
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 5,056	$ 5,040	$ 5,049
Cash paid for income taxes	$ 755	$ 96	$ —
Supplemental disclosure of non-cash investing and financing activities:			
Shares issued to acquire CircuLite	$ —	$ 329	$ 21,794
Contingent consideration related to acquisition of CircuLite	$ —	$ —	$ 67,000
Exchange of convertible notes	$101,300	$ —	$ —
Shares issued to acquire intellectual property	$ 2,000	$ 5,000	$ —
Non-cash increase to patents and intellectual property	$ —	$ 2,000	$ 5,000
Transfers from inventory to property, plant and equipment	$ 1,037	$ 1,153	$ 2,072

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Description of Business

HeartWare International, Inc., referred to in these notes collectively with its subsidiaries as "we," "our," "us," "HeartWare," "the HeartWare Group" or the "Company", is a medical device company that develops, manufactures and markets miniaturized implantable heart pumps, or ventricular assist devices, to treat patients suffering from advanced heart failure.

The HeartWare Ventricular Assist System (the "HVAD System"), which includes a ventricular assist device ("VAD") or blood pump, patient accessories and surgical tools, is designed to provide circulatory support for patients in the advanced stage of heart failure. The core of the HVAD System is a proprietary continuous flow blood pump, the HVAD pump, which is a full-output device capable of pumping up to 10 liters of blood per minute. The HVAD System is designed to be implanted adjacent to the heart, avoiding abdominal surgery, which is generally required to implant similar devices.

In November 2012, we received approval from the United States Food and Drug Administration ("FDA") for the HVAD System as a bridge-to-heart-transplantation in patients with end-stage heart failure. The HVAD System has been available in the European Union since receiving CE marking in 2009. In May 2012, we received an expanded European label for long-term use of the HVAD System in all patients at risk of death from refractory, end-stage heart failure. As of December 31, 2015, there have been over 10,000 implants of the HVAD System in patients at over 320 health care sites in 47 countries.

In August 2015, we completed enrollment of an Investigational Device Exemption ("IDE") Supplement which allowed HeartWare an additional patient cohort for the ENDURANCE clinical trial. In this supplemental cohort, HeartWare enrolled 308 patients who received the HVAD System, as well as 157 control patients using a randomization scheme consistent with the original ENDURANCE protocol. Assessment of primary endpoint is at 1 year post implant. In 2016, HeartWare intends to incorporate the data from both this supplemental cohort and ENDURANCE into an anticipated PMA Supplement Application seeking approval of the HVAD System for a destination therapy indication.

Beyond the HVAD System, we are developing our next generation miniaturized device, known as the MVAD System. The MVAD System is based on the same technology platform as the HVAD System, but adopts an axial flow, rather than a centrifugal flow, configuration and is being developed in multiple designs. The MVAD pump is less than one-half the size of the HVAD pump and can provide partial or full support. The MVAD System is designed to allow for a variety of configurations and surgical placements with the goal of further reducing surgical invasiveness while producing superior clinical results.

In July 2015, we initiated a multicenter, prospective, non-randomized, single-arm CE Mark trial that evaluates the clinical safety and performance of the MVAD System for the treatment of advanced heart failure. In September 2015, we voluntarily paused the MVAD CE Mark clinical trial to address an MVAD controller manufacturing issue. Subsequent to that action, during the fourth quarter of 2015 and in consultation with study investigators, we began evaluating MVAD System performance and reported adverse events in certain clinical trial patients, including events that showed evidence of pump thrombosis. We are currently evaluating various aspects of the MVAD System design to determine whether changes should be made. Should design changes be implemented, initiation of a new trial would likely be required. The timetable for updating affected regulatory filings and restarting clinical implants cannot be reliably projected at this time.

We are headquartered in Framingham, Massachusetts. We have operating facilities in Miami Lakes, Florida, Hannover, Germany, and Arden Hills, Minnesota.

HeartWare International, Inc. shares trade on the NASDAQ Stock Market under the symbol of "HTWR".

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 2. Liquidity

We have funded our operations primarily through product revenue, the issuance of shares of our common stock and the issuance of convertible notes. At December 31, 2015, we had approximately $244.6 million of cash, cash equivalents and investments. Our cash, cash equivalents and investments are expected to be used primarily to fund our ongoing operations including expanding our sales and marketing capabilities on a global basis, research and development (including clinical trials) of new and existing products, components and accessories, regulatory and other compliance functions as well as for general working capital. We believe our cash, cash equivalents and investment balances are sufficient to support our planned operations for at least the next twelve months.

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States, which contemplate continuation of the Company as a going concern. We have incurred substantial losses from operations since our inception, and such losses have continued through December 31, 2015. At December 31, 2015, we had an accumulated deficit of approximately $421.5 million.

Note 3. Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the HeartWare Group. All inter-company balances and transactions have been eliminated in consolidation. We hold certain investments in small privately-held development-stage entities which are included in other assets on our consolidated balance sheets. In accordance with FASB ASC 810, we analyzed the investments to determine whether the investments are variable interests or interests that give us a controlling financial interest in a variable interest entity ("VIE"). As of December 31, 2015, we determined there were no VIEs required to be consolidated, because we are not the primary beneficiary, as we do not have the power to direct the most meaningful activities of the VIE. Investments where we do not exercise operating and financial control are accounted for under the equity method or cost method depending on our ownership interest.

Accounting Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States ("U.S. GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents, which primarily consist of money market funds, are recorded in the consolidated balance sheets at cost, which approximates fair value. All highly liquid investments with an original maturity of three months or less at the date of purchase are considered to be cash equivalents.

Investments

Our investments classified as available-for-sale are stated at fair value with unrealized gains and losses reported in accumulated other comprehensive loss within stockholders' equity. We classify our available-for-sale investments as short-term if their remaining time to maturity at purchase is beyond three months, but less than

twenty-four months. Investments with maturities at purchase beyond one year, but less than twenty-four months, may be classified as short-term based on their highly liquid nature and because such marketable securities represent the investment of cash that is available for current operations. Interest on investments classified as available-for-sale is included in investment income, net. Premiums paid on our short-term investments are amortized over the remaining term of the investment and such amortization is included in investment income, net.

Receivables

Accounts receivable consists of amounts due from the sale of our HVAD System to our customers, which include hospitals, health research institutions and medical device distributors. We grant credit to customers in the normal course of business, but do not require collateral or any other security to support credit sales. Our receivables are geographically dispersed, with a significant portion from customers located in Europe and other foreign countries. At December 31, 2015, one customer had an accounts receivable balance greater than 10% of total accounts receivable representing approximately 17% of our total accounts receivable. At December 31, 2014, no customer had an accounts receivable balance greater than 10% of our total accounts receivable.

In 2015, we entered into an agreement with one customer with extended payment terms in which sales are recorded as a long-term receivable and a portion of sales are deferred. The deferred portion of sales are treated as a financing charge in which interest income is imputed and recorded as investment income over the financing period on our consolidated statement of operations. At December 31, 2015 we had approximately $2.5 million of long-term receivables and they are recorded on consolidated balance sheet under long-term investments and other assets.

We maintain allowances for doubtful accounts for estimated losses that may result from an inability to collect payments owed to us for product sales. We regularly review the allowance by considering factors such as historical experience, the age of the accounts receivable balances and local economic conditions that may affect a customer's ability to pay. Account balances are charged off against the allowance after appropriate collection efforts are exhausted and we feel it is probable that the receivable will not be recovered.

The following table summarizes the change in our allowance for doubtful accounts for the years ended December 31, 2015, 2014 and 2013:

	2015	2014	2013
		(in thousands)	
Beginning balance	$671	$495	$ 750
Charges (reversals) to expense	5	181	(255)
Charge-offs	(0)	(5)	—
Ending balance	$676	$671	$ 495

As of December 31, 2015 and 2014, we did not have an allowance for returns.

Inventories

Inventories are stated at the lower of cost or market. Cost is determined using a first-in, first-out, or FIFO, method. Work-in-process and finished goods manufactured or assembled by us include direct and indirect labor and manufacturing overhead. Finished goods include product which is ready-for-use and which is held by us or by our customers on a consignment basis.

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

We review our inventory for excess or obsolete inventory and write-down obsolete or otherwise unmarketable inventory to its estimated net realizable value. Obsolescence may occur due to product expiring or product improvements rendering previous versions obsolete.

Property, Plant and Equipment

We record property, plant and equipment and leasehold improvements at historical cost. Expenditures for maintenance and repairs are recorded to expense; additions and improvements are capitalized. We generally provide for depreciation using the straight-line method at rates that approximate the estimated useful lives of the assets. Leasehold improvements are amortized on a straight-line basis over the shorter of the useful life of the improvement or the remaining term of the lease.

Property, plant and equipment, net consists of the following:

	Estimated Useful Lives	December 31, 2015	December 31, 2014
		(in thousands)	
Property, plant and equipment			
Machinery and equipment	1.5 to 7 years	$ 21,785	$ 21,279
Leasehold improvements	3 to 10 years	8,891	9,070
Office equipment, furniture and fixtures	5 to 7 years	2,105	2,206
Purchased software	1 to 7 years	7,575	6,474
		40,356	39,029
Less: accumulated depreciation		(25,258)	(19,993)
		$ 15,098	$ 19,036

Depreciation expense was $6.7 million, $6.7 million, and $6.5 million for the years ended December 31, 2015, 2014 and 2013, respectively.

During the year ended December 31, 2015, we ceased activities at our facility in Aachen, Germany. We recorded an impairment charge of approximately $1.1 million related to certain office equipment and software at the facility upon their discontinued use. This amount is included in research and development expenses on our consolidated statement of operations.

During the year ended December 31, 2014, we ceased activities at the former headquarters of CircuLite in Teaneck, New Jersey and vacated the facility. We recorded an impairment charge of $0.6 million related to certain office equipment and software at the facility upon their discontinued use. This amount is included in selling, general and administrative expenses on our consolidated statements of operations.

We enter into agreements with medical centers participating in our U.S. clinical trials under which we loan certain equipment, including patient monitors, to the center to be used throughout the trials. The equipment loaned to the centers is classified as a long-lived asset and included as a component of property, plant and equipment (machinery and equipment) on our consolidated balance sheets. Depreciation expense on equipment subject to these agreements is classified in cost of revenue and is computed using the straight-line method based on the estimated useful life of three years.

We also enter into short-term cancellable rental agreements with certain commercial customers for components of the HVAD System, including patient monitors and controllers. Under the terms of such

agreements, we provide the equipment to the customers, but we retain title to the equipment. Equipment subject to rental agreements is classified as a long-lived asset and included as a component of property, plant and equipment (machinery and equipment). Depreciation expense on equipment subject to these agreements is classified in cost of revenue and is computed using the straight-line method based on the estimated useful life of fifteen months.

The net carrying value of equipment subject to the agreements discussed above was approximately $0.6 million and $0.7 million as of December 31, 2015 and 2014, respectively.

Deferred Financing Costs

Costs incurred in connection with the issuance of our convertible senior notes were allocated between the liability component and the equity component as further discussed in Note 10. The issuance costs allocated to convertible senior notes was capitalized within deferred financing costs, net on our consolidated balance sheets. These costs are being amortized using the effective interest method through December 15, 2017 for notes issued in December 2010 and through December 15, 2021 for notes issued in May 2015, the respective maturity dates of the notes, and such amortization expense is reflected in interest expense on our consolidated statements of operations. The amount of amortization was approximately $0.6 and $0.4 million for each of the years ended December 31, 2015 and 2014, respectively. The amount of accumulated amortization at December 31, 2015 and 2014 was approximately $0.9 million and $1.4 million, respectively.

Revenue Recognition

We recognize revenue from product sales in accordance with FASB ASC 605—*Revenue Recognition*. Revenue from product sales is recognized when persuasive evidence of an arrangement exists, substantially all the risks and rewards of ownership have transferred to our customers, the selling price is fixed and collection is reasonably assured and there are no further obligations to customers. In the U.S., we are able to charge for clinical trial unit sales, and treat proceeds from clinical trial arrangements as revenue. Sales from products are not subject to rights of return and, historically, actual sales returns have not been significant. We sell products through our direct sales force and through distributors. Sales through distributors are recognized as revenue upon sale to the distributor as these sales are considered to be final and no right of return or price protection exists. Sales to customers, when not made on consignment, are recognized upon shipment. A significant portion of our sales are made on a consignment basis. Revenue from products sold on a consignment basis is recognized on the date the consigned product is implanted or otherwise consumed. In limited circumstances, we rent peripheral equipment to patients. We recognize revenue from this arrangement when a contract is entered into with the patient's insurer over the term the equipment is rented.

Shipping fees billed to customers are included in revenue and the related shipping costs are included in cost of revenue. Value added taxes and other similar types of taxes collected from customers in connection with the sale of our products are recorded on a net basis and are not included in revenue.

Product Warranty

Certain patient accessories sold with the HVAD System are covered by a limited warranty ranging from one to two years. Estimated contractual warranty obligations are recorded as an expense when the related revenue is recognized and are included in cost of revenue on our consolidated statements of operations. Factors that affect the estimated warranty liability include the number of units sold, historical and anticipated rates of warranty claims, cost per claim, and vendor supported warranty programs. We periodically assess the adequacy of our recorded warranty liabilities and adjust the amounts as necessary. The amount of the liability recorded is equal to

the estimated costs to repair or otherwise satisfy claims made by customers. Accrued warranty is included as a component of other accrued liabilities on our consolidated balance sheets.

Share-Based Compensation

We recognize share-based compensation expense in connection with our share-based awards based on the estimated fair value of the awards on the date of grant, net of estimated forfeitures, using an accelerated accrual method over the vesting period. Therefore, we only recognize compensation cost for those awards expected to vest over the service period of the award. We estimate the forfeiture rate based on our historical experience of forfeitures. If our actual forfeiture rate is materially different from our estimate, share-based compensation expense could be significantly different from what we have recorded in the current period.

Calculating share-based compensation expense requires the input of highly subjective judgment and assumptions, including forfeiture rates, estimates of expected life of the share-based award, stock price volatility and risk-free interest rates. The assumptions used in calculating the fair value of share-based awards represent our best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our share-based compensation expense could be materially different in the future.

We value restricted stock units ("RSUs") at their intrinsic value on the date of grant. We estimate the fair value of our stock options using a Black-Scholes option pricing model. When appropriate, we estimate the expected life of a stock option by averaging the contractual term of the stock option (typically 10 years) with the associated vesting term (typically 4 years). We estimate the volatility of our shares on the date of grant considering several factors, including the historical volatility of our publicly-traded shares. We estimate the risk-free interest rate based on rates in effect for United States government bonds with terms similar to the expected lives of the stock options, at the time of grant.

We have issued share-based awards with performance-based vesting criteria. Achievement of the milestones must be "probable" before we begin recording share-based compensation expense. At each reporting date, we review the likelihood that these awards will vest and if the vesting is deemed probable, we begin to recognize compensation expense at that time. In the period that achievement of the performance based criteria is deemed probable, U.S. GAAP requires the immediate recognition of all previously unrecognized compensation since the original grant date. As a result, compensation expense recorded in the period that achievement is deemed probable could include a substantial amount of previously unrecorded compensation expense related to the prior periods. If ultimately performance goals are not met, for any share-based awards where vesting was previously deemed probable, previously recognized compensation cost will be reversed.

