HeartWare International, Inc. (HTWR)

10-K
Annual report pursuant to section 13 and 15(d)
Filed on 02/24/2011
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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, 2010

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.)

205 Newbury Street, Suite 101

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, other than shares held by persons who may be deemed affiliates of the registrant, computed by reference to the closing sale price of the common stock reported on the NASDAQ Stock Market as of June 30, 2010, was approximately $664.0 million. For purposes of the above statement only, shares of the registrant's common stock held by directors and executive officers and entities or persons that, to the registrant's knowledge, owned 10% or more of the registrant's outstanding common stock as of June 30, 2010 have been excluded from this number in that these persons may be deemed affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 11, 2011, the registrant had 13,891,230 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 2011 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, 2010.

References

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 subsidiaries, HeartWare Pty. Limited, HeartWare, Inc., HeartWare GmbH and HeartWare (UK) Limited.
- "HeartWare International, Inc." refers to HeartWare International, Inc., a Delaware corporation incorporated on July 29, 2008.
- "HeartWare Pty. Limited" refers to HeartWare Pty. Limited (formerly known as HeartWare Limited), an Australian proprietary corporation originally incorporated on November 26, 2004.
- "HeartWare, Inc." refers to HeartWare, Inc., a Delaware corporation incorporated on April 3, 2003. HeartWare, Inc. was acquired by HeartWare Pty. Limited on January 24, 2005.
- "HeartWare GmbH" refers to HeartWare GmbH, a German corporation established on February 19, 2010.
- "HeartWare (UK) Limited" refers to HeartWare (UK) Limited, a limited liability corporation established in the United Kingdom on February 19, 2010.

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. 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 expectations with respect to regulatory submissions and approvals, such as FDA approval of our premarket approval application for our HeartWare® Ventricular Assist System for a bridge-to-transplant indication;
- our expectations with respect to our clinical trials, including enrollment in or completion of our 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;
- our ability and plans to develop and commercialize new products and the expected features and functionalities and possible benefits of these products; and
- our estimates regarding our capital requirements and financial performance, including profitability.

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 regulation of the Securities and Exchange Commission. 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 future reports filed with the Securities and Exchange Commission. Investors should read the entire Annual Report on Form 10-K and consult their respective financial, legal or other professional adviser in relation to the subject matter therein, 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 Securities and Exchange Commission.

Corporate Information

HeartWare International, Inc. was incorporated in Delaware on July 29, 2008 and became the successor issuer to HeartWare Limited, an Australian corporation, on November 13, 2008, as a result of the Australian Court approved redomiciliation of HeartWare Limited from Australia to Delaware. Prior to this date, HeartWare Limited was the ultimate parent company of the HeartWare Group and, following the redomiciliation, HeartWare International, Inc. became the ultimate parent company. In January 2009, HeartWare Limited was converted to an Australian private company and was renamed HeartWare Pty. Limited.

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

In connection with the 2008 redomiciliation referred to above, each holder of HeartWare Limited ordinary shares, share options or performance rights received one share of common stock, one stock option or one restricted stock unit, of HeartWare International, Inc., for every 35 of HeartWare Limited ordinary shares, share options or performance rights, respectively, held by such holder. Unless the context requires otherwise, all information in this Annual Report on Form 10-K regarding shares, options or other securities of HeartWare International, Inc. or HeartWare Limited, as applicable, including related data on a per unit basis, has been adjusted to give effect to the 2008 redomiciliation transaction, whether such information pertains to a date or period of time subsequent or prior to the redomiciliation transaction.

Our principal executive offices are located at 205 Newbury Street, Suite 101, 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 such 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.

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, and references to "€" or "Euros" means Euros, the single currency of Participating Member States of the European Union.

Trademarks

HEARTWARE®, HVAD® and MVAD®, KRITON® and various company logos are the trademarks of the Company, in the United States, Europe, Australia and other countries. All 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 develops and manufactures small implantable heart pumps, or ventricular assist devices, for the treatment of advanced heart failure. The HeartWare Ventricular Assist System (the "HeartWare System"), which includes a left ventricular assist device ("LVAD"), 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 HeartWare 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 HeartWare System is designed to be implanted adjacent to the heart, avoiding the abdominal surgery generally required to implant similar devices.

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 pumps it 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.

In 2009, we received CE Marking for the HeartWare System in the European Union allowing for commercial sale and distribution of our device for bridge-to-transplant use. In the U.S., the device is the subject of clinical trials for two indications: bridge-to-transplant under a continued access protocol and destination therapy. Our device is also available in other countries around the world under special access programs and limited commercial availability. As of December 31, 2010, the HeartWare System has been implanted in patients at over 70 health care sites in 18 countries.

Bridge-to-transplant

HeartWare's ADVANCE clinical trial is a Food and Drug Administration approved IDE study designed to evaluate the HeartWare® Ventricular Assist System as a bridge to heart transplantation for patients with end-stage heart failure. Between August 2008 and February 2010, 140 patients at 30 hospitals in the United States received the HeartWare investigational device. The per protocol analysis includes 137 patients in the investigational device cohort.

On December 27, 2010 HeartWare submitted to the FDA a Premarket Approval, or PMA, application seeking approval of the HeartWare System for the bridge-to-transplant indication. The PMA application was supported with data from our bridge-to-transplant clinical trial, named "ADVANCE", in the U.S.

IDE Supplements have allowed us to continue to enroll patients in our ADVANCE trial under a Continued Access Protocol ("CAP"). The CAP makes the HeartWare System available to patients and clinicians while also providing additional data for the FDA to evaluate prior to determining whether or not to approve the HeartWare System. The CAP patients will be enrolled and followed under a modified protocol of the ADVANCE trial.

On November 14, 2010, data from HeartWare's bridge to heart transplantation ("BTT") study, ADVANCE, was presented at the 2010 Scientific Sessions of the American Heart Association by co-principal investigator Keith Aaronson, M.D. M.S., Associate Professor in the Division of Cardiovascular Medicine and Medical Director of the Heart Transplant Program and Center for Circulatory Support at the University of Michigan, on behalf of the ADVANCE investigators.

Results from the ADVANCE clinical study showed that 92% of the investigational device patients met the per protocol primary endpoint of the trial, which was defined as alive on the originally implanted device, transplanted or explanted for recovery at 180 days. Results from the ADVANCE clinical study also demonstrated that 94% of the investigational device patients enrolled in the study achieved a survival endpoint at 180 days.

Results for the comparator arm of the study, derived from 499 contemporaneous patients from the Interagency Registry for Mechanically Assisted Circulatory Support ("INTERMACS") demonstrated 90% success of the primary endpoint at 180 days, as well as Kaplan-Meier survival at 180 days of 90%. Based on these results for the primary endpoint of the ADVANCE study, noninferiority of the investigational device was established [$p<0.001$].

Destination Therapy

In June 2010, we received conditional IDE approval from the FDA to begin enrollment in our destination therapy clinical study for the HeartWare System. Designed to enroll up to 450 patients at 50 U.S. hospitals, the non-inferiority study, which is named "ENDURANCE," is a randomized, controlled, unblinded, multi-center clinical trial to evaluate the use of the HeartWare System as a destination therapy in advanced heart failure patients. The study population will be selected from patients with end-stage heart failure who have not responded to standard medical management and who are ineligible for cardiac transplantation. Patients in the study will be randomly selected to receive either the HeartWare System or, as part of a control group they will be implanted with any alternative left ventricular assist device ("LVAD") approved by the FDA for destination therapy, in a 2:1 ratio. Each patient receiving the HeartWare System or control LVAD will be followed to the primary endpoint at two years, with a subsequent follow-up period extending to five years post implant. In August 2010, our first patient was implanted as part of the ENDURANCE trial and we received full IDE approval from the FDA in September 2010. As of the end of December 31, 2010, 24 of the 50 sites were initiated, and approximately 50 patients had been enrolled.

Other Clinical Activities

On January 24, 2011, The University of Michigan Cardiovascular Center and the University of Pittsburgh announced that they had been awarded grants from the National Heart, Lung and Blood Institute and HeartWare International, Inc. to conduct a study exploring the potential benefits of left ventricular assist devices, or LVADs, in patients who will be given earlier access to these devices. Our financial commitment for the study is up to $9.6 million of actual costs over the five-year trial period. The terms and conditions of the financial commitment are subject to completion of a definitive agreement. In the study, called REVIVE-IT, researchers will compare whether non-transplant eligible patients with heart failure less advanced than that of current LVAD recipients do better with implanted devices than with current medical therapy. The REVIVE-IT study device will be HeartWare's left ventricular assist device, the HVAD pump. The pilot study of approximately 12 U.S. sites, including Michigan and Pittsburgh, will include 100 patients.

Other Devices

Beyond the HeartWare System, we are also evaluating our new miniaturized device, known as the MVAD. The MVAD is based on the same technology platform as the HeartWare System but adopts an axial flow, rather than a centrifugal flow, configuration and is being developed in multiple designs. The MVAD designs are currently at the preclinical stage and undergoing animal studies focused on less invasive implantation techniques, in preparation for first-in-man studies. Each of the MVAD configurations is approximately one-third the size of the HVAD Pump. We believe that the MVAD designs will be implantable by surgical techniques that are even less invasive than those required to implant the HVAD Pump.

Operations

We began generating revenue from sales of the HeartWare System in August 2008 and have incurred net losses in each year since our inception. We expect our losses to continue as we advance and expand our clinical trial activities in the United States, continue to develop commercial markets outside of the United States and expand our research and development into next generation products, including the MVAD, and peripherals such as next generation controllers.

We have financed our operations primarily through the issuance of convertible notes and the issuance of shares of our common stock. Most recently, on December 15, 2010, the Company issued Convertible Senior Notes with an aggregate principal amount of $143.75 million pursuant to the terms of an Indenture dated as of December 15, 2010. The Convertible Senior Notes are senior unsecured obligations of the Company. The Convertible Senior 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, beginning on June 15, 2011. The Convertible Senior Notes will mature on December 15, 2017, unless earlier repurchased or converted. In February 2010, we closed a public offering, under a shelf registration on Form S-3 filed with the Securities and Exchange Commission on December 24, 2009, of approximately 1.77 million shares of our common stock at an offering price of $35.50 per share for aggregate gross proceeds of approximately $62.8 million. This amount includes the underwriter's exercise of their over-allotment option to purchase an additional 230,595 shares of our common stock at the offering price. In August 2009, we sold approximately 2.74 million shares of our common stock through private placements in the United States and Australia, which raised net proceeds of approximately $58.6 million

We are headquartered in Framingham, Massachusetts. We have an operations and manufacturing facility in Miami Lakes, Florida, a small development and operations facility in Sydney, Australia and a small distribution and customer service facility in Hannover, Germany. We are also renovating a second facility in Miami Lakes, Florida to enable us to meet expected increased demand in the future. As of December 31, 2010, we had 206 employees worldwide.

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 5.8 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, approximately 670,000 new cases are diagnosed annually and approximately 300,000 patient deaths are attributed to advanced heart failure.

Our Target Markets—Class III and Class IV Patients

Our devices target certain classes of advanced heart failure patients, specifically Class III and IV patients as defined by the New York Heart Association ("NYHA"). It is estimated that the number of Class III and Class IV heart failure patients worldwide is approximately 7 million and that approximately 20% of these patients could benefit from a circulatory assist device. 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 the 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 at a lower cost.

It is estimated that there are approximately 5 million Class III heart failure patients worldwide. Of these 5 million patients, we estimate that approximately 1 million patients are severely impacted by congestive heart failure, or CHF, 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, later-stage Class IV patients and they may be less willing to undergo the more invasive procedure required for the placement of the typical LVAD. We believe that up to one-third of these 1 million patients could be candidates for a less invasive surgical approach such as the one we are developing with the MVAD. We believe that a less invasive surgical approach should make more patients and their physicians comfortable with the benefits of the implant 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, such treatments and devices do not halt the progression of CHF. Pharmacologic management of CHF focuses primarily on increasing or stimulating the force of heart contractions. Medication regimens aim to improve the effectiveness of the heart's contractions and slow the rate of CHF progression. For later stage Class III and Class IV patients, 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 CHF. 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 result in end-stage heart failure patients resuming 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.

LVAD Treatment for Advanced Heart Failure

Circulatory assist devices are designed to take over 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 fully 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 LVADs, including a bridge to transplant study and a destination therapy study, reported in the August 2007 and November 2009 articles respectively in *The New England Journal of Medicine*.