Valuation of Long-Lived Assets and Purchased Intangible Assets

We evaluate the carrying value of our long-lived assets, including purchased intangible assets, whenever events, changes in business circumstances or our planned use of long-lived assets indicate that their carrying amounts may not be fully recoverable or that their useful lives are no longer appropriate. If these facts and circumstances exist, we assess for recovery by comparing the carrying values of long-lived assets with their future undiscounted net cash flows. If the comparison indicates that impairment exists, impairment losses are recorded for the excess of the carrying value over the fair value of the long-lived assets based on discounted cash flows. Significant management judgment is required in the forecast of future operating results that are used in the preparation of expected undiscounted cash flows. In 2014, we ceased activities at CircuLite's former headquarters in Teaneck, New Jersey and vacated the facility. We recorded lease impairment charges totaling $1.7 million related to closure of the facility and an additional impairment charge of $0.6 million related to

certain office equipment and software at the facility upon their discontinued use. In 2015, due primarily to weakness in the northern New Jersey real estate market we recorded additional lease impairment charges totaling $1.5 million. These amounts are included in selling, general and administrative expenses on our consolidated statements of operations. No impairments of similar long-lived assets were identified during the year ended December 31, 2013.

We also evaluate the carrying value of intangible assets (not subject to amortization) related to in-process research and development ("IPR&D") assets which are considered to be indefinite-lived until the completion or abandonment of the associated research and development projects. Accordingly, amortization of the IPR&D assets does not occur until the product reaches commercialization. During the period the assets are considered indefinite-lived, they are tested for impairment on an annual basis, as well as between annual tests if we become aware of any events occurring or changes in circumstances that indicate that the fair values of the IPR&D assets are less than their carrying amounts. If and when development is complete, which generally occurs when regulatory approval to market the product is obtained, the associated IPR&D assets are deemed definite-lived and are then amortized based on their estimated useful lives at that point in time. If the related project is terminated, abandoned or significantly changed, we may have a full or partial impairment related to the IPR&D assets, calculated as the excess of their carrying value over fair value.

During the fourth quarter of 2015, we performed an impairment review of IPR&D acquired from CircuLite and recorded an impairment charge of $22.1 million. This change was a result of longer than anticipated timelines to develop and receive approval for a CircuLite System. We had a similar IPR&D charge of $2.6 million in 2014 when we discontinued the use of the CircuLite micro pump acquired from CircuLite in favor of using our MVAD pump for the CircuLite System. During the fourth quarter of 2015, we also recorded an impairment charge of $4.8 million related to tradenames and customer lists associated with our acquisition of CicruLite. The impairment was primarily associated with program delays which impact the certainty of development and eventual regulatory approval of a CircuLite System.

Goodwill

We test goodwill for impairment on an annual basis in the fourth quarter of each fiscal year or more frequently if we believe indicators of impairment exist. The performance of the test involves a two-step process. The first step requires comparing the fair value of the reporting unit to its net book value, including goodwill. A potential impairment exists if the fair value of the reporting unit is lower than its net book value. The second step of the process is only performed if a potential impairment exists, and it involves comparing the aggregate fair value of the reporting unit's net assets other than goodwill to the fair value of the reporting unit as a whole. Goodwill is considered impaired, and an impairment charge is recorded, if the excess of the fair value of the reporting unit over the fair value of the net assets is less than the carrying value of goodwill.

Based on the results of our annual impairment review in the fourth quarter of each year, we concluded that goodwill was not impaired in either 2015 or 2014.

Contingent Consideration

On December 1, 2013, we acquired CircuLite, Inc. In addition to initial consideration paid at closing, the former CircuLite security holders may be entitled to receive additional shares of HeartWare common stock (or cash, in certain cases, at our discretion) upon the achievement of specified regulatory and commercial milestones, not to exceed $300 million in the aggregate over a ten-year period. The estimated fair value of the contingent payments is recorded as a liability and is remeasured at each reporting period. The estimated fair value is calculated using a discounted cash flow model utilizing significant unobservable inputs including future revenue

projections, the probability of achieving each of the potential milestones and an estimated discount rate commensurate with the risks of the expected cash flows attributable to the various milestones. Material changes in any of these inputs could result in a significantly higher or lower fair value measurement and commensurate changes to this liability. Changes in the fair value of the contingent payments are recorded on a separate line item on our consolidated statements of operations.

Income Taxes

We account for income taxes in accordance with FASB ASC 740—*Income Taxes*. Under this method, deferred tax assets and liabilities are provided for differences between the carrying amounts of assets and liabilities in the consolidated financial statements and the tax bases of assets and liabilities that will result in future taxable or deductible amounts. The deferred tax assets and liabilities are measured using the enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Income tax expense is computed as the tax payable or refundable for the period, plus or minus the change during the period in deferred tax assets and liabilities. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred taxes will not be realized.

FASB ASC 740 requires that we recognize the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the “more likely than not” threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority.

We recognize interest and penalties related to unrecognized tax benefits within the provision for income taxes line on our consolidated statements of operations.

Translation of Foreign Currency

Assets and liabilities of our non-U.S. entities are translated at the period-end exchange rate and revenue and expenses are translated at the average exchange rates in effect during the respective periods. Equity transactions are translated at the spot rates on the dates of the original transactions. The net effect of these translation adjustments is shown in the accompanying consolidated financial statements as a component of stockholders’ equity, titled accumulated other comprehensive loss. Items in accumulated other comprehensive loss are not tax affected as we have incurred a net loss in each period since inception.

While most of the transactions of our domestic and international operations are denominated in the respective local currency, some transactions are denominated in other currencies. Transactions denominated in other currencies are accounted for in the respective local currency at the time of the transaction. Upon settlement of this type of transaction, any foreign currency gains or losses are included in our consolidated statements of operations.

Research and Development

Research and development costs, including new product development programs, regulatory compliance and clinical research, are expensed as incurred.

Marketing and Advertising Costs

Marketing, advertising and promotional costs are expensed when incurred. Advertising expenses were immaterial to our results of operations for the years ended December 31, 2015, 2014 and 2013.

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Leases

We lease all of our administrative and manufacturing facilities. We recognize rent expense on a straight-line basis over the terms of our leases. Any scheduled rent increases, rent holidays and other related incentives are recognized on a straight-line basis over the terms of the leases. The difference between the cash rental payments and the straight-line recognition of rent expense over the terms of the leases results in a deferred rent asset or liability. As of December 31, 2015, the long-term portion of our deferred rent liability of approximately $3.2 million is included in other long-term liabilities on our consolidated balance sheets.

Fair Value Measurements

The carrying amounts reported in the consolidated balance sheets for cash and cash equivalents, accounts receivable, accounts payable and other accrued liabilities approximate their fair value based on the short-term maturity of these instruments. *See* Note 6 (Fair Value Measurements) and Note 10 (Debt) for more information.

Vendor Concentration

For the years ended December 31, 2015, 2014 and 2013, we purchased approximately 68%, 72%, and 70%, respectively, of our inventory components and supplies from three vendors. In addition, one of the three vendors supplies consulting services and material used in research and development activities. As of December 31, 2015, 2014 and 2013, the amounts due to these vendors totaled approximately $6.1 million, $5.4 million and $5.8 million, respectively.

Concentration of Credit Risk and other Risks and Uncertainties

Financial instruments that potentially expose us to concentrations of credit risk consist primarily of cash and cash equivalents, investments and trade accounts receivable. Cash and cash equivalents are primarily on deposit with financial institutions in the United States and these deposits generally exceed the amount of insurance provided by the Federal Deposit Insurance Corporation (the "FDIC"). The Company has not experienced any historical losses on its deposits of cash and cash equivalents. Our investments consist of investment grade rated corporate and government agency debt and time deposits.

Concentration of credit risk with respect to our trade accounts receivable from our customers is primarily limited to hospitals, health research institutions and medical device distributors. Credit is extended to our customers based on an evaluation of a customer's financial condition, and collateral is not required.

We are subject to certain risks and uncertainties including, but not limited to, our ability to achieve profitability, to generate cash flow sufficient to satisfy our indebtedness, to run clinical trials in order to receive and maintain FDA and foreign regulatory approvals for our products, our ability to adequately and timely address issues raised by FDA inspections, our ability to identify and correct quality issues in a timely manner and at a reasonable cost, the ability to achieve widespread acceptance of our products, our ability to manufacture our products in a sufficient volume and at a reasonable cost, the ability to protect our proprietary technologies and develop new products, the risks associated with operating in foreign countries, and general competitive and economic conditions. Changes in any of the preceding areas could have a material adverse effect on our business, results of operations or financial position.

New Accounting Standards

In July 2013, the FASB issued ASU No. 2013-11, *Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit*

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Carryforward Exists (a consensus of the FASB Emerging Issues Task Force). U.S. GAAP does not include explicit guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The amendments in this ASU state that an unrecognized tax benefit, or a portion of an unrecognized tax benefit, should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward, except as follows: To the extent a net operating loss carryforward, a similar tax loss, or a tax credit carryforward is not available at the reporting date under the tax law of the applicable jurisdiction to settle any additional income taxes that would result from the disallowance of a tax position or the tax law of the applicable jurisdiction does not require the entity to use, and the entity does not intend to use, the deferred tax asset for such purpose, the unrecognized tax benefit should be presented in the financial statements as a liability and should not be combined with deferred tax assets. This ASU applies to all entities that have unrecognized tax benefits when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists at the reporting date. The amendments in this ASU are effective for fiscal years, and interim periods within those years, beginning after December 15, 2013, with early adoption permitted. The amendments should be applied prospectively to all unrecognized tax benefits that exist at the effective date, although retrospective application is permitted. The adoption of ASU No. 2013-11 effective January 1, 2014 did not have a material effect on our consolidated financial position, results of operations or cash flows.

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"). The updated standard is a new comprehensive revenue recognition model that requires revenue to be recognized in a manner that depicts the transfer of goods or services to a customer at an amount that reflects the consideration expected to be received in exchange for those goods or services. In July 2015, the FASB voted to approve the deferral of the effective date of ASU 2014-09 by one year. Therefore, ASU 2014-09 will become effective for us in the first quarter of our fiscal year ending December 31, 2018. Early adoption is permitted, but not earlier than the first quarter of our fiscal year ending December 31, 2017. The ASU allows for either full retrospective or modified retrospective adoption. We have not yet selected a transition method, and we are currently evaluating the effect that ASU 2014-09 will have on our consolidated financial statements and related disclosures.

In January 2015, the FASB issued ASU No. 2015-01, *Income Statement—Extraordinary and Unusual Items (Subtopic 225-20): Simplifying Income Statement Presentation by Eliminating the Concept of Extraordinary Items*. The FASB issued this ASU as part of its initiative to reduce complexity in accounting standards. This ASU eliminates from U.S. GAAP the concept of extraordinary items. Subtopic 225-20 required that an entity separately classify, present, and disclose extraordinary events and transactions. Presently, an event or transaction is presumed to be an ordinary and usual activity of the reporting entity unless evidence clearly supports its classification as an extraordinary item. If an event or transaction meets the criteria for extraordinary classification, an entity is required to segregate the extraordinary item from the results of ordinary operations and show the item separately in the income statement, net of tax, after income from continuing operations. The entity also is required to disclose applicable income taxes and either present or disclose earnings-per-share data applicable to the extraordinary item. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. A reporting entity may apply the amendments prospectively. A reporting entity also may apply the amendments retrospectively to all prior periods presented in the financial statements. Early adoption is permitted provided that the guidance is applied from the beginning of the fiscal year of adoption. The adoption of ASU No. 2015-01 is not expected to have a material effect on our consolidated financial position, results of operations or cash flows.

In February 2015, the FASB issued ASU No. 2015-02, *Consolidation (Topic 810): Amendments to the Consolidation Analysis*, which is intended to improve targeted areas of consolidation guidance for legal entities such as limited partnerships, limited liability corporations, and securitization structures (collateralized debt

obligations, collateralized loan obligations, and mortgage-backed security transactions). This ASU focuses on the consolidation evaluation for reporting organizations (public and private companies and not-for-profit organizations) that are required to evaluate whether they should consolidate certain legal entities. In addition to reducing the number of consolidation models from four to two, the new standard simplifies the FASB Accounting Standards Codification by: i) placing more emphasis on risk of loss when determining a controlling financial interest; ii) reducing the frequency of the application of related-party guidance when determining a controlling financial interest in a variable interest entity ("VIE"); and iii) changing consolidation conclusions for public and private companies in several industries that typically make use of limited partnerships or VIEs. ASU No. 2015-02 will be effective for us in periods beginning after December 15, 2015. Early adoption is permitted, including adoption in an interim period. The adoption of ASU No. 2015-02 is not expected to have a material effect on our consolidated financial position, results of operations or cash flows.

In April 2015, the FASB issued ASU No. 2015-03, *Interest—Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. The updated standard requires debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. ASU 2015-03 will be effective for us in periods beginning after December 15, 2015. Early adoption is permitted for financial statements that have not been previously issued. ASU 2015-03 should be applied on a retrospective basis, wherein the balance sheet of each individual period presented should be adjusted to reflect the period-specific effects of applying the new guidance. The adoption of ASU No. 2015-03 will result in the reclassification of debt issuance costs currently classified in long-term assets to be offset against the carrying value of our convertible notes. Based on the amount of debt issuance costs included in long-term assets as of December 31, 2015, the adoption of ASU 2015-03 is not expected to have a material effect on our consolidated financial position, results of operations or cash flows.

Note 4. Acquisitions

Valtech Cardio, Ltd.

On September 1, 2015, we entered into a Business Combination Agreement (the "BCA") by and among the Company, Valtech Cardio, Ltd. ("Valtech"), HW Global, Inc. ("Holdco"), HW Merger Sub, Inc., Valor Merger Sub Ltd. and Valor Shareholder Representative, LLC, pursuant to which we and Valtech proposed to effect a strategic combination of our respective businesses under Holdco subject to certain closing conditions. Valtech is a privately held company that specializes in the development of innovative surgical and transcatheter valve repair and replacement devices for the treatment of mitral valve regurgitation and tricuspid valve regurgitation. Effective January 28, 2016, we terminated the BCA pursuant to the terms of the BCA by delivering written notice to the other parties. As of December 31, 2015, we had invested approximately $17 million in Valtech in the original form of convertible loans, of which $10 million together with $0.5 million of accrued interest was converted into Valtech preferred shares amounting to approximately 3.0% ownership on a fully diluted basis. Pursuant to the BCA we loaned Valtech $1 million on January 7, 2016 and $30 million following termination of the BCA per provisions of the BCA, in the form of convertible loans. We have no current contractual obligations to further fund Valtech. This investment, including both our equity investment and outstanding convertible notes receivable were deemed to be realizable, are carried at cost and are included in long-term investments and other assets on our consolidated balance sheets. The fair value of this investment has not been estimated as of December 31, 2015 as there have been no impairment indicators identified.

CircuLite, Inc.

On December 1, 2013, we entered into an Agreement and Plan of Merger (the "Merger Agreement") pursuant to which we acquired CircuLite. At the effective time of the merger, all of the issued and outstanding shares of CircuLite capital stock (other than any shares of capital stock held by CircuLite or its subsidiary

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

immediately before the effective time of the Merger and any dissenting shares of CircuLite capital stock) automatically converted into the right to receive an upfront payment and certain contingent merger consideration, in accordance with the terms of the Merger Agreement, as described in our Current Report on Form 8-K filed with the Securities and Exchange Commission on December 2, 2013.

In connection with the acquisition of CircuLite, we agreed to pay $30 million consisting of approximately $18 million in shares of HeartWare common stock, par value $0.001 per share (the "Common Stock"), equal to approximately 230,000 shares of Common Stock (the "Closing Payment"), and approximately $12 million in cash to repay outstanding CircuLite indebtedness and pay certain transaction liabilities and expenses. We funded the cash payment at closing with our existing cash balances. In accordance with the terms of the Merger Agreement, a volume weighted average of the per share prices of Common Stock during the 60 consecutive trading days ending on (and including) November 27, 2013 was used to determine the number of shares of Common Stock issued in connection with the closing. For accounting purposes, these shares were valued as of closing at approximately $22 million based upon the closing price of our common stock on the trading day prior to closing. In addition to the Closing Payment, the former CircuLite security holders may be entitled to receive additional shares of Common Stock (or cash, in certain cases, at our discretion) upon the achievement of specified performance milestones (the "Contingent Payments"). The Contingent Payments were recorded as a liability at the estimated acquisition-date fair value of approximately $67.0 million. Fair value was estimated using a discounted cash flow model utilizing significant unobservable inputs including the probability of achieving each of the potential milestones and an estimated discount rate commensurate with the risks of the expected cash flows attributable to the various milestones.