A large population of end-stage heart failure patients can benefit from LVAD therapy, such as our HeartWare System. Within this population there are four different indications of use of LVADs: "bridge-to-transplant" therapy, "bridge-to-decision" therapy, "destination therapy" and "bridge-to-recovery" therapy.

Bridge-to-transplant therapy - Each year, the number of heart failure patients in need of a heart transplant exceeds the number of donor hearts that become available. According to the United Network for Organ Sharing, there were 2,229 transplants conducted in the United States in 2008, and as of February 11, 2011, 3,184 people are currently listed for heart transplant. The "*2009 Annual Report of the OPTN and SRTR: Transplant Data 1999-2008*" reported approximately 33% of transplant candidates spend one year or more on the waiting list. According to the Organ Procurement and Transplantation Network, or OPTN, approximately 30% of the patients listed for transplant in 2008 received an LVAD as a bridge to transplant or decision. Bridging the patient to transplant provides time to stabilize and clinically optimize the patient until a suitable donor heart becomes available. We expect this percentage of patients on the waiting list who receive LVAD support as a bridge-to-transplant to increase as surgeons and cardiologists become more familiar with the technology and confidence in the procedure grows in line with improving clinical data and device reliability.

Bridge-to-decision therapy — LVADs are increasingly being used to assist physicians in determining which patients previously not eligible for a transplant should be listed. Rather than disqualify certain patients based upon their pre-LVAD implant status, many patients now receive LVAD implants and then the physician subsequently evaluates whether or not to list them for heart transplant in the future. The LVAD "bridges" the physician's listing decision and enables them to determine whether or not the patient will be a good transplant candidate by evaluating their overall health status after time spent on the LVAD. This indication is best reflected in the National Institute of Health's, or NIH, sponsored INTERMACS registry, which showed in June 2010 that 43% of registered patients were listed for heart transplant at the time of their implant, while 42% were listed as "bridge to candidacy." Of note, 11.5% were registered as destination therapy.

Destination therapy - Circulatory assist devices can also be used as a permanent or lifetime therapy in medically refractory advanced heart failure patients who are deemed ineligible for heart transplantation due to, for example, their age or the presence of other diseases. The NIH estimates that destination therapy represents a long-term option for up to 100,000 patients in the United States. For these late stage patients, drug therapy historically has been the only alternative, with the 12-month mortality rate of approximately 75%. We believe that device durability and reliability, together with ease and perceived risk of implantation and better clinical outcomes, are important factors in determining whether destination therapy LVADs will become accepted by physicians and patients.

Bridge-to-recovery therapy - Circulatory assist devices that provide prolonged unloading of the heart muscle, or myocardium, have been claimed to lead to recovery of the heart in some patients. In these patients, the combination of ventricular unloading combined with pharmaceutical therapy enables the physician to wean the patient from the pump and eventually remove it. This potential application of LVADs was cited in the November 2006 *New England Journal of Medicine* article that described a recovery rate of approximately 75% in the Harefield Hospital study. While there can be no certainty that these results will be replicated or occur with sufficient repeatability in similar clinical trials, we believe that if use of LVADs in these circumstances achieves widespread physician acceptance, the potential market for use of our HeartWare System in bridge-to-recovery therapy could increase significantly since removal of the device reduces the potential clinical risks associated with pumps that are left in place for multiple years.

Our Solution and Products

Proprietary Pump Technology

The HeartWare 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 completely "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 System

The first product in our portfolio, the HeartWare System, is comprised of the HVAD Pump, a small, permanently implantable LVAD, 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 the only full-output pump implantable in the pericardial space, directly adjacent to the heart. It is also the only pump designed to be implanted above the diaphragm in all eligible patients. We believe the implanting in the pericardial space generally leads to significantly shorter surgery time and a less invasive procedure relative to alternative devices, which are normally implanted in the abdomen.

Device reliability of the HeartWare 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 minimize the risk of pump-induced damage to blood cells.

The HeartWare System has been approved for sale in Europe since early 2009. In the United States, we must obtain Premarket Approval, or PMA, before the HeartWare System can be commercialized. That PMA application was submitted to the FDA in late December 2010.

The HeartWare MVAD

The MVAD, currently under development, is a miniaturized device intended for chronic heart failure patients which is capable of being delivered in various configurations. The current design is a full-output axial flow pump with a fully suspended rotor and a displacement volume approximately one-third that of the HVAD Pump. The MVAD has been shown in animal trials to have comparable blood flow characteristics to the HVAD Pump and thus we believe should support the human heart's full cardiac output. Implantation of the MVAD is expected to require surgery less invasive than even the HVAD implant. The device is expected to be implanted without the surgeon making an incision through the midline of the breastbone, or sternum, in order to gain access to the heart (a median sternotomy).

We believe it is likely that more patients will be willing to undergo a less invasive surgical procedure than are currently comfortable with the full sternotomy required for an LVAD implantation using presently available technologies. We expect physician referrals to increase for the same reason. We anticipate that the MVAD will increase the potential pool of eligible, destination therapy patients in the United States. We have six different versions of the MVAD moving through preclinical evaluations and we expect to commence Good Laboratory Practices ("GLP") animal studies, the prelude to human clinical studies, for the first MVAD version early in 2011.

The first MVAD preclinical studies began in August 2005. More than 75 animal studies have been conducted, with the recent focus being on novel, less invasive implantation techniques. Before the MVAD product will be available for commercial sale, we will need to achieve the following milestones:

- finalization of surgical implantation techniques and procedures, including identification of necessary surgical implant tools;
- completion of pump and system designs;
- completion of confirmatory in-vivo (animal) studies;
- development and verification of system peripherals (e.g., controller, batteries, power adapters) utilizing the HeartWare System components;
- approval of and successful completion of a clinical trial; and
- receipt of regulatory approvals for commercialization.

Enhanced Quality of Life with Smaller Peripherals and Implantable Devices

Currently, the HeartWare System and all commercially available LVADs are powered by a controller and battery pack worn 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 and/or acquire the right to use smaller patient peripherals, lighter and longer lasting batteries, and an implantable system including transcutaneous energy transfer, or TET, which will be compatible across the HeartWare family of pumps. Since TET permits implanted batteries to be charged by external devices, TET will eliminate the need for a driveline and allow implantation of the complete LVAD system, including the controller and batteries.

We are still in the process of assessing the potential appeal of a TET system to physicians and patients, however, we believe that a fully implantable system will be appealing to physicians and patients. The system will enable patients to charge their implanted batteries and "detach" for periods of time, thereby allowing them to more easily engage in normal daily activities and further improving their quality of life.

Our implantable system is in the early stages of development. Before the implantable system will be available for clinical trials, there must be significant improvements in battery technology and we must undertake significant work, including building functional prototypes of the implantable system, completing animal studies, developing manufacturing processes and completing formal verification testing, Good Laboratory Practices ("GLP") animal testing, human clinical trials and regulatory approvals.

We are also working to develop a smaller controller/battery unit to provide our patients with more freedom and mobility. We believe it is important to continue to innovate in this area in order to improve our patients' quality of life.

Our Business Strategy

Our primary goal, above all else, is to focus on optimizing patient outcomes. To this end, we are leading innovation in the LVAD 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 simultaneously increase the number of patients who can benefit from our products.

We believe that our technology portfolio provides us with a significant 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 directly to VAD centers throughout Europe and through a limited number of distributors. With the receipt of CE Marking in January 2009, we began to develop the necessary infrastructure to support commercial sales in Europe. During the course of 2010, we expanded our staffing in international markets to 12 clinical and sales specialists. In 2010, we leveraged interest in our products by training and initiating additional VAD centers, adding distribution partners and expanding the number of countries from which we generated product sales. We generated sales in 2010 from customers in 17 countries outside of the United States. In the future, we intend to build wider distribution channels and ordering systems to deliver our products to the European market on a wider commercial scale. In 2011 we intend to continue to seek regulatory approval to commercially sell our device internationally outside of the European market.

Obtain regulatory approval in the United States — In September 2008, we received full IDE approval from the FDA and commenced a 150 patient bridge-to-transplant clinical trial in up to 28 centers. The FDA allowed an increase to 40 centers in 2009, and in February 2010, we completed enrollment of this trial with 140 patients implanted with the HeartWare System. The remaining 10 patients were enrolled but did not receive an implant of the HeartWare System because they failed to meet the trial's inclusion and exclusion criteria. We filed a PMA application with the FDA in late December 2010.

In June 2010, we received conditional IDE approval from the FDA to begin enrollment in our destination therapy clinical study for the HeartWare System. Designed to enroll up to 450 patients at 50 U.S. hospitals, the non-inferiority study, which is named "ENDURANCE," is a randomized, controlled, unblinded, multi-center clinical trial to evaluate the use of the HeartWare System as a destination therapy in advanced heart failure patients. Each patient receiving the HeartWare System or control LVAD will be followed to the primary endpoint at two years, with a subsequent follow-up period extending to five years post implant. In August 2010, our first patient was implanted as part of the ENDURANCE trial and we received full IDE approval from the FDA in September 2010.

Focus on continuous product development — In parallel with the clinical development of the HeartWare System, we plan to advance the development of our next generation products, such as our MVAD and to enhance our existing HeartWare System peripheral equipment. Our first MVAD animal studies began in August 2005, and in 2007 through 2010 we conducted more than 75 animal studies focused on minimally invasive surgical techniques. We expect assessment and development and/or enhancement work for the MVAD, the TET system and our existing HeartWare System peripheral equipment to continue for the foreseeable future. The MVAD designs are currently at the preclinical stage and undergoing animal studies focused on less invasive implantation techniques, in preparation for first-in-man studies. The primary objective of these projects is improved ease of implantation and use of the HeartWare System that we believe will enhance market acceptance.

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 heart centers around the world and continue to expand this network. We believe these relationships are key to our growth as they help to drive clinical awareness of our products.

Sales and Marketing

Our sales and marketing strategy is to educate and promote the benefits of left ventricular assist devices for the treatment of clinical heart failure among a variety of health care professionals. Outside of the U.S., we market directly to cardiac centers and hospitals that perform heart transplants. In the U.S., until we receive the necessary regulatory approvals, our device is not actively marketed but the device is available through clinical studies.

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 and industry representatives. Key to the development of our business is optimizing patient outcomes via effective training and clinical end-user support programs and resources.

More than 900 patients globally have been implanted with the HeartWare Ventricular Assist System. At December 31, 2010, the HeartWare System has been implanted in patients at over 70 health care sites in 18 countries. To support commercial sales and enrollments in clinical trials we have created field teams including sales and marketing personnel and clinical specialists to educate and service this larger and rapidly growing patient base. 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 about our system at scientific symposia, congresses, and trade shows, as well as publish for mass distribution in peer reviewed cardiovascular journals.

In addition, our product management team conducts market research on end-user preferences and unmet needs, indentifies ways to evergreen our HVAD technology with new enhancements, and works with research and development on new technologies that meet newly identified needs that are not currently addressed with our current platform of products.

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.

We have an extensive patent portfolio which includes, as of December 31, 2010, 21 issued U.S. patents and 10 issued Australian patents, 5 issued patents in Japan, Germany, the United Kingdom and France, as well as patents issued in the Netherlands, Spain, Italy, Korea, Canada and Israel. We also have 25 pending U.S. patent applications and a number of international patent applications filed under the Patent Cooperation Treaty, as well as in Canada, Japan, Europe, Australia, China, India, Korea and Israel.

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. 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; and
- use of platinum alloy for blood pump impellers.

Major patents and pending patent applications covering technologies for our HeartWare System are scheduled to expire at various times between 2016 and 2027. Patents and patent applications covering technologies for our MVAD pump 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. Accordingly, we intend to pursue and defend aggressively patent protection on our proprietary technologies. We have previously asserted claims and responded to counterclaims relating to our intellectual property. In connection with such processes, we entered into a settlement with various parties pursuant to which the parties or their respective successors or assigns may commercialize competing technologies or products that would have otherwise been precluded by our patents subject to the agreement. See Item 1A. "Risk Factors".

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 any such disputes or litigation arise, we may seek to enter into a royalty or licensing arrangement. However, such an arrangement may not be available on commercially acceptable terms, if at all. We may decide, in the alternative, to litigate the claims or 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. We have had communication with various parties regarding certain of our patents which are material to our business and these are discussed in Item 1A. "Risk Factors."

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.

HEARTWARE, MVAD, HVAD, KRITON and various Company logos are the trademarks of the Company in the United States, Europe, Australia and certain other countries.