The acquisition-date fair value of the consideration transferred is as follows:

	Total Acquisition Date Fair Value (in thousands)
Cash transferred, including acquisition costs and repayment of debt	$ 11,780
Shares of common stock issued	22,328
Contingent consideration	67,000
Total consideration transferred	$ 101,108

We paid $5.7 million in transaction related liabilities and expenses and repaid $6.1 million in debt on behalf of CircuLite, which are included as cash transferred in the table above.

The transaction was accounted for as a business combination under the acquisition method of accounting in accordance with the Financial Accounting Standards Board's Accounting Standards Codification Topic 805, *Business Combinations*. Accordingly, the tangible assets and identifiable intangible assets acquired and liabilities assumed were recorded at fair value as of the date of acquisition, with the remaining purchase price recorded as goodwill.

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed at the date of acquisition on December 1, 2013 (in thousands):

Cash and cash equivalents	$ 1,795
Identified intangible assets	5,500
In-process research and development	35,500
Goodwill	61,576
Other assets acquired	2,724
Total assets acquired	107,095
Other liabilities assumed	(5,987)
Total net assets acquired	$101,108

The identified intangible assets consist of customer relationships and trade names. These assets were being amortized on a straight-line basis over their estimated economic useful lives ranging from 15-20 years. We recognized a full impairment charge of $4.8 million for the remaining book value of these identified intangible assets in the fourth quarter of 2015. The impairment was associated with program delays which impact the certainty of development and eventual regulatory approval of a CircuLite System.

In-process research and development ("IPR&D") is principally the estimated fair value of the CircuLite System, with assigned values to be allocated among the various IPR&D assets acquired. IPR&D is recorded as an indefinite-lived asset until put into commercial use, upon which each applicable IPR&D asset becomes classified as developed technology and is amortized over the estimated period of economic benefit. We recognized partial impairment charges of $22.1 million and $2.6 million in 2015 and 2014, respectively, as a result of factors which impacted the realizability of the CircuLite IPR&D. The 2015 charge was primarily associated with program delays which impact the certainty of development and eventual regulatory approval of a CircuLite System, while the 2014 charge resulted from a decision to discontinue development of the acquired CircuLite micro pump in favor of replacing it with a version of our MVAD pump.

Goodwill, which largely represents the potential economic benefits of a technology that could expand our product portfolio and the patient population we can address, is calculated as the difference between the acquisition-date fair value of the consideration transferred and the fair values of the assets acquired and liabilities assumed. The goodwill is not expected to be deductible for income tax purposes. Goodwill is recorded as an indefinite-lived asset and is not amortized. Goodwill will be reviewed for impairment on an annual basis in the fourth quarter of our subsequent fiscal years or sooner if indications of impairment arise.

We incurred legal, consulting and other costs related to the acquisition aggregating approximately $2.8 million, which were expensed as incurred and are included in selling, general and administrative expenses in our consolidated statements of operations. The results of operations for CircuLite are included in our consolidated statements of operations subsequent to the December 1, 2013 date of acquisition. CircuLite's results of operations for the period from December 1, 2013 to December 31, 2013 represented approximately $3.2 million of our consolidated net loss for the year ended December 31, 2013 and included approximately $0.6 million for restructuring costs.

Note 5. Investments

We have cash investment policies that limit investments to investment grade rated securities. At December 31, 2015 and 2014, all of our investments were classified as available-for-sale and carried at fair value. At December 31, 2015 and 2014, our short-term investments had maturity dates of less than twenty-four months and our long-term investments had maturity dates within thirty-six months.

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The amortized cost and fair value of our investments, with gross unrealized gains and losses, were as follows:

At December 31, 2015

	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value
		(in thousands)		
Short-term investments:				
Corporate debt	$ 32,666	$ —	$ (100)	$ 32,566
U.S. government agency debt	25,000	—	(60)	24,940
Certificates of deposit	11,025	—	—	11,025
Total short-term investments	$ 68,691	$ —	$ (160)	$ 68,531
Long-term investments:				
Certificates of deposit	$ 980	$ —	$ —	$ 980
Total long-term investments	$ 980	$ —	$ —	$ 980

At December 31, 2014

	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value
		(in thousands)		
Short-term investments:				
Corporate debt	$ 51,241	$ 8	$ (244)	$ 51,005
U.S. government agency debt	15,000	—	(25)	14,975
Certificates of deposit	9,555	—	—	9,555
Total short-term investments	$ 75,796	$ 8	$ (269)	$ 75,535
Long-term investments:				
Certificates of deposit	$ 1,225	$ —	$ —	$ 1,225
Total long-term investments	$ 1,225	$ —	$ —	$ 1,225

For the twelve months ended December 31, 2015 and 2014, we did not have any realized gains or losses on our investments. At December 31, 2015, 13 of our available-for-sale investments with an aggregate fair value of $34.5 million had been in a continuous loss position for more than twelve months. At December 31, 2015, the gross unrealized loss on these 13 available-for-sale investments was $99,000 and was deemed to be temporary. At December 31, 2015, 5 individual securities had been in an unrealized loss position for twelve months or less. At December 31, 2014, none of our available-for-sale investments had been in a continuous loss position for more than twelve months, while 22 individual securities had been in an unrealized loss position for twelve months or less and the losses were determined to be temporary.

Note 6. Fair Value Measurements

FASB ASC 820—*Fair Value Measurements and Disclosures,* defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. FASB ASC 820 requires disclosures about the fair value of all financial instruments, whether

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

or not recognized, for financial statement purposes. Disclosures about the fair value of financial instruments are based on pertinent information available to us as of the reporting dates. Accordingly, the estimates presented in these consolidated financial statements are not necessarily indicative of the amounts that could be realized on disposition of the financial instruments.

FASB ASC 820 specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

The three levels of the fair value hierarchy are as follows:

Level 1—Quoted prices for identical instruments in active markets.

Level 2—Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3—Instruments with primarily unobservable value drivers.

We review the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels of certain securities within the fair value hierarchy. There were no transfers between Level 1, Level 2 and Level 3 during the years ended December 31, 2015, 2014 or 2013.

The following tables represent the fair value of our financial assets and financial liabilities measured at fair value on a recurring basis and which level was used in the fair value hierarchy.

	At December 31, 2015				
	Carrying Value	Fair Value	Fair Value Measurements at the Reporting Date Using		
			Level 1	Level 2	Level 3
			(in thousands)		
Assets					
Short-term investments	$ 68,531	$ 68,531	$ —	$ 68,531	$ —
Long-term investments	980	980	—	980	—
Liabilities					
Convertible senior notes	191,062(1)	200,351	—	200,351	—
Contingent consideration	12,330	12,330	—	—	12,330
Royalties	918	918	—	—	918
Lease exit costs	1,955	1,955	—	—	1,955

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	At December 31, 2014				
	Carrying Value	Fair Value	Fair Value Measurements at the Reporting Date Using		
			Level 1	Level 2	Level 3
			(in thousands)		
Assets					
Short-term investments	$ 75,535	$ 75,535	$ —	$ 75,535	$ —
Long-term investments	1,225	1,225	—	1,225	—
Liabilities					
Convertible senior notes	114,803(1)	153,978	—	153,978	—
Contingent consideration	43,740	43,740	—	—	43,740
Royalties	962	962	—	—	962
Lease exit costs	1,207	1,207	—	—	1,207

- The carrying amount of our convertible senior notes is net of unamortized discount. *See* Note 10 (Debt) for more information.

Our Level 2 financial assets and liabilities include available-for-sale investments and our convertible senior notes. The fair value of our available-for-sale investments and our convertible senior notes was determined using quoted prices (including trade data) for the instruments in markets that are not active. The fair value of our convertible senior notes is presented for disclosure purposes only.

Financial assets and liabilities are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies, or similar techniques, and at least one significant model assumption or input is unobservable. Our Level 3 financial liabilities include the following:

- **Contingent consideration**—Determining the fair value of the contingent consideration related to our acquisition of CircuLite in December 2013 requires significant management judgment or estimation. The estimated fair value is calculated using the income approach, with significant inputs that include various revenue assumptions, discount rates and applying a probability to each outcome. Material changes in any of these inputs could result in a significantly higher or lower fair value measurement. The fair value of the contingent consideration is remeasured at the estimated fair value at each reporting period. Actual amounts paid may differ from the obligations recorded.
- **Royalties**—Royalties represent future royalty payments to be made over the next 15 years pursuant to agreements related to intellectual property licensed or acquired by World Heart Corporation, which we acquired in August 2012. Determination of fair value requires significant management judgment or estimation. The royalty payment obligations were valued using a discounted cash flow model, the future minimum royalty payment amounts and discount rates commensurate with our market risk and the terms of the obligations.
- **Lease exit costs**—In the first quarter of 2014, we ceased the use of CircuLite's former headquarters in Teaneck, New Jersey, which was subject to an operating lease that runs through the end of 2020, and we recorded a liability equal to the estimated fair value of the remaining lease payments as of the cease-use date. The fair value was estimated based upon the discounted present value of the remaining lease payments, considering future estimated sublease income, estimated broker fees and required tenant improvements. This estimated fair value requires management judgment. The fair value of this liability will be remeasured at estimated fair value at each reporting period. Actual amounts paid may differ from the obligation recorded.

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table summarizes the change in fair value, as determined by Level 3 inputs, of the contingent consideration for the year ended December 31, 2015:

	Contingent Consideration (in thousands)
Beginning balance	$ 43,740
Payments	—
Change in fair value	(31,410)
Ending balance	$ 12,330

In 2015, we reassessed the timing and likelihood of achieving each remaining CircuLite milestone payment and future royalties. As a result of this review we recognized a charge of $38.1 million, which was partially offset by accretion expense of $6.7 million during the year. Adjustments associated with the change in fair value of contingent consideration are presented on a separate line item on our consolidated statements of operations. Potential valuation adjustments will be made in future accounting periods as additional information becomes available, including, among other items, progress toward developing the CircuLite System, as well as revenue and milestone targets as compared to our current projections, with the impact of these adjustments being recorded in our consolidated statements of operations.

The following table summarizes the change in fair value, as determined by Level 3 inputs, of the royalties in the year ended December 31, 2015:

	Royalties (in thousands)
Beginning balance	$ 962
Payments	(110)
Change in fair value	66
Ending balance	$ 918

The expense associated with the change in fair value of the royalty payment obligations is included in research and development expenses on our consolidated statements of operations.

The following table summarizes the change in fair value, as determined by Level 3 inputs, of the lease exit costs in the year ended December 31, 2015:

	Lease Exit Costs (in thousands)
Beginning balance	$ 1,266
Payments	(887)
Change in fair value	1,576
Ending balance	$ 1,955

The expense associated with the change in fair value of the lease exit costs is included in selling, general and administrative expenses on our consolidated statements of operations.

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table presents quantitative information about the inputs and valuation methodologies used for our fair value measurements classified in Level 3 of the fair value hierarchy as of December 31, 2015:

	Valuation Methodology	Significant Unobservable Input	Weighted Average (range, if applicable)
Contingent consideration	Probability weighted income approach	Milestone dates	2020 to 2023
		Discount rate	17.0% to 24.0%
		Probability of occurrence	50%
Royalties	Discounted cash flow	Discount rate	4.8% to 7.8%
Lease exit costs	Discounted cash flow	Sublease start date	March 2017
		Sublease rate	$22.00/square foot
		Discount rate	3.5%

Assets That Are Measured at Fair Value on a Nonrecurring Basis

Non-financial assets such as intangible assets, goodwill and property, plant, and equipment are evaluated for impairment annually or when indicators of impairment exist. In the first quarter of 2015 we recorded an impairment charge of $1.1 million related to certain office equipment and software associated with the closure of our facility in Aachen, Germany and in the fourth quarter of 2015, we recorded impairment charges totaling $26.8 million related to IPR&D, Tradenames, and Customer Relationships due to program delays which impact the certainty of development and eventual regulatory approval of a CircuLite System, (*see* Note 8 for additional information). In the first quarter of 2014, we recorded an impairment charge of $0.6 million related to certain office equipment and software and in the fourth quarter of 2014, we recorded an impairment charge of $2.6 million related to IPR&D (*see* Note 8 for additional information).

Note 7. Inventories

Components of inventories are as follows:

	December 31,	
	2015	2014
	(in thousands)	
Raw material	$25,679	$28,688
Work-in-process	8,858	10,240
Finished goods	13,149	15,118
	$47,686	$54,046

Finished goods inventories includes inventory held on consignment at customer sites of $6.1 million and $5.8 million, at December 31, 2015 and 2014, respectively.

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

Goodwill

The carrying amount of goodwill and the change in the balance for the years ended December 31, 2015 and 2014 is as follows:

	2015	2014
	(in thousands)	
Beginning balance	$61,390	$61,596
Additions	—	—
Impairment	—	—
Foreign currency translation impact	(157)	(206)
Ending balance	$61,233	$61,390

In 2013, we acquired CircuLite and recorded $61.6 million of goodwill. *See* Note 4 for additional information. Goodwill has been assigned to the Company's single reporting unit, which is the single operating segment by which the chief decision maker manages the Company. Based on our impairment review conducted annually in the fourth quarter, we concluded that goodwill was not impaired in 2015 or 2014. In 2013, we recorded a charge of $3.7 million to write-off goodwill associated with an earlier acquisition. Goodwill is not deductible for U.S. tax purposes.

In-Process Research and Development ("IPR&D")

The carrying value of our IPR&D assets, which relate to the development and potential commercialization of certain acquired technologies, consisted of the following at December 31, 2015 and 2014:

	2015	2014
	(in thousands)	
CircuLite System technology	$10,800	$32,850

In December 2013, we acquired CircuLite and recorded $35.5 million of IPR&D. *See* Note 4 for additional information. The IPR&D has an indefinite life. At the time the economic life becomes determinable (upon project completion or abandonment) the amount will be amortized over its expected remaining life.

During the fourth quarter of 2015 and 2014, we performed an impairment review of this IPR&D and recorded impairment charges of $22.1 and $2.6 million, respectively. The 2015 change was primarily associated with program delays which impact the certainty of development and eventual regulatory approval of a CircuLite System, in which the change in certainty of development resulted in the introduction of a 50% probability of success in our fair value analysis. The charge was recorded in the fourth quarter of 2015. See further discussion below. In 2014, the IPR&D charge resulted from discontinuance of the CircuLite micro pump development program. The fair value of the IPR&D asset was determined using the multi-period excess earnings method which is equal to the present value of the incremental after-tax cash flows attributable to that intangible asset. The impairment charges are included in research and development expenses on our consolidated statements of operations.