Government Regulation

United States

Our products will be 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;
- premarket approval;
- advertising and promotion;
- distribution;
- product sales and post-market activities;
- import and export;
- medical device (adverse event) reporting; and
- field corrective actions (e.g., recalls).

Premarket Approval

Each of our devices will be 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. The process of obtaining PMA can be costly, lengthy and uncertain. A PMA application must be supported by extensive data including, but not limited to, technical, preclinical and clinical trials to demonstrate the safety and effectiveness of the device to the FDA's satisfaction. Among other information, the PMA application 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 application 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, typically one year, and can take up to several years. During this 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 will conduct a pre-approval inspection of our and our key suppliers' facilities to evaluate compliance with the quality system regulation. They will also conduct a Bioresearch Monitoring ("BIMO") inspection of the clinical trial including some of the clinical data sites. Under the Medical Device User Fee and Modernization Act of 2002, the fee to submit a PMA application can be up to $200,775. We qualified for a small business exemption that allowed us to file our first PMA application at no charge. 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.

We have approval from the FDA to implant additional bridge-to-transplant patients under the Continued Access to Investigational Devices program ("Continued Access") in any U.S. center that implanted a patient in our ADVANCE bridge-to-transplant clinical study.

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 site at which a clinical trial is being performed 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 and manufacturing processes;
- 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; 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. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- 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 pre-market approval of new products;
- withdrawing pre-market approvals that are already granted; and
- criminal prosecution.

European Union

The primary regulatory environment in Europe is that of the European Union, or EU which consists of 27 member states in Europe. The EU has adopted two directives that cover medical devices—Directive 93/42/EEC covering medical devices and Directive 90/385/EEC for active implantable medical devices, as well as 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 HeartWare System in January 2009.

Australia

In Australia, the Therapeutic Goods Administration, or TGA, is responsible for administering the Australian Therapeutics Goods Act. The Office of Devices, Blood and Tissues is the department within the TGA responsible for devices. The TGA recognizes five classes of medical devices and HeartWare's circulatory assist device falls under the category of "active implantable medical devices."

The Australian Register of Therapeutic Goods, or ARTG, controls the legal supply of therapeutic goods in Australia. The ARTG is the register of information about therapeutic goods for human use that may be imported, supplied in, or exported from Australia. Any use of an unapproved medical device in humans, even in pilot trials, requires an exemption from the requirement for inclusion on the ARTG.

We currently sell the HeartWare System to centers in Australia on a limited basis, under a Special Access program. We expect to receive TGA approval in 2011.

Other International Regulations

We are also subject to international regulations in other countries where our products are sold. We currently have limited sales to customers in countries outside of the EU, U.S. and Australia including Malaysia, Canada and New Zealand. 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 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

Recent 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 ("PPACA") 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 PPACA and the Reconciliation Act (collectively, the "Acts"), when taken together, impose a 2.3% excise tax on the sale of certain medical devices that will take effect in 2013. In addition, it is possible that standard setters or regulators may address certain unique aspects of the accounting for the Acts in the future. In light of the inherent uncertainty of how these Acts and other companion legislation, if any, will be implemented and applied, we are unable to fully predict the actual impact on our business.

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

A federal law commonly known as the Medicare/Medicaid 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 HeartWare 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 provide reimbursement to healthcare professionals for training patients on the use of the HeartWare System and our other products. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance, which can be substantial.

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.

Third Party Reimbursement

In the United States, hospitals and doctors generally rely on third-party payers, 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 that receive LVADs and all patients that receive heart transplants are eligible for MD-DRG 1 reimbursement. Using the 2011 published 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 center geography and patient circumstances. In addition, when LVAD patients are discharged from the hospital and then readmitted for transplantation, hospitals may qualify for 2 separate MS-DRG 1 or 2 payments.

We believe that our products will be Medicare-eligible and therefore that they should be entitled to reimbursement. Several insurance providers have also implemented U.S. policies for circulatory assist devices, including Blue Cross and Blue Shield Plans, Aetna, Cigna, United Healthcare and others but such coverage may not be available if insurance providers refuse to cover Medicare approved investigational devices exempt (IDE) Category B2 clinical trials. We believe that many private insurers will cover our devices if they are also covered by Medicare. 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. In 2010, we added a reimbursement professional to our staff and will continue to build this team in 2011 with a view to improving insurance reimbursement outcomes for the HeartWare 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 LVAD's fall into that category of resource intensive procedures. In those hospitals that perform LVAD implantation, we believe that there are adequate budgets to purchase circulatory assist devices. As in the United States, we believe that in Europe certain groups of physicians will drive the decision as to which LVAD to purchase.

Competition

Competition in the LVAD 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 LVAD 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 only smaller, less invasive, reliable and durable devices will remain as viable alternatives for the treatment of congestive heart failure. In the long run, we believe our continued competitive success will depend on our ability to maximize patient outcomes and develop innovate products.

Our principal competitors in the implantable LVAD space include Thoratec Corporation, and to a lesser extent World Heart Corporation, Jarvik Heart, MicroMed Technology, Inc, Berlin Heart AG, and Terumo Heart, Inc., and a range of other smaller, specialized medical device companies with devices at varying stages of development.

We believe that the key features of the HeartWare System that provide us with certain advantages over our competitors' known products include:

- small device size which allows for implantation in the pericardial space immediately surrounding the heart in all patients unlike other full-output LVADs that are currently available;
- our proprietary, hybrid technology system for suspending the pump impellers, providing a "wearless" pumping system; and
- a design that includes a wide-bladed impeller and integrated inflow cannula, which is to designed to optimize blood flow characteristics.

Although we believe the HeartWare System provides us with competitive advantages over our competitors known products, we note that:

- our product's success is dependent on our clinical trials proving the safety and efficacy in the U.S.;
- our market is an emerging market and is reliant upon acceptance of LVAD technology.

See Item 1A. "Risk Factors." for additional information.

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 increase significantly as we continue to research and develop improvements to the HeartWare System, research the application of, and develop our miniaturized heart pump technology, conduct additional clinical trials and hire additional employees. For the years ended December 31, 2008, 2009 and 2010 we incurred research and development expenses of $18.6 million, $15.1 million and $33.1 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, sustaining engineering and research and development activities. We manufacture products for commercial sale internationally, primarily in Europe, and for clinical trials in the United States and under special access programs in certain countries outside the U.S.

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

In order to sell our product commercially in the European Union, the Company is 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, the company received a Full Quality Assurance Certificate, CE 540273 from BSI. It signifies that the HeartWare Ventricular Assist 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.

We do not presently have supply agreements with some of our key suppliers and we have not secured second source suppliers for all of our supplies. See Item 1A. "Risk Factors" for additional information.

Employees

As of December 31, 2010, we had 206 employees, of whom approximately 150 employees are engaged in operations activities including research and development, quality assurance and manufacturing activities, 36 are engaged in marketing and clinical activities and 20 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. We consider our relations with our employees to be good.

Legal Proceedings

We are not currently involved in any material legal proceedings.

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. Subsequent to the redomiciliation, HeartWare Limited was renamed HeartWare Pty. Limited. 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.

HeartWare Limited acquired 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 LVAD System since approximately 1995.

In May 2003, Kriton filed for protection from creditors under Chapter 11 of the United States Bankruptcy Code. On May 20, 2003, Kriton and its lead investor Apple Tree Partners I, L.P., proposed a joint plan of liquidation for Kriton. On June 20, 2003, the United States Bankruptcy Court of the Southern District of Florida issued a court order confirming the plan of liquidation. This court order, together with a supplemental court order approving a settlement between Apple Tree Partners and various stockholders of Kriton issued on July 3, 2003, approved the sale of substantially all the assets of Kriton to HeartWare, Inc. 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. The assets included all of Kriton's patents and other intellectual property which were assigned to HeartWare, Inc.

In connection with the asset purchase, HeartWare, Inc. issued Series A-1 and Series A-2 Preferred Stock to certain creditors of Kriton. The Series A-1 and Series A-2 Preferred Stock do not have any voting rights or the right to receive dividends but entitle the holders thereof to receive upon certain liquidation events of HeartWare, Inc. (but not the liquidation of or change of control of the parent of HeartWare, Inc.) an amount equal to $10 per share of Series A-1 and an amount of $21 per share of Series A-2. HeartWare, Inc. continued to operate as an independent entity until January 24, 2005, when HeartWare Limited acquired all of the voting stock of HeartWare, Inc. in exchange for the issuance by HeartWare Limited of 2.5 million shares (as adjusted for a reverse split in the ratio of 35 to 1) and a convertible note in the principal amount of $1.1 million. The convertible note was redeemed during the third quarter of 2008.

Item 1A. Risk Factors

Our business faces many risks. We believe the risks described below are material risks facing the Company. However, the risks described below 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 Securities and Exchange Commission.

Risks Related to Our Business and Industry

We have incurred operating losses since our inception and anticipate that we will continue to incur operating losses for the foreseeable future.

We have incurred net losses since our inception, including net losses of $29.4 million, $23.8 million and $21.9 million for the fiscal years ended December 31, 2010, 2009 and 2008, respectively. As of December 31, 2010, our accumulated deficit was $127.3 million. Currently, we only have one product approved for sale in Europe. None of our products are approved for commercial sale in the United States although we presently derive revenue from reimbursed sales of the HeartWare system for use in clinical trials in the United States. 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:

- manufacturing product;
- continuing to conduct multiple clinical trials;
- further product research and development for next generation products and peripherals and efforts to sustain and maintain incremental improvements to existing products and peripherals;
- building our service capabilities to meet growing customer demand;
- growing, maintaining and protecting our intellectual property;
- seeking regulatory approvals;
- expanding our sales and marketing capabilities on a global basis, including building a team to support U.S. commercialization should the FDA approve our device for marketing in the U.S.;
- increasing our manufacturing operations to meet increasing 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 both the United States and Australia.

To become and remain profitable, we must succeed in developing and commercializing products with significant market potential. This will require us to succeed in a range of challenging activities, including all of the activities listed above. We may never succeed in these activities, and we may never obtain regulatory approvals in the markets in which we expect to operate or otherwise generate revenues sufficient to achieve profitability. Further, the markets in which we operate may contract or we may not otherwise obtain significant market share so as to support our ongoing business operations. If we do achieve profitability, we may not be able to sustain it.

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

As of December 31, 2010, our total consolidated indebtedness totaled $88.9 million, all of which constituted indebtedness under our 3.5% Convertible Senior Notes due 2017 in the principal amount of $143.75 million net of discounts. Our ability to make payments on, and to refinance, our convertible senior notes, any 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 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 senior notes or on their maturity, or to fund our liquidity needs, we may be forced to refinance all or a portion of our indebtedness, including the convertible senior notes, on or before the maturity thereof, 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 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 senior notes, the holders of the convertible senior notes and/or the trustee under the indenture governing these notes may accelerate the payment of our obligations under these notes, which could have a material adverse effect on our business, financial condition and 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 and adverse changes in government regulation;
- 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 and 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 notes will be entitled to convert the notes at any time during specified periods at their option. If one or more holders elect to convert their 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 manufacture a Class III device implanted in the heart that subjects us to numerous risks.

There are risks associated with implanting our device in end stage heart failure patients, 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; should our patients experience injury due to these events, they may sue us. Any of these occurrences could have an adverse impact on our operations and financial results and condition.

Our products have not yet been approved for commercial sale within the United States, and our success will depend heavily on our ability to obtain FDA approval to market our HeartWare System in the U.S. for our initial and any future indications. If we are unable to complete, or experience significant delays in the completion of, our U.S. trials, our ability to obtain regulatory approval to commercialize our products within the United States, the largest medical device market in the world, and our ability to generate revenues, will be materially adversely affected. Delays or inability to complete trials outside of the U.S. can also negatively impact our business.

On January 30, 2009, we received approval for CE Marking and subsequently began generating net sales in Europe. However, future revenue will be limited if we do not receive regulatory approval to commercially sell our products in the United States. We submitted a premarket approval application to the U.S. FDA for our BTT trial in December 2010, and are currently conducting a U.S. clinical trial for the DT indication.