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Other Intangible Assets

Other intangible assets, net consisted of the following:

	December 31,	
	2015	2014
	(in thousands)	
Patents	$ 7,424	$ 5,310
Purchased intangible assets		
Trade names	—	3,700
Customer relationships	—	1,800
Acquired technology rights	9,925	9,925
	17,349	20,735
Less: Accumulated amortization—Patents	(1,551)	(1,118)
Less: Accumulated amortization—Purchased intangible assets	(2,753)	(1,810)
	$13,045	$17,807

Our other intangible assets are amortized using the straight-line method over their estimated useful lives as follows:

Patents	15 years
Purchased intangible assets	
Trade names	15 years
Customer relationships	20 years
Acquired technology rights	6 to 16 years

During the fourth quarter of 2015 and 2014, we performed an impairment review of these intangible assets and recorded an impairment charge of $4.8 million in 2015 with no charge recorded in 2014. The 2015 charge resulted from impairment of value which was ascribed to tradenames and customer relationships related to the 2013 acquisition of CircuLite and was associated with an evaluation of the CircuLite development program that occurred in the fourth quarter, which was necessitated by events that continued to evolve throughout the fourth quarter. These events included our progress with the MVAD System and review of clinical data from the MVAD CE Mark trial, as well as longer than anticipated project timelines impacting the certainty of development and eventual regulatory approval for a CircuLite System. The impairment charges are included in impairment of intangible asset expenses on our consolidated statements of operations.

Following satisfaction of a pre-specified milestone in the fourth quarter of 2014, we were obligated to pay an additional $2.0 million under a certain patent assignment and license agreement. The $2.0 million, which is payable in cash or shares of our common stock, was recorded as additional acquired technology rights and accrued at December 31, 2014 in other long term liabilities on our consolidated balance sheets. We settled this liability by issuing 26,042 shares of our common stock in May 2015.

Following satisfaction of a pre-specified milestone in December 2013, we were obligated to pay an additional $5.0 million under a certain patent assignment and license agreement. The $5.0 million, which was payable in cash or share of our common stock, was recorded as additional acquired technology rights and accrued at December 31, 2013 in other accrued liabilities on our consolidated balance sheets. We settled this liability through the issuance of 50,330 shares of our common stock in the first quarter of 2014.

Amortization expense for the years ended December 31, 2015, 2014 and 2013 was $2.1 million, $1.7 million and $0.6 million, respectively.

Estimated amortization expense for each of the five succeeding fiscal years based upon our intangible asset portfolio at December 31, 2015 is approximately $2.1 million.

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 9. Other Balance Sheet Information

Long-Term Investment

In October 2013, we invested $10 million in Valtech Cardio, Ltd. an early stage privately-held company focused on the development of novel, minimally invasive heart therapies in the form of a convertible promissory note with an interest rate of 6% per annum (the "2013 Note"). Pursuant to the terms of the Note, on October 7, 2014 (the maturity date), Valtech elected to convert all unpaid principal and interest on the Note (less applicable taxes) which amounted to $10.5 million, into shares of its preferred stock. As our December 31, 2015, our equity ownership in Valtech was approximately 3.0% on a fully diluted basis. During the third and fourth quarters of 2015 we invested a total of $7.0 million in the form of convertible promissory notes with terms similar to the 2013 note, which have maturity dates of July 10, 2017. This investment, including both our equity investment and outstanding convertible notes receivable were deemed to be realizable, are carried at cost and are included in long-term investments and other assets on our consolidated balance sheets. The carrying value of this investment was $17.6 million and $10.5 million at December 31, 2015 and 2014, respectively. The fair value of this investment has not been estimated as of December 31, 2015 and 2014 as no impairment indicators were identified.

Other Accrued Liabilities

Other accrued liabilities consist of the following:

	December 31,	
	2015	2014
	(in thousands)	
Accrued payroll and other employee costs	$14,068	$13,404
Accrued product recall costs	8,503	1,888
Accrued warranty	6,116	4,685
Accrued material purchases	4,107	4,284
Accrued professions fees	2,685	1,624
Accrued research and development costs	2,191	2,663
Accrued restructuring costs	1,955	1,266
Accrued VAT	1,238	1,637
Other accrued expenses	5,026	5,138
	$45,889	$36,589

Accrued Payroll and Other Employee Costs

Accrued payroll and other employee costs included year-end employee bonuses of approximately $8.0 million and $7.9 million at December 31, 2015 and 2014, respectively.

Accrued Warranty

The following table summarizes changes in our warranty liability for the years ended December 31, 2015, 2014 and 2013:

	2015	2014	2013
	(in thousands)		
Beginning balance	$4,685	$ 2,498	$ 543
Accrual for warranty expense	2,040	4,141	2,721
Warranty costs incurred during the period	(609)	(1,954)	(766)
Ending balance	$6,116	$ 4,685	$2,498

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

During 2015 and 2014, increases in warranty reserves resulted from the substantial increase in commercial sales activity, taking into consideration our historical return and replacement experience.

Accrued Field Action Costs

The costs to repair or replace products associated with product recalls and voluntary service campaigns are recorded when they are determined to be probable and reasonably estimable as a cost of revenue and are not already incorporated in our accrued product warranty liability.

In September 2015, we recorded charges for estimated costs associated with planned field actions related to certain older batteries and international AC adapters. The AC Adapter field action was implemented to mitigate potential risks for international AC Adapters which have a higher risk of failure in event of a power surge and the battery replacement action is to remove certain older batteries for newer batteries containing improved cells from a new supplier. These actions ensued in January 2016.

In February 2015, we expanded a 2013 voluntary Field Safety Corrective Action, by initiating a voluntary medical device recall of certain older controllers distributed in the U.S. during the ADVANCE and ENDURANCE clinical trial periods. The affected controllers exhibit a higher susceptibility to electrostatic discharge than newer, commercial controllers. This recall was completed as of December 31, 2015.

On April 30, 2014, we implemented a corrective action to notify clinicians and patients of an observed increase in complaints related to earlier-than-expected battery depletion and routine battery handling. This notification provided information to assist patients and clinicians with monitoring battery performance, recognizing abnormal behaviors and reinforcing proper power management of the HVAD System. On July 30, 2014, we extended this field action to include a voluntary recall of certain older batteries. The recall instructed sites to replace certain older batteries in the field upon patients' routine visits in order to further mitigate the potential risks associated with premature battery depletion.

We recorded charges of $8.6 million, $5.0 million, and $0 for the years ended December 31, 2015, 2014 and 2013, respectively, for the field actions described above.

Accrued Restructuring Costs

The following table summarizes changes in our accrued restructuring costs for the year ended December 31, 2015:

	Facility Leases	Severance and Related	Contract Termination	Total
		(in thousands)		
Beginning balance	$ 1,266	$ —	$ —	$ 1,266
Restructuring charges	139	598	338	1,075
Payments	(887)	(598)	(338)	(1,823)
Adjustments to estimated obligations	1,386	—	—	1,386
Change in fair value	51	—	—	51
Ending balance	$ 1,955	$ —	$ —	$ 1,955

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The restructuring obligations reflected above resulted from the following actions:

Facility Closures

In the first quarter of 2014, we ceased the use of CircuLite's former headquarters in Teaneck, New Jersey, which was subject to an operating lease that runs through the end of 2020 (*see* Note 11). In connection with this action, we recorded a $1.7 million liability equal to the estimated fair value of the remaining lease obligation as of the cease-use date (*see* Note 6). In 2015, due primarily to weakness in the northern New Jersey real estate market we recorded additional lease impairment charges totaling $1.5 million. In the first quarter of 2014, we also relocated our corporate headquarters and ceased activities at our former headquarters in Framingham, Massachusetts. In connection with this action, we recorded a $0.5 million liability equal to the aggregate of the remaining payments on the lease for our former headquarters as of the cease-use date. Both of these items are included in selling, general and administrative expenses on our consolidated statements of operations.

In the first quarter of 2015, we ceased activities at our facility in Aachen, Germany, which was subject to an operating lease that runs through October 2017. In connection with this action, we recorded a $0.1 million liability equal to the lease termination payment that was negotiated with the landlord. This amount is included in research and development expenses on our consolidated statement of operations.

Severance Agreements

In 2015, we incurred various costs related to the closure of our facility in Aachen, Germany due to discontinuance of the CircuLite micro pump development program, including severance costs totaling $0.6 million. These costs recorded in the first quarter of 2015 as research and development expenses on our consolidated statement of operations.

In 2014, we incurred various costs related to the integration of CircuLite's operations, including severance costs aggregating $0.6 million, the majority of which were recorded in the first quarter of 2014. We recorded $0.4 million in research and development expenses and the remaining $0.2 million in selling, general and administrative expenses on our consolidated statements of operations.

Contract Termination

In 2015, we incurred various costs related to closure of our facility in Aachen, Germany due to discontinuance of the CircuLite micro pump development program, including contract termination costs totaling $0.3 million. These costs were primarily recorded in the first quarter of 2015 as research and development expenses on our consolidated statement of operations.

As a result of anticipated design modifications to the CircuLite System and our decision to move manufacturing of the CircuLite System to our Miami Lakes facility, we terminated a supply agreement with a vendor in Germany for the purchase of components necessary to produce the prior-to-modification version of the CircuLite System. In connection with the termination of this supply agreement, we recorded a charge of $0.7 million in the first quarter of 2014, which is included in research and development expenses on our consolidated statements of operations.

Note 10. Debt

3.5% Convertible Senior Notes

On December 15, 2010, we completed the sale of 3.5% convertible senior notes due December 15, 2017, unless earlier repurchased by us or converted (the "2017 Notes") for an aggregate principal amount of

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

$143.75 million pursuant to the terms of an Indenture dated December 15, 2010 (the "Indenture"). The 2017 Notes are the senior unsecured obligations of the Company. The 2017 Notes bear interest at a rate of 3.5% per annum, payable semi-annually in arrears on June 15 and December 15 of each year.

In May 2015, we entered into separate, privately negotiated, exchange agreements (the "Exchange") with certain holders of our outstanding 2017 Notes. Pursuant to these agreements, we exchanged $101.3 million aggregate principal amount of the 2017 Notes for $118.2 million principal amount of 1.75% convertible senior notes due 2021. We did not receive any proceeds related to the Exchange. As of December 31, 2015, the aggregate principal value of the 2017 Notes outstanding was $42.5 million following the Exchange Transaction completed in May 2015. (see further discussion below).

The 2017 Notes offering was completed pursuant to a prospectus supplement, dated December 9, 2010, to a shelf registration statement on Form S-3 that was previously filed with the SEC and which was declared effective on December 9, 2010.

The 2017 Notes will be convertible at an initial conversion rate of 10 shares of our common stock per $1,000 principal amount of 2017 Notes, which corresponds to an initial conversion price of $100.00 per share of our common stock. The conversion rate is subject to adjustment from time to time upon the occurrence of certain events.

Prior to June 15, 2017, holders may convert their 2017 Notes at their option only upon satisfaction of one or more of the conditions specified in the Indenture relating to the (i) sale price of our common stock, (ii) the trading price per $1,000 principal amount of 2017 Notes or (iii) specified corporate events. As of the date of this report on Form 10-K, none of the events that would allow holders to convert their 2017 Notes have occurred. On or after June 15, 2017, until the close of business of the business day immediately preceding the date the 2017 Notes mature, holders may convert their 2017 Notes at any time, regardless of whether any of the foregoing conditions have been met. Upon conversion, we will pay or deliver, as the case may be, cash, shares of our common stock or a combination thereof, at our election.

We may not redeem the 2017 Notes prior to maturity. Holders of the 2017 Notes may require us to purchase for cash all or a part of their 2017 Notes at a repurchase price equal to 100% of the principal amount of the 2017 Notes to be repurchased, plus accrued and unpaid interest, upon the occurrence of certain fundamental changes (as defined in the Indenture) involving the Company. The Indenture does not contain any financial or operating covenants or restrictions on the payment of dividends, the incurrence of indebtedness or the issuance or repurchase of securities by us or any of our subsidiaries.

The Indenture contains customary terms and nonfinancial covenants and defines events of default. If an event of default (other than certain events of bankruptcy, insolvency or reorganization) involving the Company occurs and is continuing, the Trustee (by notice to the Company) or the holders of at least 25% in principal amount of the outstanding 2017 Notes (by notice to the Company and the Trustee) may declare 100% of the principal of and accrued and unpaid interest, if any, on all the 2017 Notes to be due and payable. In case of certain events of bankruptcy, insolvency or reorganization, involving the Company, 100% of the principal of and accrued and unpaid interest on the 2017 Notes will automatically become due and payable. Notwithstanding the foregoing, the Indenture provides that, to the extent we elect, the sole remedy for an event of default relating to certain failures by us to comply with certain reporting covenants in the Indenture consists exclusively of the right to receive additional interest on the 2017 Notes.

In accordance with FASB ASC 470-20, *Debt with Conversion and Other Options*, which applies to certain convertible debt instruments that may be settled in cash or other assets, or partially in cash, upon conversion, we

recorded the long-term debt and equity components on our 2017 Notes separately on the issuance date. The amount recorded for long-term debt was determined by measuring the fair value of a similar liability that does not have an associated equity component. The equity component of $7.6 million was recorded in additional paid-in-capital. The measurement of fair value required the Company to make estimates and assumptions to determine the present value of the cash flows of the 2017 Notes, absent the conversion feature. This treatment increased interest expense associated with our 2017 Notes by adding a non-cash component to interest expense in the form of amortization of a debt discount calculated based on the difference between the 3.5% cash coupon rate and the effective interest rate on debt borrowing of approximately 12.5%. The discount is being amortized to interest expense through the December 15, 2017 maturity date of the 2017 Notes using the effective interest method. Additionally, we allocated the costs related to issuance of the 2017 Notes on the same percentage as the long-term debt and equity components, such that a portion of the costs is allocated to the long-term debt component and the equity component included in additional paid-in capital. The portion of the costs allocated to the long-term debt component is presented as deferred financing costs, net on our consolidated balance sheets. These deferred financing costs are also being amortized to interest expense through the December 15, 2017 maturity date of the 2017 Notes using the effective interest method.

Based on the initial conversion rate of 10 shares of our common stock per $1,000 principal amount of 2017 Notes, which corresponds to an initial conversion price of $100.00 per share of our common stock, the number of shares issuable upon conversion of the remaining outstanding 2017 Notes is 424,710. The value of these shares, based on the closing price of our common stock on December 31, 2015 of $50.40 per share, was approximately $21.4 million. The fair value of our 2017 Notes as presented in Note 6 was $38.2 million at December 31, 2015.

1.75% Convertible Senior Notes

In May 2015, we issued $84.2 million principal amount of 1.75% convertible senior notes due December 15, 2021 (the “2021 Notes”), unless earlier repurchased, redeemed or converted. Combined with the 2021 Notes issued in connection with the Exchange described above, the aggregate principal amount issued under the 2021 Notes was $202.4 million. The Exchange resulted in the retirement of outstanding 2017 Notes with a carrying value of $83.1 million, the write-off of unamortized debt issuance costs of $1.0 million and settlement of $10.7 million related to the conversion feature embedded in the 2017 Notes. The 2021 Notes offered in the Exchange had a fair value of $88.0 million, which resulted in a loss on extinguishment of debt of $16.6 million in the three months ended June 30, 2015.

The net proceeds from the issuance of the 2021 Notes amounted to $74.7 million, net of deferred issuance costs paid as of December 31, 2015. In connection with the issuance of the 2021 Notes, we incurred costs of approximately $5.2 million.

Interest on the 2021 Notes is payable semiannually in arrears on June 15 and December 15, at a rate of 1.75% per annum, beginning on December 15, 2015.

The 2021 Notes will mature on December 15, 2021 unless earlier repurchased, redeemed or converted. Prior to the close of business on the business day immediately preceding June 15, 2021, holders may convert their 2021 Notes at their option only under the following circumstances: (1) during any calendar quarter commencing after the calendar quarter ending on June 30, 2015 (and only during such calendar quarter), if the last reported sale price of the common stock for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day; (2) during the five business day period after any five consecutive trading day period (the “measurement period”) in which the trading price per $1,000 principal amount of notes for each trading day of the measurement period was less than 98% of the

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

product of the last reported sale price of our common stock and the conversion rate on such trading day; (3) upon the occurrence of specified corporate events, or (4) if we call the 2021 Notes for redemption, until the close of business on the business day immediately preceding the redemption date. As of the date of this report on Form 10-Q, none of the events that would allow holders to convert their 2021 Notes have occurred. On or after June 15, 2021 until the close of business on the scheduled trading day immediately preceding the maturity date, holders may convert their 2021 Notes at any time, regardless of whether any of the foregoing conditions has been met. Upon conversion, we will satisfy our conversion obligation by paying or delivering, as the case may be, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election.