Completion of any of our clinical trials could be delayed or adverse events during a trial could cause us to amend, repeat or terminate the trial. If this were to happen our costs associated with the trial will increase, and it will take us longer to obtain regulatory approvals and commercialize the product or we may never obtain such regulatory approvals. Our clinical trials may also be suspended or terminated at any time by regulatory authorities, the Data Safety and Monitoring Board or by us including during the closing stages of enrollment of the trial and the subsequent patient date follow-up period in the event that, for example, there should be a series of adverse clinical events such as stroke, bleeding or pump exchanges. Any failure or significant delay in completing clinical trials for our products will 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 our competitors undertaking similar clinical trials or having functionally comparable products that have received approval for sale;
- failure of patients to complete the clinical trial;
- patients preferring to use approved devices or other experimental treatments or devices rather than our HeartWare System;
- unforeseen safety issues;
- perceived lack of product efficacy during clinical trials;
- inability or unwillingness of patients or medical investigators to follow our clinical trial protocols;
- inability to monitor patients adequately during or after treatment;
- risks associated with trial design, which may result in a failure of the trial to show statistically significant results even if the product is effective;
- governmental and regulatory delays or changes in regulatory requirements, policies or guidelines;
- varying interpretation of data by regulatory agencies; and
- perceived lack of product efficacy during clinical trials;

The process of obtaining marketing approval or clearance from the FDA for our HeartWare System, or any future products or enhancements or modifications to any products, could:

- take a significant period of time;
- require the expenditure of substantial resources;
- involve rigorous pre-clinical and clinical testing;
- require changes to our products; and
- result in limitations on the indicated uses of the products.

Assuming we are successful at timely filing the required FDA regulatory premarket approval applications with respect to trials for indications for our HeartWare System, there can be no assurance that we will receive the required approvals from the FDA or**,** if we do receive the required approvals, that we will receive them on a timely basis or that we will otherwise be able to satisfy the conditions of such approval, if any. The failure to receive product approval clearance by the FDA, or any significant delay in such receipt, will have a material adverse effect on our business, financial condition or results of operations. For example, we submitted a premarket approval application to the U.S. FDA for our BTT trial in December 2010, and any failure to obtain an approval of that application, or a delay in receiving approval, could have an adverse impact on our business.

While the U.S. is the largest medical device market in the world, the risks described above concerning U.S. trials and regulatory approval also apply to our foreign clinical trials and regulatory filings. If we cannot timely conduct foreign trials in our major target markets (to the extent required in order to market our device in such locations) and receive timely approval in such jurisdictions to market our device, our business will suffer.

We currently rely entirely on sales of our sole product, the HeartWare System, to generate revenues. Our products may never achieve 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 product is the HeartWare System, which we introduced to the European market in January 2009 and which does not have regulatory approval in the United States. We expect to continue to derive substantially all of our revenue 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.

Even if we obtain the necessary regulatory approvals in all jurisdictions to commercialize the HeartWare System or any other product that we may develop, our products may not gain market acceptance among physicians, patients, health care payers or the medical community.

The degree of market acceptance of any of the devices that we may develop will depend on a number of factors, including:

- the perceived effectiveness of the product;
- the prevalence and severity of any adverse events or side effects especially as it relates to survival, quality of life, stroke and bleeding;
- potential advantages over alternative treatments or competitive products;
- the strength of marketing and distribution support;
- the strength and perceived advantages of our peripherals such as the monitor, controller and batteries; and
- sufficient third party coverage or reimbursement.

If the HeartWare System, or any other product that we may develop, does not achieve an adequate level of acceptance by physicians, patients, health care payers and the medical community, we may not generate or maintain positive gross margins and we may not become profitable or be able to sustain profitability. If we do achieve market acceptance of our products, we may not be able to sustain it or otherwise achieve it to a degree which would support the ongoing viability of our operations.

Our ability to achieve profitability from a current net loss level will depend on our ability to increase gross revenue and reduce the per unit cost of producing the HeartWare System by increasing our customer orders and manufacturing volume.

Currently, gross sales and the gross profit from those sales of the HeartWare System are not sufficient to cover our operating expenses. To achieve profitability, we need to, among other things, substantially reduce the per unit cost of our products. We believe this can be achieved by decreasing our product assembly costs and increasing our manufacturing volume, which will allow for volume purchase discounts to reduce our raw material and component costs and improve absorption of manufacturing overhead costs. 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 severely constrained. Any increase in manufacturing volumes must be accompanied by a concomitant increase in customer orders. As part of our efforts to prepare for commercialization in the U.S., we have added an additional manufacturing facility in Miami Lakes, Florida and have entered into a lease for such purposes. Such lease will increase our operating expenses. The occurrence of one or more factors that negatively impact sales of our products or our ability to forecast future sales may prevent us from achieving our desired increase in manufacturing efficiency, which would prevent us from attaining profitability.

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 Thoratec Corporation and World Heart Corporation, as well as several private companies, such as Jarvik Heart, Inc, Circulite, Evaheart and Terumo Heart, Inc. Some of these competitors have significantly greater financial and human resources than we do and have established reputations or approved products or significantly greater name recognition, as well as distribution channels and sales and marketing capabilities that are significantly larger and more established than ours. For example, Thoratec Corporation has received marketing approval in the United States for HeartMate II for both destination and bridge-to-transplant indications. Additional competitors may enter the market, and we are likely to compete with new companies in the future. We also face competition from other medical therapies which may focus on our target market as well as competition from manufacturers of pharmaceutical and other devices that have not yet been developed. Competition from these companies could adversely affect our business.

In addition, in Europe our customers are geographically dispersed and, at this stage, a significant portion of our revenue is sourced in Germany among a small number of clinical sites, which also use other competing products. If these sites were to cease using our products or use our products on a reduced or inconsistent basis, such events would have a material adverse effect on our financial condition and results of operations.

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;
- product performance and design;
- product safety;
- sales, marketing and distribution capabilities;
- comparable clinical outcomes;
- success and timing of new product development and introductions; and
- intellectual property protection.

We have limited sales, marketing and distribution experience.

To develop and increase sales, distribution and marketing capabilities, we will have to invest significant amounts of financial and management resources. In developing these sales, marketing and distribution functions ourselves, we will face a number of risks, including:

- we may not be able to attract and build a significant, successful or qualified marketing or sales force;
- the cost of establishing, training and providing regulatory oversight for a marketing or sales force may be substantial; and
- there are significant legal and regulatory risks in medical device marketing and sales, and any failure to comply with all legal and regulatory requirements for sales, marketing and distribution could result in enforcement action by the FDA or other authorities that could jeopardize our ability to market the product or could subject us to substantial liability.

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

If we are unable to produce sufficient quantities of our HeartWare 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, even if we are able to produce 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 substantially 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 developing 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 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 HeartWare System in sufficient quantities to meet future demand.

If we are unable to manufacture a sufficient or consistent supply of the HeartWare System or any other product we are developing, or if we cannot do so efficiently, our revenues, business and financial prospects would be adversely affected.

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 revenues. To date, the majority of our revenues have been sourced from international sales, mainly in Europe and denominated in Euros, while most of our expenditures are incurred in U.S. dollars. We presently derive revenue in the United States from our clinical trials but until our products receive regulatory approval in the United States, if ever, our United States sourced revenue will likely constitute less than half of our net revenues.

With limited exceptions our international sales will be 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 revenues and earnings. Due to the size and stage of development of our operations and revenues, we do not presently mitigate our exposure to exchange risk other than by holding the majority of our funds in U.S. dollars or U.S. dollar denominated investments.

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.

Revenue generated from the HeartWare System is currently limited to commercial sales outside of the U.S. (particularly in the EU where we enjoy CE Marking), clinical trials within the United States, and through special access programs in other countries. Depending on a range of outcomes, especially our achievement 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 on terms favorable to us, or at all. If we raise additional funding through the issuance of equity 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.

In addition, our operating subsidiary, HeartWare, Inc., issued Series A-1 and Series A-2 Preferred Stock to certain creditors of Kriton Medical, Inc. when HeartWare, Inc. purchased substantially all of the assets of Kriton in July 2003. The Series A-1 and Series A-2 Preferred Stock do not have any voting rights or the right to receive dividends but entitle the holders thereof to receive upon certain liquidation events (including deemed liquidation events, which are defined as a merger or consolidation of HeartWare, Inc., the sale of all or substantially all of its assets or the sale of a majority of its voting power) of HeartWare, Inc., an amount equal to $10 per share of Series A-1 and an amount equal to $21 per share of Series A-2, which currently represent an aggregate liquidation preference of $15 million. Such rights or any other similar rights in the future, to receive a payment if there is a deemed liquidation event of HeartWare, Inc. may restrict our ability to restructure our Company and its operations and could inhibit our ability to obtain financings.

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, product approvals and clearances by the FDA or other regulatory bodies can be withdrawn due to failure to comply with regulatory standards or the occurrence of problems following initial approval. 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. The FDA enforces the QSR through periodic unannounced site inspections. 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, could 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 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.

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 issues could result in recalls, substantial costs and write-downs; this could also lead to delay or termination of our trials.

Our products are subject to various regulatory guidelines, involve complex technologies and are perishable. Identified quality problems, such as failure of critical components such as batteries or controllers, or the failure of third parties to supply us with sufficient 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. Quality issues could result in the rework, recall or replacement of entire lots of products, substantial costs and write-offs and harm to our business reputation and financial results. Further such activities could adversely affect our relationships with our customers or affect our reputation which could materially adversely affect our earnings, results and financial viability.

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

Even if we obtain regulatory approvals in specific jurisdictions to commercialize the HeartWare System or any other product 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 licensing may differ from those of the FDA. Some jurisdictions may even require additional trials be conducted. 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.

If we fail to obtain and maintain adequate level of reimbursement for our products by third party payers, 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 payers 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. Payers may attempt to limit coverage and the level of reimbursement of new therapeutic products or experimental devices. Government and other third party payers also continually attempt to contain or reduce the costs of health care by challenging prices charged for health care products and services.

To obtain reimbursement or pricing approval in some countries, we may be required to produce clinical 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 any 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 payers may adversely affect the demand for our products currently under development and limit our ability to sell our product candidates 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. For example, the American Recovery and Reinvestment Act of 2009 includes funding to study the comparative effectiveness of health care treatments and strategies. This funding will be used, among other ways, to conduct, support or synthesize research that compares and evaluates the risk and benefits, clinical outcomes, effectiveness and appropriateness of medical products. Although Congress has indicated that this funding is intended to improve the quality of health care, it remains unclear how the research will impact coverage, reimbursement or other third-party payer policies.

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 revenues would be materially adversely affected. During 2009 and 2010, we were unable to implant a significant number of patients under our IDE in the United States as the relevant insurance providers refused to provide reimbursement for our products on the basis that our products are "experimental" and do not have the requisite regulatory approval in the United States. If this practice reoccurs then this would materially adversely affect our revenues, earnings, business and stock price.

If hospitals do not conduct or encourage the conduct of destination therapy, or DT, procedures using the HeartWare System in the future, market opportunities for our product will be diminished.

While we cannot currently promote a DT indication for our device as such indication is not approved, if physicians and hospitals do not conduct or encourage the conduct of destination therapy procedures using our products in our current U.S. DT trial, or in the future when we either have an approved DT indication or the physician permissibly and legally determines to prescribe our device for such indication as an off label use, our market opportunities will be diminished. 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 of destination therapy procedures;
- cardiology and referring physician education, and their commitment to destination therapy;
- the economics of the destination therapy procedure for individual hospitals, which includes the costs of the LVAD and related pre- and post-operative procedures and their reimbursement; and
- the economics of hospitals not conducting a destination therapy procedure, including the costs and related reimbursements of long-term hospitalization.

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

The long and variable sales and deployment cycles for our ventricular assist device, or VAD, systems 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 most of our customers. In addition, cardiac centers that buy the majority of our products are usually led by cardiac surgeons who are heavily recruited by competing centers or by centers looking to increase their profiles. When one of these surgeons moves to a new center we sometimes experience a temporary but significant reduction in purchases by the departed center 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.

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, difficulties in the financial services sector, tight credit markets, softness in the housing 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 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. We cannot predict the timing, strength or duration of the lingering effects of the severe global economic downturn or the timing or strength of the subsequent recovery. Healthcare spending in the United States and foreign jurisdictions has been, and is expected to continue to be, negatively affected by these economic trends. For example, patients who have lost their jobs may no longer be covered by an employee-sponsored health insurance plan and patients reducing their overall spending may eliminate purchases requiring co-payments. Since the sale of the HeartWare System to a new patient is generally dependent on the availability of third-party reimbursement and normally requires the patient to make a significant co-payment, the impacts of the effects of the recession on our potential customers may reduce the referrals generated and thereby reduce our customer orders. Similarly, the impacts of the challenging economy on our existing customers may cause some of them to cease purchasing HeartWare Systems and this will reduce our revenues, 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 has impacted the financial stability of many private health insurers. As a result, it has been reported that some insurers are scrutinizing claims more rigorously and delaying or denying reimbursement more often. Since the sale of the HeartWare System is generally dependent on the availability of third-party reimbursement, any delay or decline in such reimbursement will adversely affect our revenues.