Both the 2017 and 2021 Notes offer noteholders the right to convert during the period beginning 35 trading days prior to the anticipated closing date of certain merger transactions and ending 35 trading days following the actual closing date.

We may not redeem the 2021 Notes prior to June 19, 2019. On or after June 19, 2019, we may redeem for cash all or part of the 2021 Notes if the last reported sale price per share of our common stock for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the trading day immediately preceding the date on which we provide the notice of redemption exceeds 130% of the applicable conversion price for the 2021 Notes on each applicable trading day. The redemption price will equal 100% of the principal amount of the 2021 Notes being redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. No sinking fund is provided for the 2021 Notes.

If we undergo a fundamental change, as defined in the Indenture among the Company and Wilmington Trust, N.A., holders may require us to repurchase for cash all or part of their 2021 Notes at a fundamental change repurchase price equal to 100% of the principal amount of the 2021 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. The fundamental change is primarily triggered by a change of control, liquidation, dissolution or delisting from NASDAQ.

The 2021 Notes are senior unsecured obligations and rank senior in right of payment to our future indebtedness that is expressly subordinated in right of payment to the 2021 Notes; equal in right of payment to our existing and future unsecured indebtedness that is not subordinated; effectively subordinated in right of payment to any of our secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally subordinated to all existing and future indebtedness and other liabilities of our subsidiaries.

The 2021 Notes will be convertible at an initial conversion rate of 10 shares of our common stock per $1,000 principal amount of 2021 Notes, which corresponds to an initial conversion price of $100.00 per share of our common stock. The conversion rate is subject to adjustment from time to time upon the occurrence of certain events.

In accordance with FASB ASC 470-20, *Debt with Conversion and Other Options*, which applies to certain convertible debt instruments that may be settled in cash or other assets, or partially in cash, upon conversion, we recorded the long-term debt and equity components on our 2021 Notes separately on the issuance date. The amount recorded for long-term debt was determined by measuring the fair value of a similar liability that does not have an associated equity component. The equity component of $47.4 million was recorded in additional paid-in-capital. The measurement of fair value required the Company to make estimates and assumptions to determine the present value of the cash flows of the 2021 Notes, absent the conversion feature. This treatment increased interest expense associated with our 2021 Notes by adding a non-cash component to interest expense in the form of amortization of a debt discount calculated based on the difference between the 1.75% cash coupon rate and the effective interest rate on debt borrowing of approximately 7.2%. The discount is being amortized to interest expense through the December 15, 2021 maturity date of the 2021 Notes using the effective interest

method. Additionally, we allocated the costs related to issuance of the 2021 Notes on the same percentage as the long-term debt and equity components, such that a portion of the costs is allocated to the long-term debt component and the equity component included in additional paid-in capital. The portion of the costs allocated to the long-term debt component is presented as deferred financing costs, net on our consolidated balance sheets. These deferred financing costs are also being amortized to interest expense through the December 15, 2021 maturity date of the 2021 Notes using the effective interest method.

Based on the initial conversion rate of 10 shares of our common stock per $1,000 principal amount of 2021 Notes, which corresponds to an initial conversion price of $100.00 per share of our common stock, the number of shares issuable upon conversion of the 2021 Notes is 2,023,660. The value of these shares, based on the closing price of our common stock on December 31, 2015 of $50.40 per share, was approximately $102.0 million. The fair value of our 2021 Notes as presented in Note 6 was $162.1 million at December 31, 2015.

The Convertible Notes and the equity component, which is recorded in additional paid-in-capital, consisted of the following:

	December 31, 2015	December 31, 2014
	(in thousands)	
Principal amount of the 3.5% convertible senior notes, due 2017	$ 42,471	$ 143,750
Unamortized discount	(5,994)	(28,947)
	$ 36,477	$ 114,803
Equity component	$ 7,629	$ 55,038
Principal amount of the 1.75% convertible senior notes, due 2021	$ 202,366	$ —
Unamortized discount	(47,781)	—
	$ 154,585	$ —
Equity component	$ 47,400	$ —

Interest expense related to the Convertible Notes consisted of interest due on the principal amount, amortization of the discount and amortization of the portion of the deferred financing costs allocated to the long-term debt component. For the years ended December 31, 2015 and 2014, interest expense related to the Convertible Notes was as follows:

	2015	2014
	(in thousands)	
Coupon rate	$ 5,055	$ 5,031
Amortization of discount	8,691	7,678
Amortization of deferred financing costs	556	412
	$14,302	$13,121

Note 11. Leases

Corporate Headquarters

On October 17, 2013, we entered into a lease for our corporate headquarters in Framingham, Massachusetts that commenced in January 2014 and was amended in May 2015. The facility is used primarily for office and

ancillary laboratory purposes including development testing. Under the lease we rent approximately 74,000 square feet of company space and approximately 4,000 square feet of common space for an initial seven year period, with an option to renew for a period of fifty-seven months, but in no event beyond September 30, 2025. Annual base rent, as amended, of approximately $1.6 million is payable monthly as of January 1, 2016. Annual base rent is subject to periodic increases beginning March 1, 2017 and will increase to approximately $1.8 million per year for the final four years of the lease. A security deposit of $0.3 million was paid in connection with the lease, which is included in other assets on our consolidated balance sheets.

Under the lease for our former headquarters in Framingham, Massachusetts, which was last amended on July 30, 2012, we rented approximately 21,300 square feet. Effective January 1, 2013, base rent obligations were approximately $0.4 million per year. The lease term for approximately 17,800 square feet ended on December 31, 2014, while the lease term for the remaining 3,500 square feet ended on June 30, 2015. In connection with the move to our corporate headquarters, we recorded a $0.5 million liability in the first quarter of 2014, which equaled the aggregate of the remaining payments on the lease for our former headquarters as of the cease-use date (s*ee* Note 9).

Florida Facility

On December 9, 2010, we entered into a lease for our facility in Miami Lakes, Florida. The facility is used primarily for manufacturing, research and development and administrative functions. Under the lease, which was amended in November 2012 and July 2013, we rent approximately 132,000 square feet for a period ending February 28, 2022, with an option to renew for two five-year terms. Effective with the July 2013 amendment, base rent payments are $10.00 per square foot and are subject to a 3% annual escalation on March 1 of each subsequent year. The lease is secured by a security deposit of $1.25 million in the form of an unconditional stand-by letter of credit. The letter of credit is supported by a certificate of deposit for the same amount, which is included in other assets on our consolidated balance sheets.

New Jersey Facility

In connection with the acquisition of CircuLite in December 2013, we assumed a non-cancelable operating lease that CircuLite entered into for its headquarters in Teaneck, New Jersey in December 2012. Under the lease, we rent approximately 22,200 square feet mixed use office space for a period ending October 2020. The lease provides for a fixed monthly rent, plus utilities, with a six-month rent abatement during the first year. Base rent obligations are approximately $0.7 million per year and subject to a 2% annual escalation starting on September 1, 2014. Pursuant to the lease agreement, we are required to maintain cash on deposit of $0.8 million, which is included in other assets on our consolidated balance sheets.

In the first quarter of 2014, we initiated a plan to close this facility. The facility closure was accounted for in accordance with ASC 420 *Exit or Disposal Cost Obligations*, pursuant to which we recorded a liability equal to the fair value of the remaining lease payments as of the cease-use date. The fair value of this liability was estimated to be $1.7 million at the initial valuation date and was based upon the discounted present value of remaining lease rentals for the space no longer occupied, considering future estimated sublease income, estimated broker fees and required tenant improvements (s*ee* Note 6 and Note 9). In 2015, due primarily to weakness in the northern New Jersey real estate market we recorded additional lease impairment charges totaling $1.5 million and the fair value of this liability was estimated to be $2.0 million as of December 31, 2015.

Other Facilities

In addition to the leases discussed above, we have entered into various operating lease agreements for miscellaneous office and research space and equipment. The duration of these agreements is typically twelve to

thirty-six months from origination. The aggregate base annual rental payment on these leases is less than $0.3 million.

Rent expense was approximately $3.3 million, $3.6 million, and $2.9 million in 2015, 2014 and 2013, respectively. Future minimum rental commitments under non-cancelable operating lease agreements with remaining terms of at least one year as of December 31, 2015 are as follows:

	Operating Leases (in thousands)
Year Ending December 31,	
2016	$ 3,853
2017	4,029
2018	4,075
2019	4,056
2020	3,882
Thereafter	2,370
Total minimum lease payments	$ 22,265

Aachen Germany Facility Closure

In January 2015, we initiated a plan to close our facilities located in Aachen, Germany. One facility is covered under an operating lease that ends on October 31, 2017. During the first quarter of 2015, we reached a lease termination agreement with the landlord and recorded a $0.1 million charge.

Closure of this facility resulted in a write-off of leasehold improvements, furnishings and other fixed assets that will not be transferred to our other facilities of approximately $1.1 million and a charge for non-cancellable purchase obligations of approximately $0.3 million. In January 2015, employees at this facility were notified of the closure and elimination of their positions. The employee-related costs associated with severance payments were approximately $0.6 million.

Note 12. Stockholders' Equity

Preferred Stock

We are authorized to issue up to 5,000,000 shares of preferred stock, $.001 par value per share. Our board of directors is authorized, subject to any limitations prescribed by law, to provide for the issuance of the shares of preferred stock in series, and by filing a certificate pursuant to the applicable law of the state of Delaware, to establish from time to time the number of shares to be included in each such series, and to fix the designation, powers, preferences and rights of the shares of each such series and any qualifications, limitations or restrictions thereof. No shares of preferred stock have been issued or are outstanding.

Common Stock

We are authorized to issue up to 50,000,000 shares of common stock, $.001 par value per share. As of December 31, 2015, we had 17,405,451 shares outstanding. Holders are entitled to one vote for each share of common stock (or its equivalent).

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Shares of our common stock reserved at December 31, 2015, for possible future issuance are as follows:

	(in thousands)
Convertible senior notes	3,164
Equity award plans	2,291
	5,455

See the Consolidated Statement of Stockholders' Equity for details related to our equity transactions.

2013 Public Offering

On March 12, 2013, we entered into an Underwriting Agreement (the "Underwriting Agreement") with J.P. Morgan Securities LLC, as representative of the several underwriters named in the Underwriting Agreement (the "Underwriters"), pursuant to which we agreed to sell and the Underwriters agreed to purchase, subject to and upon terms and conditions set forth therein, an aggregate of 1,500,000 shares of our common stock at a net sales price of $81.9114 per share (the public offering price of $86.45 per share minus the underwriting discount). We also granted the Underwriters an option to purchase 225,000 additional shares of our common stock at the public offering price less the underwriting discount, which the Underwriters exercised in full on March 13, 2013. The closing of the offering occurred on March 18, 2013. After fees and related expenses, net proceeds from the offering were approximately $141.0 million.

The offering was completed pursuant to a prospectus supplement, dated March 12, 2013, to a shelf registration statement on Form S-3 that was previously filed with the SEC and which was declared effective on December 9, 2010. This shelf registration statement expired on December 9, 2013.

On January 30, 2014, we filed a shelf registration statement with the SEC on Form S-3. This shelf registration statement allows us to offer and sell from time to time, in one or more series or issuances and on terms that we will determine at the time of the offering any combination and amount of the securities described in the prospectus contained in the registration statement or in the prospectus supplement filed with respect to a particular offering. An aggregate of 530,816 shares of our common stock were registered for issuance pursuant to various prospectus filings on January 30, 2014 in connection with the CircuLite acquisition. As of December 31, 2014, there remained 248,872 shares reserved for potential issuance in connection with future contingent milestone payments under the terms of the merger agreement (*see* Note 4).

Note 13. Share-Based Compensation

We allocate share-based compensation expense to cost of revenue, selling, general and administrative expense and research and development expense based on the award holder's employment function. For the years ended December 31, 2015, 2014 and 2013, we recorded share-based compensation expenses as follows:

	2015	2014	2013
		(in thousands)	
Cost of revenue	$ 1,975	$ 2,032	$ 2,539
Selling, general and administrative	13,544	13,573	12,184
Research and development	8,286	7,937	7,151
	$23,805	$23,542	$21,874

Deferred tax benefits attributed to our share-based compensation expense are not recognized in the accompanying consolidated financial statements because we are in a net operating loss position and a full

valuation allowance is maintained for all net deferred tax assets. We receive a tax deduction for certain stock option exercises during the period the options are exercised, and for the vesting of restricted stock units during the period the restricted stock units vest. For stock options, the amount of the tax deduction is generally for the excess of the fair market value of our shares of common stock over the exercise price of the stock options at the date of exercise. For restricted stock units, the amount of the tax deduction is generally for the fair market value of our shares of common stock at the vesting date. Excess tax benefits are not included in the accompanying consolidated financial statements because we are in a net operating loss position and a full valuation allowance is maintained for all net deferred tax assets.

Equity Plans

We have issued share-based awards to employees, non-executive directors and outside consultants through various approved plans and outside of any formal plan. New shares are issued upon the exercise of share-based awards.

Upon receipt of stockholder approval on May 31, 2012, and amended as of June 29, 2015, we adopted the HeartWare International, Inc. 2012 Incentive Award Plan ("2012 Plan"). The 2012 Plan provides for the grant of incentive stock options, non-qualified stock options, restricted stock, restricted stock units, performance awards, dividend equivalent rights, deferred stock, deferred stock units, stock payments and stock appreciation rights (collectively referred to as "Awards"), to our directors, employees and consultants. Under the terms of the 2012 Plan, the total number of shares of our common stock initially reserved for issuance under Awards is 2,475,000, provided that the total number of shares of our common stock that may be issued pursuant to "Full Value Awards" (Awards other than options, SARs or other awards for which the holder pays the intrinsic value existing as of the date of grant whether directly or by forgoing a right to receive a payment from the Company) is 2,375,000. As of December 31, 2015, 277,375 shares have been issued upon vesting of Awards issued under the 2012 Plan and Awards with respect to 640,896 shares were issued and outstanding under the 2012 Plan. Subsequent to adoption of the 2012 Plan, no new awards will be granted under our prior plans. Any outstanding awards under the prior will continue to be subject to the terms and conditions of the plan under which they were granted.

Stock Options

Each option allows the holder to subscribe for and be issued one share of our common stock at a specified price, which is generally the quoted market price of our common stock on the date the option is issued. Options generally vest on a pro-rata basis on each anniversary of the issuance date within four years of the date the option is issued. Options may be exercised after they have vested and prior to the specified expiry date provided applicable exercise conditions are met, if any. The expiry date can be for periods of up to ten years from the date the option is issued.

The fair value of each option is estimated on the date of grant using the Black-Scholes option pricing model using the assumptions established at that time. The following table includes the weighted average assumptions used for options issued in the years ended December 31, 2015, 2014 and 2013.

	2015	2014	2013
Dividend yield	0.00%	0.00%	0.00%
Expected volatility	37.50%	39.00%	40.00%
Risk-free interest rate	1.69%	1.65%	1.15%
Estimated holding period (years)	5.00	5.00	6.25

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Information related to options granted under all of our plans at December 31, 2015 and activity during the year then ended is as follows (certain amounts in U.S. $ were converted from AU$ at the then period-end spot rate):

	Number of Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2014	107	$ 48.32		
Granted	7	76.60		
Exercised	(3)	27.95		
Forfeited	—	—		
Expired	—	—		
Outstanding at December 31, 2015	111	$ 49.20	3.78	$ 1,550
Exercisable at December 31, 2015	99	$ 45.08	3.20	$ 1,550

The aggregate intrinsic values at December 31, 2015 noted in the table above represent the number of in-the-money options outstanding or exercisable multiplied by the closing price of our common stock traded on NASDAQ less the respective weighted average exercise price at period end.