Healthcare policy changes, including recent federal legislation to reform the U.S. healthcare system, 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 below, recent federal legislation would impose significant new taxes on medical device makers such as us. The adoption of some or all of these proposals, including the recent federal legislation, could have a material adverse effect on our financial position and results of operations.

On March 23, 2010, the Patient Protection and Affordable Care Act ("PPACA") 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 PPACA and the Reconciliation Act (collectively, the "Acts"), when taken together, impose a 2.3% excise tax on the sale of certain medical devices that will take effect in 2013. In addition, it is possible that standard setters or regulators may address certain unique aspects of the accounting for the Acts in the future. In light of the inherent uncertainty of how these Acts and other companion legislation, if any, will be implemented and applied, we are unable to fully predict the actual impact on our financial statements. Other elements of this legislation such as comparative effectiveness research, an independent payment advisory board, 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.

Our manufacturing facilities and the manufacturing facilities of our suppliers must comply with applicable regulatory requirements. If we fail to achieve regulatory approval for these 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 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 CE marking in Europe. 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 and record-keeping and quality assurance efforts and subject us and our suppliers to potential regulatory inspections and stoppages. If we or our suppliers fail to comply with the regulatory requirements for our manufacturing operations, our commercialization efforts could be delayed, which would harm our business and our results of operations.

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. We rely on suppliers for various critical components including the center post, housing and impeller that are assembled into our primary product, the HeartWare System, as well as finished products that comprise our peripheral and external equipment that is included in the HeartWare System. Lead times for our components are significant and can be up to as long as sixteen weeks and many of our components are manufactured to very tight tolerances and specifications. We do not presently have supply agreements with the vast 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 many 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;
- 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 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;
- switching components or changes to our components, specifications or designs may require product redesign and submission to the FDA or a PMA supplement, which can lead to production interruptions;
- our suppliers manufacture products for a range of customers, and fluctuations in demand for the products these suppliers manufacture for others may affect their ability to deliver products to us in a timely manner; and
- our 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 assure you 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 HeartWare 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 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 acquired in 2003 in connection with a plan of liquidation for Kriton Medical, Inc. and which pertain to technology used in the HeartWare System. As a result, we may have less complete knowledge and records with respect to the development and ownership of such Kriton 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, including with respect to the development and ownership thereof, or 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 or identical to ours. In addition, in November 2005, we entered into a settlement agreement with Ventrassist Pty., Limited, Ventracor Limited (collectively "Ventracor") and the University of Technology, Sydney, under which the parties resolved all of the claims and counterclaims filed by the parties in the United States District Court for the Southern District of Florida in 2004 and 2005, and agreed to mutual non-assertion covenants. As part of that agreement, we agreed not to sue Ventracor or the University of Technology, Sydney, or any of their respective successors, assigns, affiliates, customers or suppliers for infringement of 29 of our issued U.S. and worldwide patents existing as of the date of the agreement or any patents that issue from any patent applications existing as of such date (including any type of patent that claims priority or shares common priority to such patents). We also agreed not to sue such parties for infringement of all of our issued patents existing as of September 30, 2005, or any patents that issue from any patent applications existing as of such date, in respect of Ventracor's blood pump devices existing as of the date of the agreement or any device embodying a modification of such devices which does not give rise to a new independent claim for patent infringement. As a result, Ventracor, the University of Technology, Sydney, or their respective successors or assigns may commercialize competing technology or products that would have otherwise been precluded by our patents subject to the agreement. We understand that Ventracor's patent portfolio, or certain elements therein, have since been acquired by Thoratec Corporation.

In order to preserve and enforce our patent and other intellectual property rights, we may need to make claims or file lawsuits against third parties. This can entail significant costs to us and divert our management's attention from developing and commercializing our products. The occurrence of these events may have a material adverse effect on our business, financial condition or 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 revenues increase, the number of competitors grows 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 infringe. For example, we are aware of certain patents and patent applications owned by third parties that cover different aspects of mechanical circulatory support, methodologies for the pumping of blood and other fluids and the related devices and technologies. Any of these third parties might make a claim of infringement against us.

In particular, in an August 2008 letter, Jarvik Heart invited us to discuss "an exclusive license" as it relates to a Jarvik patent concerning hybrid blood pumps. The patent referenced by this letter relates to technology that is material to our business. We have not had any substantive discussions with Jarvik Heart concerning this matter since our receipt of this letter and we do not believe that our blood pump infringes this patent. In addition, we received a letter from Abiomed, Inc. in September 2009 in which Abiomed suggested that we "may be interested in licensing Abiomed's technology" as it relates to an Abiomed patent concerning bearingless blood pumps. Further, in a subsequent letter received in February 2010, it was stated that Abiomed was "concerned that HeartWare's left ventricular assist rotary blood pump infringes one or more claims" of an Abiomed patent. We have had communications with Abiomed, Inc. since receipt of the initial letter. The patent referenced by these letters relates to technology that is potentially material to our business and any litigation in this regard, irrespective of the outcome, may have a material adverse effect on our financial position, liquidity or results of operations. We believe the HeartWare System does not infringe this patent.

There can be no certainty that litigation will not arise in relation to the above matters 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 were 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 revenues 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.

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 and our patent applications at risk of not issuing. 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.

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 our unpatented proprietary technology, trade secrets, processes and know-how. Despite these measures, any of our intellectual property rights could, however, 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, for any of the above reasons, 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 our employees or we 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.

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. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business. We can be liable for our distributors' failure to comply with these laws as well.

A federal law commonly known as the Medicare/Medicaid 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 HeartWare 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 provide reimbursement to healthcare professionals for training patients on the use of the HeartWare System and our other products. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance, which can be substantial. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, 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 the laws described above.

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, we could be subject to civil or criminal penalties, which could increase our liabilities, harm our reputation and have a material adverse effect on our business, financial condition and results of operations.

If we are unable to manage our expected growth, we may not be able to commercialize our product candidates.

We expect to continue to expand our operations and grow our research and development, product development, 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 and operational and financial resources. To manage any further growth and to commercialize our products, we will be required to improve existing and implement new operational and financial systems, procedures and controls and expand, train and manage our growing employee base. Specifically, our information technology and back-up systems and access to such systems will need to be improved and upgraded to accommodate our growth. In addition, we will need to manage relationships with various persons and entities participating in our clinical trials, manufacturers, suppliers and other organizations, including various regulatory bodies in the United States and other jurisdictions. Our ability to manage our operations and growth will require us to improve our operational, financial and management controls, as well as our internal reporting systems and controls. We may not be able to implement such improvements to our management information and internal control systems in an efficient and timely manner and may discover deficiencies in existing systems and controls. Our failure to accomplish any of these tasks could materially harm our business.

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 product. 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 and new indications on a timely basis, or if they are not well accepted by the market, our future growth may suffer. For example, we are developing a next generation pump based on our MVAD technology, designing a new and improved controller and working on a clinical strategy for a bi-ventricular indication, among others. If we are not successful in these efforts, among others, our future business opportunities and growth potential will suffer.

If we choose to license, invest in or acquire new businesses, products or technologies, instead of developing them ourselves, these licenses, investments or acquisitions could disrupt our business and could result in the use of significant amounts of equity, cash or a combination of both.

From time to time we may seek to license, invest in or acquire new businesses, products or technologies, instead of developing them ourselves. Licenses, investments and acquisitions involve numerous risks, including:

- the inability to complete the license, investment or acquisition;
- disruption of our ongoing businesses and diversion of the attention of management and other personnel;

- difficulties in integrating the acquired entities, products or technologies;
- risks associated with acquiring intellectual property;
- difficulties in operating the acquired business profitably;
- the inability to achieve anticipated synergies, cost savings or growth;
- potential loss of key employees, particularly those of the acquired business;
- difficulties in transitioning and maintaining key customer, distributor and supplier relationships;
- risks associated with entering markets in which we have no or limited prior experience; and
- unanticipated costs.

In addition, any future licenses, investments or acquisitions may result in one or more of the following:

- dilutive issuances of equity securities, which may be sold at a discount to market price;
- the use of significant amounts of cash;
- the incurrence of debt;
- the assumption of significant liabilities;
- increased operating costs or reduced earnings;
- financing obtained on unfavorable terms;
- large one-time expenses; and
- the creation of certain intangible assets, including goodwill, the write-down of which in future periods may result in significant charges to earnings.

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

If we cannot successfully manage the additional business and regulatory risks that result from our expansion into multiple foreign markets, we may experience an adverse impact to our business, financial condition and results of operations.

We have aggressively expanded, and expect to continue to expand, into additional foreign markets. This expansion will subject us to new business and regulatory risks, including, but not limited to:

- failure to fulfill foreign regulatory requirements on a timely basis or at all to market the HeartWare System or other future products;
- availability of, and changes in, reimbursement within prevailing foreign health care payment systems;
- adapting to the differing laws and regulations, business and clinical practices, and patient preferences in foreign countries;
- difficulties in managing foreign relationships and operations, including any relationships that we may establish with foreign partners, distributors or sales or marketing agents;
- differing levels of protection for intellectual property rights in some countries;
- difficulty in collecting accounts receivable and longer collection periods;
- costs of enforcing contractual obligations in foreign jurisdictions;
- recessions in economies outside of the United States;
- political instability and unexpected changes in diplomatic and trade relationships;
- currency exchange rate fluctuations; and
- potentially adverse tax consequences, including our ability to interpret local tax rules and implement appropriate tax treatment/collection.

We will be impacted by these additional business risks, which may adversely impact our business, financial condition and results of operations. In addition, expansion into additional foreign markets imposes additional burdens on our small executive and administrative personnel, research and sales department 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 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 our financial statements.

The competition for qualified personnel is particularly intense in our industry. If we are unable to retain or hire 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 and financial personnel. During 2011 we intend to hire a substantial number of employees in these areas and others in order to prepare for U.S. commercialization and the expected growth in our business. We face intense competition for such personnel, and we may not be able to attract, retain and motivate these individuals. We compete for talent with numerous companies, as well as 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, manage our operations and maintain a cohesive and stable 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.

Product liability claims could damage our reputation or adversely affect our business.

The design, manufacture and marketing of human medical devices, particularly implantable life-sustaining medical devices, carries an inherent risk of product liability claims and other damage claims. Such liability 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 clinical trial insurance and limited product liability insurance. We cannot be certain that such 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 such insurance on acceptable terms or at reasonable costs. A successful claim brought against us in excess, or outside, of our insurance coverage could seriously harm our financial condition and results of operations. Generally, our clinical trials will be conducted in (and our commercial sales will be made to sites in respect of) patients with serious life-threatening diseases for whom conventional treatments have been unsuccessful or for whom no conventional treatment exists, and, during the course of treatment, these patients could suffer adverse medical effects or die for reasons that may or may not be related to our medical devices. Any of these events could result in a claim of liability. For example, in 2009 we received a claim in connection with the death of a patient from multiple organ failure participating in our clinical trial in Germany. We may receive similar claims from time to time in the future. Such 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 and prospects. A product liability or other damages claim, product recall or product misuse involving any type of LVAD, but especially involving one of ours, could also materially and adversely damage our reputation and affect our ability to attract and retain customers, irrespective of whether or not the claim or recall was meritorious.

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 in our Annual Report on Form 10-K for the year ended December 31, 2010. 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, 2010. 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, 2010. Our independent registered public accounting firm has issued their attestation report on our internal control over financial reporting, which is also included in Item 9A of our Annual Report on Form 10-K for the year ended December 31, 2010.

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 will need to enhance our accounting and financial controls functions, particularly as they relate to accounting for revenue and inventory, and we will 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 such deficiencies will effectively mitigate or remedy such deficiencies. The existence of one or more such 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.

Risks Related to Our Common Stock

The price of our common stock may fluctuate significantly.

The ordinary shares of HeartWare Limited had been traded on the ASX from January 31, 2005 until November 13, 2008 when the shares of common stock of HeartWare International, Inc. started trading on the ASX in the form of CHESS Depositary Interests, or CDIs, each representing one thirty-fifth of a share of our common stock. The trading price of the common stock and the CDIs, as applicable, has been, and is likely to continue to be, volatile, which means that it could decline substantially within a short period of time. In addition, our shares of common stock began trading on The NASDAQ Stock Market LLC on February 24, 2009. 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.$33.96 to U.S.$93.76 in the period from January 1, 2010 to December 31, 2010. The price of our common shares, whether traded in the form of common stock or CDIs, could fluctuate significantly for many reasons, including the following:

- future announcements or new information concerning us or our competitors reimbursement, or the potential market for our products;
- regulatory developments (such as the status of FDA approval of our device for the BTT indication), enforcement actions bearing on advertising, marketing or sales, and disclosure regarding completed, ongoing or future clinical trials;
- quarterly variations in operating results and our liquidity, which we have experienced in the past and expect to experience in the future;
- introduction of new products or changes in product pricing policies by us or our competitors;
- acquisition or loss of significant customers, distributors or suppliers;
- business acquisitions or divestitures;
- changes in third party reimbursement practices;
- fluctuations of investor interest in the medical device sector; and
- fluctuations in the economy, world political events, foreign currency movements or general market conditions.

In addition, stock markets in general and the market for shares of health care 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 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 be subject to arbitrage risks.

Investors may seek to profit by exploiting the difference, if any, in the price of our shares of common stock as reflected by the trading price of our CDIs, each representing one thirty-fifth of a share of our common stock, on the ASX and the trading price of our shares of common stock on the NASDAQ Stock Market. Such arbitrage activities could cause the price of our securities (as adjusted to reflect the fact that each CDI represents one thirty-fifth of a share of common stock) in the market with the higher value to decrease to the price set by the market with the lower value.

We are currently considering the possibility of delisting our CHESS Depositary Interests from the Australian Securities Exchange. If we should decide to pursue delisting, the market for our common stock in the United States could be disrupted, which would have an adverse affect on our stock price.

We are currently considering delisting our CHESS Depositary Interests from the Australian Securities Exchange. Any decision will take into account, among other things, due notification, and a desire to minimize the disruption, to stockholders. The delisting of our CHESS Depositary Interests from the ASX could disrupt the market for our common stock listed on the NASDAQ Stock Market in the United States as a result of the sudden influx onto the NASDAQ Stock Market of the shares of our common stock previously represented by CHESS Depositary Interests, which could have an adverse affect on our stock price. In addition, the delisting of our CHESS Depositary Interests from the ASX could have an adverse effect on our ability to raise capital, if needed, on terms acceptable to us.

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 carryforwards from prior years to reduce taxable income in future tax years will be limited by operation of the Internal Revenue Code. Certain changes in the ownership of our common stock, including the sale of our common stock by Apple Tree Partners I, L.P., one of our largest holders, may result in such an ownership change.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our corporate headquarters are located in Framingham, Massachusetts. We have an operations and manufacturing facility in Miami Lakes, Florida, a small development and operations facility in Sydney, Australia and a small distribution and customer service facility in Hannover, Germany.

Our office in Framingham, Massachusetts consists of approximately 15,000 square feet of office space. The lease expires on December 31, 2014 and we have an option to renew the lease for one additional four-year term. We also have an option to expand with an additional 3,002 square foot space in the building.

Our operations and manufacturing facility in Miami Lakes, Florida consists of approximately 59,000 square feet and includes office space, laboratories, research and development space and three clean rooms which are ISO Class 100,000 compliant. The lease expires on June 30, 2013 and we have an option to renew the lease for two additional, three-year terms.

On December 8, 2010, we entered into a lease for a new facility in Miami Lakes, Florida as part of our planned expansion to support our efforts to prepare for U.S. commercialization. The facility will be used primarily for manufacturing, research and development and administrative functions. Under the lease, we will rent approximately 131,000 square feet for a period ending February 28, 2022, with an option to renew for two five-year terms.

Our facility in Sydney, Australia is approximately 2,600 square feet. The lease commenced on August 31, 2009 with an initial term of two years. We have an option to renew the lease for two additional three-year terms.

Our facility in Hannover, Germany is approximately 3,900 square feet. The lease commenced on October 11, 2010 with an initial term of two years. We have an option to renew the lease for one additional three-year term.

Our manufacturing activities to date consist primarily of process development, component assembly, quality control testing, sustaining engineering and research and development activities. Currently, approximately 80% of our space in Miami Lakes, Florida is being used for these activities.

We believe that the facilities noted above are suitable and adequate for our needs now and for the foreseeable future.

Item 3. Legal Proceedings

The Company is not a party to any material legal proceedings at the date of filing of this Annual Report on Form 10-K.

Item 4. (Removed and Reserved)

Part II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

On February 24, 2009 we listed on the NASDAQ Stock Market with trading commencing on February 25, 2009 under the symbol "HTWR". Our shares of common stock also trade in the form of CHESS Depositary Interests ("CDIs"), each CDI representing one thirty-fifth of a share of our common stock, on the Australian Securities Exchange ("ASX") under the symbol "HIN" since November 13, 2008. Prior to that date, our ordinary shares of HeartWare Limited, (since renamed HeartWare Pty. Limited), of which we are the successor issuer, were traded on the ASX under the symbol "HTW".

The following table sets forth, for the periods indicated, the high and low closing prices for our common stock on the NASDAQ (commencing February 25, 2009) and the high and low closing prices for our CDIs on the ASX (from January 1, 2009 through February 23, 2009). The prices of our CDIs have been adjusted to give effect to the 35 for one exchange ratio and have been converted to U.S. dollars using the spot rate applicable on the relevant date.

Period	High (U.S.$)	Low (U.S.$)
Fiscal Year 2009:		
First Quarter	$ 30.00	$ 22.80
Second Quarter	29.70	23.54
Third Quarter	30.27	21.65
Fourth Quarter	36.80	29.61
Fiscal Year 2010:		
First Quarter	$ 44.47	$ 33.96
Second Quarter	74.65	45.14
Third Quarter	74.67	60.49
Fourth Quarter	93.76	61.90

As of February 11, 2011 we had 13,891,230 shares of common stock issued and outstanding and there were approximately 20 holders of record of our common stock. In addition, as of that date, there were approximately 760 registered owners of our CDIs.

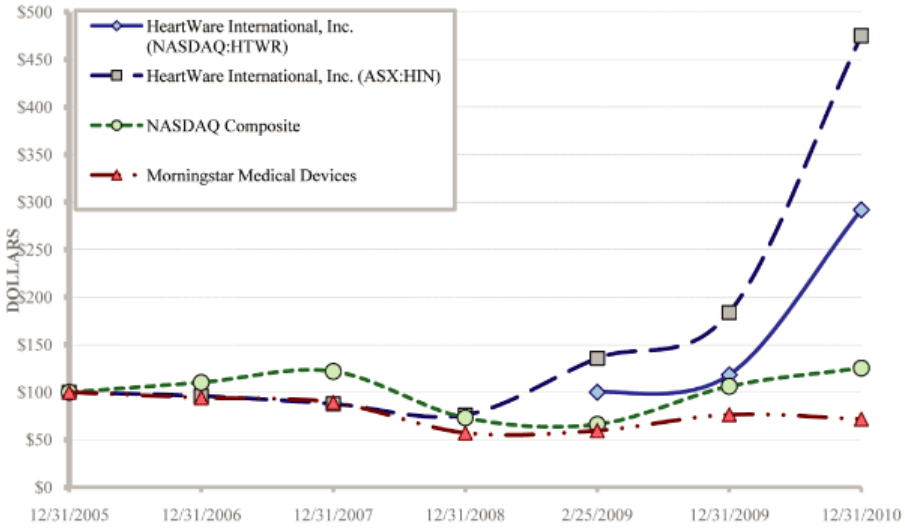
We have not declared or paid any cash dividends on our shares, and we currently do not anticipate paying any cash dividends in the foreseeable future. Our convertible notes were issued pursuant to the terms of an Indenture dated December 15, 2010. The Indenture does not contain any covenants or restrictions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

As long as CDIs representing our common stock are listed on the ASX, prior to February 1, 2012, we will not issue any shares of our common stock (other than upon conversion of our convertible notes) or any securities convertible into our common stock unless either (1) our stockholders approve such proposed issuance; (2) our stockholders ratify the issuance of the convertible notes and the common stock underlying the convertible notes; or (3) the ASX provides a waiver of the requirement to seek stockholder approval for the issue of shares of our common stock or securities convertible into our common stock, in each case within the meaning of ASX rules and regulations.

Stock Price Performance Graph

The graph below compares the cumulative total stockholder return on an investment in our CDI's, the NASDAQ Composite Index (U.S. companies only) and the Morningstar Medical Devices Index for the five-year period ended December 31, 2010. The graph assumes the value of an investment in our CDI's traded on the ASX and each index was $100 on December 31, 2005 and the reinvestment of all dividends, if any.

The graph also presents the cumulative total stockholder return on an investment in our common stock for the period from February 25, 2009 to December 31, 2010. The graph assumes the value of an investment in our common stock was $100 on February 25, 2009, the date our common stock commenced trading on the NASDAQ Stock Market, and the reinvestment of all dividends, if any.



Company/Market/Peer Group	12/31/2005	12/31/2006	12/31/2007	12/31/2008	2/25/2009	12/31/2009	12/31/2010
HeartWare International, Inc. (NASDAQ:HTWR)					$ 100.00	$ 118.23	$ 291.90
HeartWare International, Inc. (ASX:HIN)	$ 100.00	$ 95.99	$ 87.78	$ 76.04	$ 135.64	$ 183.90	$ 475.11
NASDAQ Composite	$ 100.00	$ 110.25	$ 121.88	$ 73.10	$ 66.21	$ 106.22	$ 125.36
Morningstar Medical Devices	$ 100.00	$ 94.21	$ 89.25	$ 57.19	$ 59.57	$ 76.35	$ 71.68

Equity Compensation Plans

The following table sets forth information regarding the Company's Equity Compensation Plans as of December 31, 2010:

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)	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	324,690	$ 31.92	352,390(1)
HeartWare International, Inc. Restricted Stock Unit Plan	64,289	$ 0.00	14,654(1)
HeartWare International, Inc. 2008 Stock Incentive Plan (2)	555,110	$ 5.03	—(1)(3)
Equity compensation plans not approved by security holders:			
Non-Plan options	5,142	$ 26.67	N/A

(1) Future issuances to employees and directors are expected to be made solely under the 2008 Stock Incentive Plan as any grants under the other plans reduce the availability of grants under the 2008 Stock Incentive Plan.

(2) Outstanding awards under the 2008 Stock Incentive Plan include stock options granted with exercise prices equal to the fair value of our common stock on the date of grant and restricted stock units granted with exercise prices of $0.

(3) The 2008 Stock Incentive Plan includes an annual adjustment to shares available for future issuance at each January 1 based on the prior number of weighted average share outstanding in the prior year. As of January 1, 2011, the number of shares available for future issuance under the 2008 Stock Incentive Plan was approximately 671,000.

Item 6. Selected Financial Data

The following selected consolidated statement of operations data for the years ended December 31, 2010, 2009 and 2008 and the selected consolidated balance sheet data as of December 31, 2010 and 2009 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, 2007 and 2006 and balance sheet data as of December 31, 2008, 2007 and 2006 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.

In connection with the 2008 redomiciliation of our corporate parent entity from Australia to the United States, each holder of HeartWare Limited ordinary shares received one share of common stock of HeartWare International, Inc., for every 35 of HeartWare Limited ordinary shares held by such holder. The per share information listed below has been adjusted to give effect to the 2008 redomiciliation transaction, whether such information pertains to a date or period of time subsequent or prior to the redomiciliation transaction.

	Years Ended December 31,				
(In thousands, except per share data)	**2010**	**2009**	**2008**	**2007**	**2006**
Consolidated Statement of Operations Data:					
Revenues	$ 55,164	$ 24,172	$ 332	$ —	$ —
Cost of revenues	24,441	13,211	78	—	—
Selling, general and administrative expenses	26,642	16,444	10,981	7,303	6,024
Research and development expenses	33,108	15,067	18,644	14,636	11,650
Other income (expense), net	(370)	(359)	5,607	—	248
Provision for income taxes	—	—	—	—	—
Net loss	(29,397)	(20,909)	(23,764)	(21,939)	(17,427)
Basic and diluted net loss per share	(2.17)	(2.15)	(3.00)	(3.60)	(3.49)

	As of December 31,				
(In thousands)	**2010**	**2009**	**2008**	**2007**	**2006**
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 213,478	$ 50,835	$ 20,804	$ 28,276	$ 16,698
Total assets	267,577	77,953	30,338	32,355	20,243
Convertible senior notes, net of discounts (a)	88,922	—	—	—	—
Total stockholders' equity	167,764	70,983	26,756	29,272	17,464

(a) At December 31, 2010, the aggregate principal amount of our 3.5% convertible senior notes due December 15, 2017 was $143.75 million.