The weighted average grant date fair value per share of options granted in the years ended December 31, 2015, 2014 and 2013 was $27.10, $32.41, and $38.51, respectively.

The total intrinsic value of options exercised during the years ended December 31, 2015, 2014 and 2013 was approximately $0.2 million, $1.9 million, and $10.3 million, respectively. Cash received from options exercised in the years ended December 31, 2015, 2014 and 2013 was approximately $0.1 million, $0.9 million and $4.9 million.

At December 31, 2015, there was approximately $0.1 million of unrecognized compensation expense, net of estimated forfeitures, related to non-vested option awards. The expense is expected to be recognized over a weighted average period of 0.5 years.

Restricted Stock Units

Each restricted stock unit (“RSU”) represents a contingent right to receive one share of our common stock. RSUs generally vest on a pro-rata basis on each anniversary of the issuance date over three or four years or vest in accordance with performance-based criteria. The RSUs with performance-based vesting criteria vest in one or more tranches contingent upon the achievement of pre-determined milestones related to the development of our products, the achievement of certain prescribed clinical and regulatory objectives, the achievement of specific financial performance measures or similar metrics. There is no consideration payable on the vesting or exercise of RSUs issued under the plans. Upon vesting, the RSUs are exercised automatically and settled in shares of our common stock.

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Information related to RSUs at December 31, 2015 and activity during the year then ended is as follows:

	Number of Units (in thousands)	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2014	589		
Granted	312		
Vested/Exercised	(221)		
Forfeited	(57)		
Outstanding at December 31, 2015	623	1.50	$ 31,384
Exercisable at December 31, 2015	—	—	$ —

The aggregate intrinsic value at December 31, 2015 noted in the table above represents the closing price of our common stock traded on NASDAQ multiplied by the number of RSUs outstanding.

At December 31, 2015, 64,772 of the RSUs outstanding are subject to performance-based vesting criteria as described above.

The total intrinsic value of RSUs vested during the years ended December 31, 2015, 2014 and 2013 was approximately $15.2 million, $15.4 million, and $16.4 million, respectively.

The fair value of each RSU award equals the closing price of our common stock on the date of grant. The weighted average grant date fair value per share of RSUs granted during the years ended December 31, 2015, 2014 and 2013 was $87.72, $97.50, and $91.21, respectively.

At December 31, 2015, we had approximately $22.9 million of unrecognized compensation expense, net of estimated forfeitures, related to non-vested RSU awards. The expense is expected to be recognized over a weighted average period of 1.5 years.

On February 19, 2016, our board of directors approved the grant of an aggregate of 293,100 RSUs to a group of employees, including officers of the Company. Approximately 245,350 of the RSUs granted in February 2016 will vest on a pro-rata basis on each anniversary of the issuance date over four years, while the remainder is subject to performance-based vesting criteria. Also on February 19, 2016, our board of directors approved the grant of an aggregate of 149,938 stock options to a group of employees, including officers of the Company. Approximately 149,938 of the stock options granted in February 2016 will vest on a pro-rata basis on each anniversary of the issuance date over three years.

Note 14. Income Taxes

During 2015, we were subject to income taxes on foreign taxable income in certain jurisdictions. The 2015 income tax provision of $1.0 million, of which $0.2 million is currently payable, related primarily to foreign income taxes.

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Income (loss) before taxes on a geographic basis during 2015 was as follows:

	2015	2014	2013
		(in thousands)	
United States	$(75,861)	$(20,684)	$(58,063)
Non-U.S.	4,095	1,878	(781)
	$(71,766)	$(18,806)	$(58,844)

Our effective tax rate of less than 1% differs from the statutory United States federal income tax rate of 34% for all periods presented due primarily to the valuation allowance on deferred tax assets, and differences in foreign tax rates.

The primary components of net deferred tax assets and liabilities at December 31, 2015 and 2014 were as follows:

	2015	2014
	(in thousands)	
Deferred tax assets:		
U.S. losses carried forward	$ 137,825	$ 128,216
Non-U.S. losses carried forward	3,709	4,227
Total net operating losses carried forward	141,534	132,443
Equity awards	12,017	9,902
Other deferred tax assets	19,506	11,935
Gross deferred tax assets	173,057	154,280
Deferred tax liabilities:		
Convertible debt	(18,119)	(10,632)
Purchased intangible assets	(4,423)	(13,549)
Net deferred tax assets	150,515	130,099
Less: valuation allowance	(150,395)	(130,099)
Net deferred tax asset/(liability)	$ 120	$ —

FASB ASC 740—*Income Taxes* requires that a valuation allowance be established to reduce a deferred tax asset to its realizable value when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence needs to be considered, including the utilization of past tax credits and length of carry-back and carry-forward periods, reversal of temporary differences, tax planning strategies, our current and past performance, the market environment in which we operate, and the evaluation of tax planning strategies to generate future taxable income.

At December 31, 2015 and 2014, we had gross deferred tax assets in excess of deferred tax liabilities of $150.5 million and $130.1 million, respectively. We determined that it is not “more likely than not” that substantially all of our deferred tax assets will not be realized and therefore we should apply a valuation allowance to reduce our net deferred tax assets to their estimated realizable value. The valuation allowance primarily relates to the deferred tax assets arising from operating loss carry-forwards. The valuation allowance on our net deferred tax assets increased by approximately $20.3 million for the year ended December 31, 2015 decreased by approximately $41.2 million for the year ended December 31, 2014 and increased by approximately $97.3 million for the year ended December 31, 2013.

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In 2014 we completed an evaluation of our net operating loss and credit carry-forwards as outlined under section 382, which resulted in a deferred tax asset reduction of approximately $56.4 million due to limitations on our U.S. net operating loss carry-forwards. Such deferred tax asset had been fully reserved. We have adjusted our net operating loss and credit carry-forwards according to the results of this evaluation.

Net operating losses representing excess tax benefits attributable to share based compensation are not included in the table of deferred tax assets and liabilities shown above because they have not been realized for financial statement purposes. Pursuant to ASC 718, excess tax benefits attributable to share based compensation will only be recorded to additional paid-in capital when they are realized through a reduction of taxes payable. As of December 31, 2015, the portion of the federal and state net operating loss related to share based compensation is approximately $34.7 million and $29.4 million, respectively.

At December 31, 2015, we had unexpired net operating loss carry-forwards of approximately $425.7 million and $149.3 million for U.S. federal and state income tax purposes, respectively, which are available to offset future taxable income and begin to expire starting in 2024 through 2035. We also have foreign tax loss carry-forwards of approximately $15.8 million that do not expire.

We operate within multiple taxing jurisdictions and are subject to audit in those jurisdictions. Because of the complex issues involved, any claims can require an extended period to resolve.

During the fourth quarter of 2015, the German Tax authority began an audit at HeartWare GmbH for Corporate, Trade and VAT (Value Added Tax) taxes. The audit was initiated as part of routine inspection by the German Authorities. As of December 31, 2015 field work was in its initial stages and no estimates or assessments, and as such no charges, have been made.

Uncertain tax positions

The amount of gross unrecognized tax benefits as of December 31, 2015 and December 31, 2014 was $2.1 million and $3.2 million, respectively. The fiscal years 2012 through 2014 are considered open tax years (however, any year with net operating loss carryforwards remain open to adjustment) in U.S. federal and state and Australian tax jurisdictions. The fiscal years 2011 through 2014 are considered open tax years for German and United Kingdom tax jurisdictions. The fiscal years 2012 through 2014 are considered open tax years for tax jurisdictions in France.

We evaluate tax positions for recognition using a more-likely-than-not recognition threshold, and those tax positions eligible for recognition are measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon the effective settlement with a taxing authority that has full knowledge of all relevant information. A reconciliation of the beginning and ending amount of gross unrecognized tax benefits is as follows:

Uncertain tax position	Year ended December 31, 2015
	(in thousands)
Unrecognized tax benefits—beginning of the year	$ 3,228
Gross increases/(decrease)—prior year	17
Gross increases/(decrease)—current year	(1,159)
Unrecognized tax benefits—end of the year	$ 2,086

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Included in the balance of unrecognized tax benefits at December 31, 2015, are $1.4 million of tax benefits that, if recognized, would impact the effective tax rate. The remainder of the unrecognized tax benefits would increase our net operating loss carry-forwards and would not impact the effective tax rate, so long as we continue to maintain a full valuation allowance. We anticipate that no material amounts of unrecognized tax benefits will either expire or be settled in the next 12 months of the reporting date. Additionally, no uncertain tax positions had been identified prior to 2015.

Note 15. Net Loss Per Share

Basic net loss per common share was computed by dividing net loss for the period by the weighted-average number of common shares outstanding for each respective period. Diluted net loss per common share adjusts basic net loss per common share for the dilutive effects of share-based awards as determined under the treasury stock method, our convertible senior notes as determined under the if-converted method, and other potentially dilutive instruments only in the periods in which the effect is dilutive. Due to our net loss for all periods presented, all potentially dilutive instruments were excluded because their inclusion would have been anti-dilutive. The following instruments were excluded from the calculation of diluted weighted average shares outstanding, as their effect would be anti-dilutive.

Common shares issuable upon:	2015	2014	2013
		(in thousands)	
Conversion of convertible senior notes	2,448	1,438	1,438
Exercise or vesting of share-based awards	734	696	608
	3,182	2,134	2,046

Note 16. Business Segment, Geographic Areas and Major Customers

For financial reporting purposes, we have one reportable segment which designs, manufactures and markets medical devices for the treatment of advanced heart failure. Products are distributed to customers located in the United States through our clinical trials and as commercial products, as commercial products to customers in Europe and under special access in other countries. Product sales attributed to a country or region are based on the location of the customer to whom the products are sold. Long-lived assets are primarily held in the United States.

Product sales by geographic location for the years ended December 31, 2015, 2014 and 2013 are as follows:

	2015	2014	2013
		(in thousands)	
United States	$161,848	$151,335	$105,345
Germany	52,907	63,629	54,793
International, excluding Germany	62,088	63,456	47,791
	$276,843	$278,420	$207,929

The percentage of our revenue generated in the U.S. increased in 2015 and 2014 as compared to 2013 due to receipt in November 2012 of FDA approval to sell the HVAD System commercially in the U.S as well as foreign currency effects related to strengthening of the United States Dollar.

As a significant portion of our revenue is generated outside of the U.S., we are dependent on favorable economic and regulatory environments for our products in Europe and other countries outside of the U.S. For the years ended December 31, 2015, 2014 and 2013, no customers individually accounted for more than 10% of product sales.

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 17. Commitments and Contingencies

We received a warning letter from the FDA, dated June 2, 2014, following an inspection of our Miami Lakes, Florida facility conducted in January 2014. The FDA letter cited four categories for us to address: (1) procedures for validating device design, including device labeling; (2) procedures for implementing corrective and preventive action (CAPA); (3) maintaining records related to investigations; and (4) validation of computer software used as part of production or quality systems. The warning letter did not require any action by physicians or patients and did not restrict the use of our devices.

We provided the FDA our initial response to the warning letter within the required fifteen business days of receipt, and committed to undertaking certain quality system improvements and providing the FDA with periodic updates. During 2014 and continuing in 2015, we implemented systemic changes and organizational enhancements to address the four warning letter items and related quality systems. We have established teams to review and address the items cited by the FDA and have engaged external subject matter experts to assist in assessment and remediation efforts. As we continue to evaluate our quality systems, it is possible that we may need to take additional actions including the possibility of voluntary product recalls when necessary to ensure patient safety and effective performance of the HVAD System. We anticipate a follow-up inspection by the FDA of our Miami Lakes, Florida facility in 2016.

At December 31, 2015, we had purchase order commitments of approximately $42.9 million related to product costs, supplies, services and property, plant and equipment purchases. Many of our materials and supplies require long lead times. Our purchase order commitments reflect materials that may be received up to one year from the date of order.

In addition to the above, we have entered into employment agreements with all of our executive officers. These contracts do not have a fixed term and are constructed on an at-will basis. Some of these contracts provide executives with the right to receive certain additional payments and benefits if their employment is terminated after a change of control, as defined in such agreements.

From time to time we invest in certain development stage entities in connection with research activities. Certain contingent milestone payments in connection with these arrangements have not been accrued in the accompanying consolidated financial statements as the amounts are indeterminate at this time.

The taxation and customs requirements, together with other applicable laws and regulations of certain foreign jurisdictions, can be inherently complex and subject to differing interpretation by local authorities. We are subject to the risk that either we have misinterpreted applicable laws and regulations, or that foreign authorities may take inconsistent, unclear or changing positions on local law, customs practices or rules. In the event that we have misinterpreted any of the above, or that foreign authorities take positions contrary to ours, we may incur liabilities that may differ materially from the amounts accrued in the accompanying consolidated financial statements.

Litigation

From time to time we may be involved in litigation or other contingencies arising in the ordinary course of business. Except as set forth below (*see* note 21), and based on the information presently available, management believes there are no contingencies, claims or actions, pending or threatened, the ultimate resolution of which will have a material adverse effect on our financial position, liquidity or result of operations.

In accordance with FASB ASC 450*, Contingencies*, we accrue loss contingencies including costs of settlement, damages and defense related to litigation to the extent they are probable and reasonably estimable.

Otherwise, we expense these costs as incurred. If the estimate of a probable loss is a range and no amount within the range is more likely, we accrue the minimum amount of the range.

Contingent Consideration and Milestone Payments

In December 2013, we acquired CircuLite using a combination of cash, stock and post-acquisition milestone and royalty payments. The post-acquisition payments are payable based upon the achievement of five specified performance milestones and revenue over periods ranging from 8-10 years subsequent to the acquisition date. The maximum amount of the aggregate post-acquisition payments could be $300 million. As of December 31, 2015, the fair value of this contingent consideration was estimated to be $12.3 million (*see* Note 6).

License and Development Agreements

From time to time, we license rights to technology or intellectual property from third parties. These licenses may require us to pay upfront payments as well as development or other payments upon successful completion of preclinical, clinical, regulatory or revenue milestones. In addition, these agreements may require us to pay royalties on sales of products arising from the licensed technology or intellectual property. Because the achievement of these milestones is not reasonably estimable, we have not recorded a liability in the accompanying consolidated financial statements for any of these contingencies.

Note 18. Guarantees

On December 16, 2008, we entered into a Deed of Cross Guarantee (the "Deed") by and among the Group's then-existing entities; HeartWare International, Inc., HeartWare Pty. Limited (formerly HeartWare Limited) and HeartWare Inc., whereby the companies have agreed to cross-guarantee each other's liabilities. The Deed was established as a condition to obtaining financial reporting relief under ASIC Class Order 98/1418 which provided relief for us from the requirement to prepare and lodge audited accounts for HeartWare Pty. Limited in Australia. HeartWare International, Inc. is the holding entity, HeartWare, Inc. is the alternative Trustee and HeartWare Pty. Limited is a member of the Closed Group for purposes of the Class Order.

Note 19. Retirement Savings Plan

We have established a 401(k) plan in which substantially all of our U.S. employees are eligible to participate. Contributions made by employees are limited to the maximum allowable for U.S. federal income tax purposes. Beginning in April 2010, we commenced a matching program whereby we match employee contributions at a rate of 100% of applicable contributions up to 3% of included compensation plus 50% of applicable contributions up to the next 2% of included compensation. Our contributions to the 401(k) plan were approximately $1.8 million, $1.4 million and $1.1 million for the years ended December 31, 2015, 2014 and 2013.