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, judgment 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 develops and manufactures small implantable heart pumps, or ventricular assist devices, for the treatment of advanced heart failure.

The HeartWare Ventricular Assist System (the "HeartWare System"), which includes a left ventricular assist device ("LVAD"), 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 HeartWare 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 HeartWare System is designed to be implanted adjacent to the heart, avoiding the abdominal surgery generally required to implant similar devices.

In 2009, we have received CE Marking for the HeartWare System in the European Union allowing for commercial sale and distribution of our device. In the U.S., the device is the subject of clinical trials for two indications: bridge-to-transplant under a CAP and destination therapy. Our device is also available in other countries around the world under special access programs.

Recent key milestones in the development of the HVAS include the following:

- Completion of enrollment in our ADVANCE trial,
- FDA approval of a CAP for the ADVANCE trial allowing for the continued enrollment of patients,
- Submission of PMA application for bridge-to-transplant indication,
- IDE approval of our ENDURANCE trial for destination therapy indication, and
- Being named to the REVIVE-IT study, a study to be completed by the Universities of Michigan and Pittsburgh on the benefits of LVAD's in patients with earlier access to the device.

Beyond the HeartWare System, we are also evaluating our next generation device, the MVAD. The MVAD is based on the same technology platform as the HeartWare System but adopts an axial flow, rather than a centrifugal flow configuration, and is being developed in multiple configurations. The MVAD designs are currently at the preclinical stage and undergoing animal studies focused on minimally invasive implantation techniques. Each of the MVAD configurations is approximately one-third the size of the HVAD Pump. We believe that the MVAD designs will be implantable by surgical techniques that are even less invasive than those required to implant the HVAD Pump.

We began generating revenue from our product sales in August 2008 and have incurred net losses in each year since our inception. We expect our losses to continue as we advance and expand our clinical trial activities in the U.S., continue to develop commercial markets outside of the U.S. and expand our research and development into next generation products including the MVAD.

We have financed our operations primarily through the issuance of convertible notes and the issuance of shares of our common stock. Most recently, on December 15, 2010, the Company issued Convertible Senior Notes with an aggregate principal amount of $143.75 million pursuant to the terms of an Indenture dated as of December 15, 2010. The Convertible Senior Notes are senior unsecured obligations of the Company. The Convertible Senior 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, beginning on June 15, 2011. The Convertible Senior Notes will mature on December 15, 2017, unless earlier repurchased or converted. In February 2010, we closed a public offering, under a shelf registration on Form S-3 filed with the Securities and Exchange Commission on December 24, 2009, of approximately 1.77 million shares of our common stock at an offering price of $35.50 per share for aggregate gross proceeds of approximately $62.8 million. This amount includes the underwriter's exercise of their over-allotment option to purchase an additional 230,595 shares of our common stock at the offering price. In August 2009, we sold approximately 2.74 million shares of our common stock through private placements in the United States and Australia, which raised net proceeds of approximately $58.6 million.

We are headquartered in Framingham, Massachusetts. We have an operations and manufacturing facility in Miami Lakes, Florida, a small development and operations facility in Sydney, Australia and a small distribution and customer service facility in Hannover, Germany.

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 make estimates and judgments in preparing the financial statements that affect the reported amounts of our assets, liabilities, revenue and expenses. 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 most critical accounting policies and estimates include: revenue recognition, inventory capitalization, accounting for share-based compensation, measurement of fair value, income taxes and reserves. We also have other key accounting policies that are less subjective and, therefore, their application would not 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*. Pursuant to agreements or orders from customers, we ship product to our customers. Revenue from product sales is only recognized when substantially all the risks and rewards of ownership have transferred to our customers, the selling price is fixed and collection is reasonably assured. A majority of product sales are made on a consignment basis and as such, pursuant to the terms of the consignment arrangements, revenue is recognized on the date the consigned product is implanted or otherwise consumed. Revenue from product sales not sold on a consignment basis is recognized upon customer receipt and acceptance of the product. Revenue recognized to date is from sales of our devices in connection with our U.S. clinical trial and commercial sales in Europe and to a lesser extent under special access in other countries.

Inventory Capitalization

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. We received a full Investigational Device Exemption in September 2008 from the FDA for the HeartWare System and subsequently began selling our product through our U.S. clinical trial. Therefore, effective September 1, 2008, we adopted a policy for capitalizing inventory and recognizing cost of sales related to the HeartWare System.

Inventories are stated at the lower of cost or market. Cost is determined on a first-in, first out (FIFO) method. We utilize a standard costing system, which requires significant management judgment and estimates in determining and applying labor and overhead rates. Labor and overhead rates are estimated based on our best estimate of annual production volumes and labor rates and hours per manufacturing process. These estimates are based on historical experience and budgeted expenses and production volume. Estimates are set at the beginning of the year and updated periodically. While we believe our standard costs are reliable, actual production costs and volume changes may impact inventory, costs of sales and the absorption of production overhead expenses.

We review our inventory for excess or obsolete inventory and write down obsolete or otherwise unmarketable inventory to its estimated net realizable value.

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, net of an estimated forfeiture rate, and therefore only recognize compensation cost for those awards expected to vest over the service period of the award. We value Restricted Stock Units ("RSU's") at their intrinsic value on the date of grant. We use a Black-Scholes option pricing model to estimate the fair value of our stock options. Calculating share-based compensation expense requires the input of highly subjective judgment and assumptions, including estimates of expected life of the award, stock price volatility, forfeiture rates 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.

When appropriate, we estimate the expected life of an option by averaging the contractual term of the stock option grants (up to 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 forfeiture rate based on our historical experience of forfeitures and our employee retention rate. If our actual forfeiture rate is materially different from our estimate, the share-based compensation expense could be significantly different from what we have recorded in the current period. 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 awards, 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 period, 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. During 2009 and 2010, we determined that achievement of certain performance-based vesting criteria for awards originally granted in 2007 and 2008 was probable. Therefore, we began recording compensation expense during 2009 and 2010 in connection with certain share-based awards that had been outstanding but for which we had not previously recorded any compensation expense. If ultimately performance goals are not met, for any 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 respective 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 the Company's 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 in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange-traded instruments and listed equities.

Level 2 — Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 includes financial instruments that are valued using models or other valuation methodologies. These models consider various assumptions, including volatility factors, current market prices and contractual prices for the underlying financial instruments. Substantially all of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace.

Level 3 — Unobservable inputs for the asset or liability. Financial instruments are considered Level 3 when their fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable.

Calculating fair value utilizing Level 2 and Level 3 inputs requires the input of highly subjective judgment and assumptions. 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.

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, 2010, we have historically concluded that a full valuation allowance is required to offset our net deferred tax assets.

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 judgments 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 HeartWare 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 revenues" 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.

Results of Operations

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

Fiscal Years 2010 and 2009

Revenue, net

	Years Ended December 31,		
	2010	2009	Change
	(in thousands)		
Revenue, net	$ 55,164	$ 24,172	128%

For the year ended December 31, 2010, we generated revenue from commercial sales outside of the U.S. and sales in connection with our U.S. clinical trials. The increase in revenue is primarily due to increased market penetration outside of the U.S. and increased activity in our U.S. bridge-to-transplant study including sales after completion of the study through a Continued Access Protocol ("CAP"). Approximately 73% of our product sales in 2010 were derived outside of the U.S. as compared to 59% in the prior year. The increase in the portion of our revenues derived from outside of the United States is due to the continued commercial rollout of the HeartWare System in Europe and other countries with additional implants at existing sites and the addition of new sites.

We expect to continue to generate and grow commercial revenue from product sales as we further expand our sales and marketing efforts outside of the United States, continue implanting under CAP for a bridge-to-transplant indication, and increase the number of implants in our destination therapy clinical trial, ENDURANCE, in the U.S. Notwithstanding our plans to generally expand our U.S. clinical programs, revenues from U.S. sources in connection with our trials may vary from quarter to quarter as the number of implants under CAP is subject to FDA approval for each cohort of patients.

Future product sales are dependent on many factors, including receiving and maintaining the necessary regulatory approvals in the United States and internationally, market acceptance among physicians, patients, health care payers and the medical community as well as our capacity to meet customer demand by manufacturing sufficient quantities of our products.

Cost of Revenues

Cost of revenues totaled approximately $24.4 million for the year ended December 31, 2010 and approximately $13.2 million for the year ended December 31, 2009.

Gross profit and gross margin percentage are as follows:

	Years Ended December 31,	
	2010	2009
Gross profit (in thousands)	$ 30,723	$ 10,961
Gross margin %	56%	45%

The increase in gross margin is primarily due to the increase in unit production reducing the overhead and labor costs applied on a per unit basis.

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, depreciation of fixed assets, travel, 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 revenues.

Selling, general and administrative expenses were as follows:

	Years Ended December 31,		
	2010	2009	Change
	(in thousands)		
Total selling, general and administrative expenses	$ 26,642	$ 16,444	62%
% of operating expenses	45%	52%	

During 2010, we experienced significant growth as we expanded European sales and distribution capabilities and increased the number of implants in the U.S. under clinical trials. We also experienced growth in administrative costs as we continued to manage dual listings of our securities in the United States and Australia, raised additional capital and expanded our administrative capabilities to support overall corporate growth. As a result, we experienced expansion of our staff, including in senior management, and overall growth in selling and marketing and administrative functions and experienced a related expansion in infrastructure costs.

The increase of $10.2 million in selling, general and administrative costs are primarily a result of an increase in share-based payment expense of $5.6 million, an increase in employee costs, including salaries and wages and related costs, of $3.7 million, and an increase in travel of $1.2 million. In addition, we experienced increases in costs of $508,000 related to accounting and tax matters, consultants and contractors of $469,000, office expenses of $350,000, marketing expenses of $396,000 and bad debt expense related to the establishment of a reserve for doubtful accounts of $600,000. Increases in costs were partially offset by a decrease in legal fees in 2010 as compared to 2009 of approximately $4.4 million associated with a failed merger transaction in 2009. The decrease in sales and marketing expenses as a percentage of operating expenses is due to R&D expenses comprising a higher percentage of overall costs as discussed below.

Research and Development

Research and development expenses are the direct and indirect costs associated with developing our products prior to commercialization and are expensed as incurred. These expenses fluctuate based on project level activity and availability of funding to support new and ongoing projects and consist primarily of salaries and wages and related employee costs of our research and development and clinical and regulatory staff, external research and development costs, materials and expenses associated with clinical trials. Additional costs include travel, facilities and overhead allocations.

Research and development expenses were as follows:

	Years Ended December 31,		
	2010	2009	Change
	(in thousands)		
Total research and development expenses	$ 33,108	$ 15,067	120%
% of operating expenses	55%	48%	

As discussed above, we experienced significant growth in 2010. We achieved significant research and development milestones including enrolling a substantial number of patients in our U.S. clinical trial, developing three design configurations for the MVAD and furthering animal studies for less invasive implantable techniques related to the MVAD. The increase in research and development expenses, in total and as a percentage of total operating expenses, was primarily a result of increased clinical trial activity, continued development of next generation products, and costs associated with preparing the PMA application submission to the FDA.

The increase in research and development expenses of approximately $18.0 million is primarily due to an increase in costs associated with our U.S. clinical trials of $5.5 million, an increase in costs associated with development projects including outside engineering, consultants and contractors of $6.9 million related to MVAD development and preparation for our PMA application for HVAD and an increase in headcount and related employee costs, including salaries and wages and related costs, of approximately $2.8 million.

Even with commercial approval of the HeartWare System in Europe, we expect that research and development expenses will continue to represent a significant portion of our operating expenses for the foreseeable future related to clinical trials in the U.S. and new product development, including costs related to the development of the MVAD.

Foreign Exchange

Foreign exchange losses totaled approximately $502,000 in the year ended December 31, 2010, as compared to a loss of approximately $285,000 for the prior year. In 2010, the majority of our realized and unrealized foreign exchange gains and losses were experienced upon the collection of certain accounts receivable that were denominated in foreign currencies, and the translation to U.S. dollars of customer accounts receivable denominated in foreign currencies at period end, primarily the Euro. We expect this trend to continue for the foreseeable future as the majority of our sales denominated in foreign currencies are settled in Euros. In 2009, the majority of our foreign exchange gains and losses were due to remeasurement of our cash holdings denominated in U.S. dollars held by our Australian subsidiary as a result of movements in the exchange rate between the Australian dollar and the U.S. dollar. During the first half of 2009, we maintained the majority of our cash and cash equivalents in Australia, denominated in both Australian and U.S. dollars. However, beginning in the second half of 2009, the majority of our cash and cash equivalents are in U.S. dollars on deposit with banks located in the United States.