Note 20. Quarterly Financial Information (Unaudited)

The following table presents selected quarterly financial information for the periods indicated. This information has been derived from our unaudited quarterly consolidated financial statements, which in the opinion of management include all adjustments (consisting only of normal recurring adjustments) necessary for a fair presentation of such information. The quarterly per share data presented below was calculated separately and

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

may not sum to the annual figures presented in the consolidated financial statements. These operating results are also not necessarily indicative of results for any future period.

	Three Months Ended			
	March 31	June 30	September 30	December 31
	(in thousands, except per share data)			
2015				
Revenue, net	$ 70,021	$ 73,569	$ 65,166	$ 68,087
Gross profit	47,981	48,341	32,176	45,057
Net loss	(14,535)	(27,393)	(29,927)	(926)
Net loss per common share—basic and diluted (1)	$ (0.85)	$ (1.59)	$ (1.73)	$ (0.05)
Weighted average shares outstanding—basic and diluted	17,193	17,269	17,303	17,327
2014				
Revenue, net	$ 66,472	$ 70,131	$ 68,608	$ 73,209
Gross profit	43,557	47,176	45,631	49,860
Net income (loss)	(19,444)	8,364	(7,370)	(916)
Net income (loss) per common share—basic (1)	$ (1.15)	$ 0.49	$ (0.43)	$ (0.05)
Net income (loss) per common share—diluted (1)	$ (1.15)	$ 0.48	$ (0.43)	$ (0.05)
Weighted average shares outstanding—basic	16,934	16,989	17,007	17,037
Weighted average shares outstanding—diluted	16,934	17,305	17,007	17,037

(1) Net income (loss) per common share for each quarter is computed using the weighted-average number of shares outstanding during that quarter while net loss per common share for the full year is computed using the weighted-average number of shares outstanding during the year. Thus, the sum of the four quarters' net income (loss) per common share may not equal the full-year loss per share.

Significant amounts in per quarter information listed above include:

- Net loss for the quarters ended March 31, June 30, September 30 and December 31, 2015 included share-based compensation expense of approximately $6.0 million, $6.7 million, $6.1 million and $5.0 million, respectively.
- Net loss for the quarter ended December 31, 2015 included $1.0 million in restructuring costs, foreign exchange losses of $1.1 million, $26.8 million for the impairment of certain purchased intangible assets and a $38.1 million decrease in the fair value of contingent consideration associated with the acquisition of CircuLite.
- Net loss for the quarter ended September 30, 2015 included foreign exchange losses of $0.4 million and a $2.4 million increase in the fair value of contingent consideration associated with the acquisition of CircuLite.
- Net loss for the quarter ended June 30, 2015 included loss on extinguishment of debt of $16.6 million, foreign exchange gains of $0.8 million and a $2.2 million increase in the fair value of contingent consideration associated with the acquisition of CircuLite.
- Net loss for the quarter ended March 31, 2015 included $2.6 million in restructuring costs, foreign exchange losses of $3.7 million and a $2.1 million increase in the fair value of contingent consideration associated with the acquisition of CircuLite.
- Net loss for the quarter ended December 31, 2014 included $2.6 million for the impairment of certain purchased intangible assets and a $9.1 million decrease in the fair value of contingent consideration associated with the acquisition of CircuLite.

HEARTWARE INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

- Net loss for the quarter ended September 30, 2014 included a $3.6 million decrease in the fair value of contingent consideration associated with the acquisition of CircuLite.
- Net income for the quarter ended June 30, 2014 included a $13.7 million decrease in the fair value of contingent consideration associated with the acquisition of CircuLite.
- Net loss for the quarter ended March 31, 2014 included $4.1 million in restructuring costs and a $3.1 million increase in the fair value of contingent consideration associated with the acquisition of CircuLite.
- Net loss for the quarter ended March 31, 2014 included foreign exchange gains of $0.2 million.
- Net loss for the quarters ended September 30 and December 31, 2014 included foreign exchange losses of $3.3 million and $1.8 million, respectively.
- Net income (loss) for the quarters ended March 31, June 30, September 30 and December 31, 2014 included share-based compensation expense of approximately $4.4 million, $6.5 million, $6.4 million and $6.2 million, respectively.

Note 21. Subsequent Events

We have evaluated events and transactions that occurred subsequent to December 31, 2015 through the date the financial statements were issued, for potential recognition or disclosure in the accompanying consolidated financial statements. Except for the events discussed below, we did not identify any events or transactions that should be recognized or disclosed in the accompanying consolidated financial statements.

On January 22, 2016, the St. Paul Teachers' Retirement Fund Association filed a putative class action complaint (the "Complaint") in the United States District Court for the Southern District of New York on behalf of all persons and entities who purchased or otherwise acquired shares of the company from June 10, 2014 through January 11, 2016 (the "Class Period"). The Complaint claims that the company and two of our executives violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by making false and misleading statements about, among other things, the company's response to the June 2014 FDA Warning Letter, the development of the MVAD System and the acquisition of Valtech. The Complaint claims that the disclosure of the purportedly false and misleading statements caused the price of the company's stock to drop, and seeks to recover damages on behalf of all purchasers or acquirers of the company's stock during the Class Period. The company intends to vigorously defend itself against these claims. Because of the many questions of fact and law that may arise, the outcome of this legal proceeding is uncertain at this point. As a result we cannot reasonably estimate a range of loss for this action and accordingly have not accrued any liability associated with this action.

On January 28, 2016, we entered into a Cooperation Agreement with Engaged Capital, LLC and certain affiliates (collectively, "Engaged Capital") pursuant to which, subject to the terms of the Cooperation Agreement, the we agreed, among other things, to jointly select an additional independent director to be appointed to the company's board of directors and form a business strategy committee of the company's board of directors. In addition, Engaged Capital agreed to withdraw its previously nominated slate of directors for election at the company's 2016 annual meeting of stockholders and to certain customary standstill provisions. A copy of the Cooperation Agreement is attached as Exhibit 10.1 to the company's Current Report on Form 8-K filed with the SEC on January 28, 2016.

On September 1, 2015, we entered into a Business Combination Agreement (the "BCA") by and among the Company, Valtech Cardio, Ltd. ("Valtech"), HW Global, Inc. ("Holdco"), HW Merger Sub, Inc., Valor Merger Sub Ltd. and Valor Shareholder Representative, LLC, pursuant to which we and Valtech proposed to effect a strategic combination of our respective businesses under Holdco subject to certain closing conditions. Valtech is

a privately held company that specializes in the development of innovative surgical and transcatheter valve repair and replacement devices for the treatment of mitral valve regurgitation and tricuspid valve regurgitation. Effective January 28, 2016, we terminated the BCA pursuant to the terms of the BCA by delivering written notice to the other parties. As of December 31, 2015, we had invested approximately $17 million in Valtech in the original form of convertible loans, of which $10 million together with $0.5 million of accrued interest was converted into Valtech preferred shares amounting to approximately 3.0% ownership on a fully diluted basis. Pursuant to the BCA we loaned Valtech $1 million on January 7, 2016 and $30 million following termination of the BCA per provisions of the BCA, in the form of convertible loans.

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 the Chief Executive Officer and the Chief Financial Officer, carried out an evaluation required by the Securities Exchange Act of 1934, as amended (the "Exchange Act"), of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) of the Exchange Act, as of December 31, 2015. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2015, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

Management's Annual Report on Internal Control over Financial Reporting

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). 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 our assets; (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 our receipts and expenditures are being made only in accordance with authorizations of our management and directors; 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 our financial statements.

Under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2015 based on the framework in *Internal Control—Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2015.

Our independent registered public accounting firm, Grant Thornton LLP, has issued a report on our internal control over financial reporting, which is included in Item 8 of this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the fiscal quarter ended December 31, 2015, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Controls and Procedures

Our management, including the Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs.

Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Thus, misstatements due to error or fraud may occur and not be detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of controls.

Item 9B. Other Information

None.

Part III

Item 10. Directors, Executive Officers and Corporate Governance

Our executive officers and their respective ages as of December 31, 2015 are as follows:

Name	Age	Position
Douglas Godshall	51	Director, President and Chief Executive Officer
Jeffrey LaRose	53	Executive Vice President and Chief Scientific Officer
Katrin Leadley	53	Chief Medical Officer
Peter McAree	51	Senior Vice President and Chief Financial Officer
Larry Knopf	54	Senior Vice President, General Counsel and Secretary
James Schuermann	47	Senior Vice President, Sales and Marketing
Mark Strong	44	Senior Vice President, Research & Development and Quality Assurance

Biographical Summaries

Douglas Godshall. Mr. Godshall has been our President and Chief Executive Officer since September 2006 and a director since October 2006. Prior to joining HeartWare, Mr. Godshall served in various executive and managerial positions at Boston Scientific Corporation, where he had been employed since 1990, including as a member of Boston Scientific's Operating Committee and since January 2005, as President, Vascular Surgery. Mr. Godshall also spent five years as Vice President, Business Development, at Boston Scientific, where he was focused on acquisition strategies for the cardiology, electrophysiology, neuroradiology and vascular surgery divisions. Mr. Godshall, since March 2012, serves on the board of directors of pSivida Corp., a public company traded on both the NASDAQ Stock Market and the ASX that specializes in the development of miniaturized, injectable drug delivery systems and, since May of 2013, Vital Therapies, Inc. a public company traded on the NASDAQ Stock Market that develops cell based therapies for the treatment of liver disease. Additionally, since May 2014, Mr. Godshall serves on the Board of Directors of the Medical Device Manufacturers Association, a national trade association. Mr. Godshall has a Bachelor of Arts in Business from Lafayette College and Masters of Business Administration from Northeastern University in Boston, Massachusetts.

Jeffrey LaRose. Mr. LaRose is our Chief Scientific Officer and has been with the Company since its inception. Prior to joining HeartWare, since April 1999, he was involved in the development of HeartWare's technology through his employment with Kriton Medical, which the Company acquired in 2003. He is responsible for all aspects of the design and physiological controls for HeartWare's left ventricular assist device, the HVAD System. Mr. LaRose also leads the development of our miniaturization technology and has twenty years of experience in hydraulic technology development including roles with AEA Technology Engineering Software and Babcock and Wilcox. He holds a Master of Science in Mechanical Engineering from the University of Akron, Ohio.

Dr. Katrin Leadley. Dr. Leadley joined HeartWare in September 2014 as our Chief Medical Officer responsible for all medical, clinical and regulatory affairs, including the design and execution of HeartWare's clinical trial program. Prior to joining HeartWare, Dr. Leadley served as the Chief Medical Officer of JenaValve Technology from 2011 until September 2014. From 2003 until 2011, Dr. Leadley held a variety of leadership positions at Boston Scientific Corporation, a global medical device company. From 2009 until 2011, Dr. Leadley served as Boston Scientific's Global Senior Medical Director, Clinical Services where she provided medical and scientific leadership for the development of clinical research programs. She also served as its Medical Director, Clinical services from 2005 until 2009 and its Associate Medical Director from 2003 until 2005. Prior to joining Boston Scientific, Dr. Leadley held managerial positions at several other life sciences companies based in California, including Advanced Stent Technologies, Pulmonx and Quintiles/The Lewin Group in San Francisco. She has authored numerous scientific and medical publications and presented at industry conferences and events around the world. Dr. Leadley earned her medical degree at Ludwig-Maximillian University Medical School in Munich. She was also awarded a National Institute of Health Postdoctoral Fellowship by the School of Public Health at the University of California at Berkeley.

Peter McAree. Mr. McAree joined HeartWare in July 2012 as our Senior Vice President, Chief Financial Officer and Treasurer. Previously, he served as Senior Vice President and Chief Financial Officer of Caliper Life Sciences, Inc. from April 2008 through November 2011, after having held the position of Vice President of Finance since 2003. Mr. McAree was Chief Financial Officer of Zymark Corporation from May 2000, until the acquisition of Zymark by Caliper in 2003. Having also served in financial leadership positions in other industries, Mr. McAree began his career with Arthur Andersen, Boston, where he held various positions over nearly a decade. He received his B.S. in Accountancy from Bentley University, and is a licensed Certified Public Accountant in Massachusetts.

Lawrence Knopf. Mr. Knopf joined HeartWare in March 2011 as our Senior Vice President, General Counsel and Secretary. Mr. Knopf has overall responsibility for the Company's legal, reimbursement and compliance functions. Between 1993 and 2010, Mr. Knopf served in a variety of legal positions at Boston Scientific Corporation, a global medical device company. From 2007, Mr. Knopf was Senior Vice President and Deputy General Counsel, from 1994, Vice President and Assistant General Counsel and from 1993, Assistant General Counsel. Previously, Mr. Knopf was a corporate associate at the Boston law firms of Bingham McCutchen, LLP and Gaston & Snow. Mr. Knopf received a Juris Doctor from the University of Michigan School of Law and holds a Bachelor of Science, Accounting and Political Science, from The Wharton School of the University of Pennsylvania. He is admitted to the Bar in Massachusetts, New York and Connecticut and passed the Certified Public Accountant examination in Connecticut.

James Schuermann. Mr. Schuermann joined HeartWare in September 2007 as our Senior Vice President, Sales and Marketing. Mr. Schuermann has overall responsibility for HeartWare's global sales and marketing activities. Mr. Schuermann has over 20 years of sales and marketing experience in the medical device arena. Prior to joining HeartWare, Mr. Schuermann spent nine years in sales and marketing at Boston Scientific Corporation and held various management positions including Director of Marketing. Before joining Boston Scientific, he spent 5 years in medical sales and sales management at Sherwood Davis & Geck and 3 years in marketing at Armstrong World Industries. Mr. Schuermann received his undergraduate degree in marketing from Kelley School of Business, Indiana University, Bloomington, and his MBA from Ageno School of Business, Golden Gate University, San Francisco.

Mark Strong. Mr. Strong joined HeartWare on September 30, 2013 and currently serves HeartWare as Senior Vice President, Research and Development and Quality. Prior to joining HeartWare, he held a variety of research and development leadership positions at Boston Scientific Corporation, a global medical device company. From 2011 to 2013, Mr. Strong served as Boston Scientific's Vice President of Research and Development for CRV, its largest business unit. He also served as Director, Systems Engineering and Product Development Process from 2009 to 2011 and Director of Design Engineering from 2006 to 2009. From 1993 until 2006, Mr. Strong held a variety of research and development and engineering positions at Boston Scientific. Mr. Strong holds a B.S. in electrical engineering and biomedical engineering from North Dakota State University. In addition, he earned a Master's degree in electrical engineering at the University of Minnesota and an MBA at the University of St. Thomas in St. Paul, Minnesota.

Other Information

We have a code of business conduct and ethics that applies to each director, officer and employee of the Company, including the executive, financial and accounting officers. Our code of conduct is available in the "Corporate Governance" section on our website at www.heartware.com.

We expect to make all required disclosures regarding any amendments to, or waivers from, this Code of Conduct on our website.

The other information required by this Item 10 is incorporated herein by reference to the applicable information in our definitive proxy statement for our 2016 annual meeting of stockholders to be filed with the Securities and Exchange Commission or is to be included in Item 10 of an amendment to this Annual Report on Form 10-K to be filed with the Securities and Exchange Commission.

Item 11. Executive Compensation

The information required by this Item 11 is incorporated herein by reference to the applicable information in our definitive proxy statement for our 2016 annual meeting of stockholders to be filed with the Securities and Exchange Commission, including the information set forth under the caption "Executive Compensation" or is to be included in Item 11 of an amendment to this Annual Report on Form 10-K to be filed with the Securities and Exchange Commission.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item 12 is incorporated herein by reference to the applicable information in our definitive proxy statement for our 2016 annual meeting of stockholders to be filed with the Securities and Exchange Commission, including the information set forth under the caption "Security Ownership of Certain Beneficial Owners and Management" or is to be included in Item 12 of an amendment to this Annual Report on Form 10-K to be filed with the Securities and Exchange Commission.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item 13 is incorporated herein by reference to the applicable information in our definitive proxy statement for our 2016 annual meeting of stockholders to be filed with the Securities and Exchange Commission, including the information set forth under the captions "Certain Relationships and Related Transactions, and Director Independence", "Policies and Procedures for Review and Approval of Related Party Transactions", "Corporate Governance" and "Compensation Committee Interlocks and Insider Participation," or is to be included in Item 13 of an amendment to this Annual Report on Form 10-K to be filed with the Securities and Exchange Commission.

Item 14. Principal Accounting Fees and Services

The information required by this Item 14 is incorporated herein by reference to the applicable information in our definitive proxy statement for our 2016 annual meeting of stockholders to be filed with the Securities and Exchange Commission, including the information set forth under the captions "Principal Accounting Fees and Services" and "Audit Committee's Pre-Approval Policy," or is to be included in Item 14 of an amendment to this Annual Report on Form 10-K to be filed with the Securities and Exchange Commission.

Part IV.

Item 15. Exhibits, Financial Statement Schedules

The following documents are filed as part of this Annual Report on Form 10-K:

1. Financial Statements:

   Report of Independent Registered Public Accounting Firm
   Consolidated Balance Sheets
   Consolidated Statements of Operations
   Consolidated Statements of Comprehensive Loss
   Consolidated Statement of Stockholders' Equity
   Consolidated Statements of Cash Flows
   Notes to Consolidated Financial Statements

2. Financial Statement Schedules:

   Required schedule information is included in the Notes to Consolidated Financial Statements or is omitted because it is either not required or not applicable.

3. Exhibits:

   See Exhibit Index

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

HeartWare International, Inc.

Date: February 26, 2016

By /s/ Douglas Godshall
Name: Douglas Godshall
Title: President and Chief Executive 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.

Name	Title	Date
/s/ Douglas Godshall Douglas Godshall	President, Chief Executive Officer and Director (Principal Executive Officer)	February 26, 2016
/s/ Peter McAree Peter McAree	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 26, 2016
/s/ C. Raymond Larkin, Jr. C. Raymond Larkin, Jr.	Chairman and Director	February 26, 2016
/s/ Timothy Barberich Timothy Barberich	Director	February 26, 2016
/s/ Cynthia Feldmann Cynthia Feldmann	Director	February 26, 2016
/s/ Seth Harrison Seth Harrison	Director	February 26, 2016
/s/ Robert Stockman Robert Stockman	Director	February 26, 2016
/s/ Robert Thomas Robert Thomas	Director	February 26, 2016
/s/ Denis Wade Denis Wade	Director	February 26, 2016

Exhibit Index

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated as of December 1, 2013, by and among HeartWare International, Inc., Chronos Merger Sub Inc., CircuLite, Inc., and Shareholder Representative Services LLC, as securityholder representative. (10)
3.1	Certificate of Incorporation of HeartWare International, Inc. (3)
3.2	Certificate of Amendment, dated June 25, 2015, to the Company's Certificate of Incorporation (13)
3.3	Bylaws of HeartWare International, Inc. (3)
10.01	Amended and Restated Employment Agreement, dated as of December 16, 2009, by and between HeartWare International, Inc. and Douglas Godshall (9) +
10.02	Amended and Restated Employment Agreement, dated as of December 16, 2009, by and between HeartWare, Inc. and Jeffrey LaRose (16) +
10.03	Employment Agreement, dated as of December 5, 2008, between HeartWare, Inc. and James Schuermann (4) +
10.05	Form of Amendment to Employment Agreement (for Section 16 officers), dated December 2010 (23) +
10.06	Form of Deed of Indemnity, Access and Insurance Agreement for directors and executive officers (1) +
10.07	Letter of Appointment as a Director of the Company dated December 1, 2006 between HeartWare Limited and Robert Stockman (1) +
10.08	Letter of Appointment as a Director of the Company dated December 15, 2004 between HeartWare Limited and Robert Thomas (1) +
10.09	Letter of Appointment as a Director of the Company dated December 15, 2004 between HeartWare Limited and Denis Wade (1) +
10.10	Letter of Appointment as a Director of the Company dated September 3, 2008 between HeartWare International, Inc. and Ray Larkin (11) +
10.11	Letter of Appointment as a Director of the Company dated April 16, 2008 between HeartWare International, Inc. and Timothy J. Barberich (12) +
10.12	Letter of Appointment as a Director of the Company dated December 21, 2011 between HeartWare International, Inc. and Cynthia Feldmann (2) +
10.13	Letter of Appointment as a Director of the Company dated January 11, 2016 between HeartWare International, Inc. and Stephen N. Oesterle, M.D. (14) +
10.14	HeartWare International, Inc. 2008 Stock Incentive Plan (5) +
10.15	HeartWare International, Inc. Employee Stock Option Plan (6) +
10.16	HeartWare International, Inc. Restricted Stock Unit Plan (7) +
10.17	Form of HeartWare International, Inc. Incentive Option Terms (8) +
10.18	Nonstatutory Stock Option Notice and Agreement to 2008 Stock Incentive Plan (20) +
10.19	Restricted Stock Units Notice and Agreement to 2008 Stock Incentive Plan (21) +
10.20	Sublease Agreement, dated as of October 17, 2013, by and between The TJX Companies, Inc. and HeartWare International, Inc. (32)

Exhibit No.	Description
10.21	Amendment to Sublease Agreement, dated as of October 17, 2013, by and between The TJX Companies, Inc. and HeartWare International, Inc., dated May 1, 2015 (15)
10.22	Lease Agreement dated December 8, 2010 by and between MCP EWE LLC, as Landlord, HeartWare, Inc., as Tenant, and guaranteed by HeartWare International, Inc., as Guarantor (24)
10.23	First Amendment to Lease Agreement dated December 8, 2010 by and between MCP EWE LLC, as Landlord, HeartWare, Inc., as Tenant, and guaranteed by HeartWare International, Inc., as Guarantor, dated November 30, 2012 between The Graham Companies, as successor in interest to MCP EWE LLC, and HeartWare, Inc. (34)
10.24	Indenture dated as of December 15, 2010 between the Company and Wilmington Trust FSB, as trustee (17)
10.25	First Supplemental Indenture dated as of December 15, 2010 between the Company and Wilmington Trust FSB, as Trustee (18)
10.26	Form of 3.50% Convertible Senior Notes due 2017 (19)
10.27	Form of Exchange/Subscription Agreement relating to the Company's 1.75% Convertible Senior Notes due 2021 (22)
10.28	Second Supplemental Indenture dated as of May 13, 2015 between the Company and Wilmington Trust, National Association, (as successor by merger to Wilmington Trust FSB), as Trustee (26)
10.29	Form of 1.75% Convertible Senior Notes due 2021 (33)
10.30	Offer letter, dated as of March 21, 2011, between HeartWare, Inc. and Lawrence J. Knopf (27) +
10.31	Offer letter, dated as of June 6, 2011, between HeartWare, Inc. and Robert E. Yocher (28) +
10.32	Offer Letter, dated as of June 18, 2012, between HeartWare, Inc. and Peter McAree (25) +
10.33	Offer letter, dated as of September 23, 2013, between HeartWare, Inc. and Mark Strong (35) +
10.34	Promotion letter, effective as of July 21, 2014, between HeartWare, Inc. and Mark Strong (36)+
10.35	Employment Contract, dated as of September 1, 2014, between HeartWare GmbH and Katrin Leadley, M.D. (37)+
10.36	HeartWare International, Inc. 2012 Incentive Award Plan(29)
10.37	Amendment No. 1 to the HeartWare International, Inc. 2012 Incentive Award Plan, dated June 29, 2015 (39)
10.38	Form of HeartWare International Inc. 2012 Incentive Award Plan Stock Option Notice and Award Agreement (30)
10.39	Form of HeartWare International Inc. 2012 Incentive Award Plan Restricted Stock Unit Notice and Award Agreement (31)
10.40	Registration Rights Agreement, dated as of December 1, 2013, by and among HeartWare International, Inc., Shareholder Representative Services LLC, as securityholder representative, and the other parties thereto. (10)
10.41	Cooperation Agreement, dated as of January 28, 2016, by and among HeartWare International, Inc., Engaged Capital, LLC, Engaged Capital Master Feeder I, LP, Engaged Capital Master Feeder II, LP, Engaged Capital I, LP, Engaged Capital I Offshore, Ltd., Engaged Capital II, LP, Engaged Capital II Offshore Ltd., Engaged Capital Holdings, LLC and Glenn W. Welling. (38)
21.1	List of Subsidiaries *

Exhibit No.	Description
23.1	Consent of Independent Registered Public Accounting Firm *
31.1	Certification pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 *
31.2	Certification pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 *
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 **
32.2	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 **
101	The following materials from the Company's Annual Report on Form 10-K for the year ended December 31, 2015, formatted in XBRL (Extensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Comprehensive Loss, (iv) Consolidated Statement of Stockholders' Equity, (v) Consolidated Statements of Cash Flows, and (vi) Notes to the Consolidated Financial Statements.

(1) Incorporated by reference to the respective exhibits filed with the Company's Registration Statement on Form 10 (File No. 000-52595) filed with the Securities and Exchange Commission on April 30, 2007.
(2) Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 28, 2012.
(3) Incorporated by reference to the respective exhibits filed with the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 13, 2008.
(4) Incorporated by reference to Exhibit 99 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 5, 2008.
(5) Incorporated by reference to Appendix 12 to the Information Memorandum contained in the Company's Proxy Statement on Form DEF 14A filed with the Securities and Exchange Commission on September 22, 2008.
(6) Incorporated by reference to Appendix 9 to the Information Memorandum contained in the Company's Proxy Statement on Form DEF 14A filed with the Securities and Exchange Commission on September 22, 2008.
(7) Incorporated by reference to Appendix 10 to the Information Memorandum contained in the Company's Proxy Statement on Form DEF 14A filed with the Securities and Exchange Commission on September 22, 2008.
(8) Incorporated by reference to Exhibit 99.4 to the Company's Registration Statement on Form S-8 (File No. 333-155359) filed with the Securities and Exchange Commission on November 13, 2008.
(9) Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 18, 2009.
(10) Incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 2, 2013.
(11) Incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 26, 2009.
(12) Incorporated by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 26, 2009.
(13) Incorporated by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 3, 2015.
(14) Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 11, 2016.
(15) Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 3, 2015.
(16) Incorporated by reference to Exhibit 10.6 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 23, 2010.

(17) Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 15, 2010.
(18) Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 15, 2010.
(19) Incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 15, 2010.
(20) Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 6, 2010.
(21) Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 6, 2010.
(22) Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 7, 2015.
(23) Incorporated by reference to Exhibit 10.08 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 24, 2011, and with respect to Amendment No. 1, to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 29, 2015.
(24) Incorporated by reference to Exhibit 10.29 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 24, 2011.
(25) Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 8, 2012.
(26) Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 19, 2015.
(27) Incorporated by reference to Exhibit 10.38 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 27, 2012.
(28) Incorporated by reference to Exhibit 10.39 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 27, 2012.
(29) Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 8, 2012.
(30) Incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (File No. 333-184358) filed with the Securities and Exchange Commission on October 10, 2012.
(31) Incorporated by reference to Exhibit 99.3 to the Registrant's Registration Statement on Form S-8 (File No. 333-184358) filed with the Securities and Exchange Commission on October 10, 2012.
(32) Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 7, 2013.
(33) Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 19, 2015.
(34) Incorporated by reference to Exhibit 10.29 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 27, 2013.
(35) Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on October 31, 2014.
(36) Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on October 31, 2014.
(37) Incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on October 31, 2014.
(38) Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 28, 2016.
(39) Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 29, 2015.

* Filed herewith
** Furnished herewith
\+ Management contract or compensatory plan or arrangement.

Exhibit 21.1

LIST OF SUBSIDIARIES

NAME OF SUBSIDIARY	STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION
HeartWare Pty. Limited (formerly HeartWare Limited) (1)	Australia
HeartWare, Inc. (2)	Delaware
HeartWare GmbH (3)	Germany
HeartWare (UK) Limited (4)	United Kingdom
HeartWare France SAS (5)	France
World Heart Corporation (6)	Delaware
HeartWare Hong Kong Limited (7)	Hong Kong
7210914 Canada, Inc. (8)	Province of Ontario, Canada
World Hearts Inc. (9)	Delaware
CircuLite, Inc. (10)	Delaware
World Heart B.V. (11)	Netherlands
CircuLite GmbH (12)	Germany
HeartWare Sweden, AB (13)	Sweden
HW Global, Inc. (14)	Delaware
HW Merger Sub, Inc. (15)	Delaware
Valor Merger Sub Ltd. (16)	Israel

(1) A subsidiary of HeartWare International, Inc. and incorporated on November 26, 2004;
(2) A subsidiary of HeartWare Pty. Limited and incorporated on April 8, 2003;
(3) A subsidiary of HeartWare, Inc. and formed on April 15, 2010;
(4) A subsidiary of HeartWare, Inc. and incorporated on February 19, 2010;
(5) A subsidiary of HeartWare, Inc. and formed on August 16, 2011;
(6) A subsidiary of HeartWare, Inc. and originally incorporated under the laws of the Province of Ontario, Canada and converted to a Delaware corporation on January 1, 2010;
(7) A subsidiary of HeartWare, Inc. and incorporated on December 30, 2013;
(8) A subsidiary of World Heart Corporation and incorporated on July 22, 2009;
(9) A subsidiary of World Heart Corporation and incorporated on May 22, 2000;
(10) A subsidiary of World Heart Corporation and incorporated on June 21, 2004;
(11) A subsidiary of World Hearts, Inc. and formed on March 5, 2004;
(12) A subsidiary of CircuLite, Inc. and formed on July 14, 2004;
(13) A subsidiary of HeartWare, Inc. and formed on October 17, 2014;
(14) A subsidiary of HeartWare International, Inc. and incorporated on August 26, 2015;
(15) A subsidiary of HW Global, Inc. and incorporated on August 26, 2015;
(16) A subsidiary of HW Global, Inc. and formed on August 26, 2015.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We have issued our report dated February 26, 2016, with respect to the consolidated financial statements and internal control over financial reporting included in the Annual Report of HeartWare International, Inc. on Form 10-K for the year ended December 31, 2015. We hereby consent to the incorporation by reference of said report in the Registration Statements of HeartWare International, Inc. on Forms S-8 (File No. 333-155359, effective November 13, 2008, File No. 333-172424, effective February 24, 2011, File No. 333-184358, effective October 10, 2012, and File No. 333-193649, effective January 30, 2014), and Form S-3 (File No. 333-193646, effective January 30, 2014).

/s/ Grant Thornton LLP

Fort Lauderdale, Florida
February 26, 2016

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a) OR RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934

I, Douglas Godshall, certify that:

1. I have reviewed this Annual Report on Form 10-K of HeartWare International, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2016

/s/ Douglas Godshall

Douglas E. Godshall
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a) OR RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934

I, Peter McAree certify that:

1. I have reviewed this Annual Report on Form 10-K of HeartWare International, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2016

/s/ Peter McAree
Peter F. McAree
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906 OF THE
SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of HeartWare International, Inc. (the "Company") for the fiscal year ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned President and Chief Executive Officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that based on his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 26, 2016

/s/ Douglas Godshall
Douglas E. Godshall
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906 OF THE
SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of HeartWare International, Inc. (the "Company") for the fiscal year ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned Chief Financial Officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that based on his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 26, 2016

/s/ Peter McAree
Peter F. McAree
Chief Financial Officer
(Principal Financial Officer)