Interest Expense

Interest expense was approximately $431,000 for the year ended December 31, 2010, which consists of accrued interest incurred on the principal amount of the convertible senior notes of approximately $210,000 and non-cash amortization of the related discount and deferred financing costs totaling approximately $221,000. Interest expense was approximately $820,000 for the year ended December 31, 2009, which consists of interest incurred on the principal amount of the convertible loans from Thoratec of approximately $149,000 and non-cash amortization of the deferred financing costs of approximately $671,000.

Interest on the convertible senior notes is payable at a rate of 3.5% per annum. Interest expense also includes amortization of the discount on the convertible senior notes and amortization of the deferred financing costs associated with the convertible senior notes. We expect interest expense to significantly increase in 2011 due to the issuance of these convertible senior notes.

Interest expense in 2009 consists of interest incurred on the principal amount of the convertible loans from Thoratec that were drawn down in August and December 2009 and amortization of deferred (non cash) financing costs related to the Thoratec Loan Agreement. Interest on the convertible loans was payable at a rate of 10% per annum. The deferred financing costs were being amortized over the term of the Thoratec Loan Agreement, which was set to expire no later than November 1, 2011. However, with the repayment of all amounts available to be borrowed under the terms of the agreement, we effectively extinguished all debt under this agreement. There was no such interest expense in 2010 as the convertible loans were repaid and the Loan Agreement terminated in the fourth quarter of 2009.

Interest Income, net

Interest income is 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 interest income, net. Interest income, net was approximately $564,000 for the year ended December 31, 2010 as compared to approximately $101,000 for the prior year. The increase was primarily due to higher cash balances during the 2010 period resulting from the capital raises completed in the second half of 2009 and in February 2010. However, we experienced lower interest rates in 2010 compared to 2009.

Change in Fair Value of Derivative Instrument

As further discussed in Note 8 to the accompanying financial statements, we recorded the fair value of a derivative instrument on July 31, 2009 related to the Australian dollar denominated conversion feature in the Thoratec Loan Agreement. We were required to initially record this derivative at fair value on July 31, 2009 and re-measure fair value at each reporting period. During the year ended December 31, 2009 we recognized aggregate non-cash expenses of approximately $3.9 million due to the increase in the fair value of this derivative between July 31, 2009 and December 29, 2009, the date the derivative was extinguished. This increase in fair value was primarily due to an increase in the fair value of our common stock and is non-cash in nature.

Gain on Early Extinguishment of Debt

As further discussed in Note 8 to the accompanying financial statements, in 2009, we recorded a net gain (non-cash) on the early extinguishment of debt related to the Thoratec Loan Agreement. Due to the repayment of all amounts borrowed under the Loan Agreement, our inability to re-borrow amounts repaid and Thoratec's inability to convert any repaid amounts into our common stock, the fair value of the derivative instrument at the repayment dates, aggregating approximately $7.8 million, was recorded as a gain on the extinguishment of debt. Further, the unamortized balance of the deferred financing costs at the repayment dates, aggregating approximately $3.2 million, was recorded as a reduction of the gain on early extinguishment of debt, resulting in a net gain on the early extinguishment of debt of $4.6 million for the year ended December 31, 2009. Since there are no funds held in escrow, there are no amounts remaining for us to borrow and no amounts remaining for Thoratec to convert into shares of HeartWare common stock. Therefore, Thoratec's conversion rights, and thus the derivative, have been eliminated.

Income Taxes

We are subject to taxation in multiple jurisdictions. We have incurred losses since inception. Changes in share ownership, as well as other factors, may limit our ability to utilize any net operating loss carry-forwards, and as such a 100% valuation allowance has been recorded against our net deferred tax assets.

As of December 31, 2010, we did not have revenues or profit which would be sufficient to allow any portion of our deferred tax assets to be recorded. We intend to monitor closely the question of whether to record a deferred tax asset as we expand the commercialization of our products.

Fiscal Years 2009 and 2008

Revenue, net

For the year ended December 31, 2009, we generated net revenue from product sales of approximately $24.2 million as compared to $332,000 in the year ended December 31, 2008. For the year ended December 31, 2009, we generated revenue from sales in connection with our U.S. clinical trial and commercial sales outside of the U.S. For the year ended, December 31, 2008, revenue consisted of a limited number of unit sales following commencement of our U.S. bridge-to-transplant clinical trial in August 2008 with no revenue being derived during that period from sources outside the U.S. As of December 31, 2009, we had enrolled 114 of the 150 patients we intend to enroll in the U.S. trial. In January 2009, we received CE Marking approval for our HeartWare System and began generating commercial revenue in Europe. Approximately 59% of our product sales in 2009 were derived internationally.

We expect to continue to generate and grow commercial revenue from product sales as we further expand our sales and marketing efforts outside of the United States. Notwithstanding our plans to generally expand our U.S. clinical programs, revenues from U.S. sources in connection with our bridge-to-transplant trial may wane, after the first half of 2010 as we complete enrollment of this trial and we await approvals from the FDA to commence a destination therapy clinical trial and to continue implanting additional bridge-to-transplant patients under a Continued Access Program, or CAP, protocol in any U.S. center that implanted a patient in the bridge-to-transplant trial. Future product sales are dependent on many factors, including receiving and maintaining the necessary regulatory approvals in the United States and internationally, market acceptance among physicians, patients, health care payers and the medical community as well as our capacity to meet customer demand by manufacturing sufficient quantities of our products.

Cost of Revenues

Cost of revenues totaled approximately $13.2 million for the year ended December 31, 2009 and approximately $78,000 for the year ended December 31, 2008.

Gross profit and gross margin percentage are as follows:

	Years Ended December 31,	
	2009	**2008**
Gross profit (in thousands)	$ 10,961	$ 254
Gross margin %	45%	77%

We began capitalizing inventory on September 1, 2008. Prior to that time, product costs were expensed as R&D costs (see Critical Accounting Policies and Estimates — Inventories). At September 1, 2008, we had product on hand that was previously expensed as R&D costs but was subsequently utilized in the production and sale of finished goods. From September 2008 through the first half of 2009, the carrying value of our inventories and our cost of revenues were reduced by the value of product on hand that had been previously expensed as R&D. Therefore, cost of revenues for the last four months of 2008 and the first half of 2009 did not include the cost of this existing or pre-launch inventory and this resulted in a higher than expected gross margin until all pre-launch inventory was consumed. In addition, as we have limited manufacturing experience and we use a standard costing method for determining costs of inventory based on limited historical data, our actual results may differ from standards. As a result, gross margins have been and may continue to be inconsistent from quarter to quarter.

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, depreciation of fixed assets, travel, 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 revenues.

During 2009, we experienced significant growth as we established European sales and distribution capabilities and sold commercially throughout Europe and under special access in other countries. We also experienced growth in the U.S. as we initiated wider enrollment in our first human clinical trial in the United States, continued to manage dual listings of our securities in the United States and Australia, raised additional capital and expanded our research and development and manufacturing activities. As a result, we experienced expansion of our staff, including senior management, and a related expansion in infrastructure costs.

Also, in 2009, we entered into a merger agreement with Thoratec Corporation that ultimately was not consummated due to intervention from the U.S. Government on anti-competitive grounds. This unsuccessful merger did however result in the expenditure of substantial legal and other professional expenses.

In 2009, selling, general and administrative expenses were approximately $16.4 million, or 52%, of operating expenses, as compared to $11.0 million, or 37% of operating expenses in 2008. The increase was primarily a result of $4.7 million of legal and other expenses related to the proposed merger with Thoratec Corporation and increased share-based compensation of approximately $981,000. The increase in share-based compensation was due to the issuance of additional awards and the recognition in 2009 of expense related to awards previously granted in 2007 and 2008 with performance criteria that were not previously deemed probable. Upon being deemed probable in 2009, compensation expense was recognized from the initial grant date through the date the achievement of the performance criteria were deemed probable (see Note 9 of the accompanying financial statements).

Research and Development

Research and development expenses are the direct and indirect costs associated with developing our products prior to commercialization and are expensed as incurred. These expenses consist primarily of salaries and wages and related employee costs of our research and development and clinical and regulatory staff external research and development costs, materials and expenses associated with clinical trials. Additional costs include travel, facilities and overhead allocations.

Even with commercial approval of the HeartWare System in Europe, we expect that research and development expenses will continue to represent a significant portion of our operating expenses for the foreseeable future related to clinical trials in the U.S. and new product development, including costs related to the development of the MVAD.

As discussed above, we experienced significant growth in 2009. We achieved significant research and development milestones including enrolling a substantial number of patients in our U.S. clinical trial, developing three design configurations for the MVAD and furthering animal studies for less invasive implantable techniques related to the MVAD.

In 2009, research and development expenses were $15.1 million, or 48%, of operating expenses as compared to $18.6 million, or 63% of operating expenses, in 2008. The decrease was primarily a result of recognizing the labor, material and overhead costs of manufacturing the HeartWare System as part of inventory, and upon sale, as costs of revenue, in 2009 subsequent to the recognition of revenue and the capitalization of inventory (see Critical Accounting Policies and Estimates — Inventories). The decrease was partially offset by an increase in headcount and related employee costs in our research and development and clinical and regulatory groups as well as increased clinical trial costs, professional fees and other research and development expenses related to existing research projects and on-going clinical trials and regulatory activities.

Foreign Exchange

Foreign exchange losses totaled approximately $285,000 in the year ended December 31, 2009, as compared to a gain of approximately $4.6 million for the prior year. The difference was due to fluctuations in the overall balance, proportion and value of our cash holdings denominated in U.S. dollars held by our Australian subsidiary as a result of movements in the exchange rate between the Australian dollar and the U.S. dollar.

Historically, we maintained the majority of our cash and cash equivalents in Australia, denominated in both Australian and U.S. dollars throughout 2009, and as of December 31, 2009, the majority of our cash and cash equivalents were in U.S. dollars on deposit with banks located in the United States. Therefore, we expect that the amount of foreign exchange gains and losses on cash holdings held by our Australian subsidiary will not be as significant as historical amounts.

Interest Expense

Interest expense in 2009 consists of interest incurred on the principal amount of the convertible loans from Thoratec that were drawn down in August and December 2009 and amortization of deferred (non cash) financing costs related to the Thoratec Loan Agreement. Interest on the convertible loans was payable at a rate of 10% per annum. The deferred financing costs were being amortized over the term of the Thoratec Loan Agreement, which was set to expire no later than November 1, 2011. However, with the repayment of all amounts available to be borrowed under the terms of the agreement, we effectively extinguished all debt under this agreement. We will not incur any further amortization costs related to this agreement.

Interest expense was approximately $820,000 for the year ended December 31, 2009. Interest incurred on the principal amount of the convertible loans was approximately $149,000 and non-cash amortization of the deferred financing costs totaled approximately $671,000.

Interest Income, net

Interest income is primarily derived from cash and short-term deposit accounts, denominated in both Australian and U.S. dollars, held in Australia and the U.S. Interest income was approximately $101,000 for the year ended December 31, 2009 as compared to approximately $1.3 million for the prior year. The decrease was primarily due to lower interest rates earned and lower average daily cash balances during the 2009 period.

Change in Fair Value of Derivative Instrument

As further discussed in Note 8 to the accompanying financial statements, we recorded the fair value of a derivative instrument on July 31, 2009 related to the Australian dollar denominated conversion feature in the Thoratec Loan Agreement. We were required to initially record this derivative at fair value on July 31, 2009 and re-measure fair value at each reporting period. During the year ended December 31, 2009 we recognized aggregate non-cash expenses of approximately $3.9 million due to the increase in the fair value of this derivative between July 31, 2009 and December 29, 2009, the date the derivative was extinguished. This increase in fair value was primarily due to an increase in the fair value of our common stock and is non-cash in nature.

Gain on Early Extinguishment of Debt

As further discussed in Note 8 to the accompanying financial statements, in 2009, we recorded a net gain (non-cash) on the early extinguishment of debt related to the Thoratec Loan Agreement. Due to the repayment of all amounts borrowed under the Loan Agreement, our inability to re-borrow amounts repaid and Thoratec's inability to convert any repaid amounts into our common stock, the fair value of the derivative instrument at the repayment dates, aggregating approximately $7.8 million, was recorded as a gain on the extinguishment of debt. Further, the unamortized balance of the deferred financing costs at the repayment dates, aggregating approximately $3.2 million, was recorded as a reduction of the gain on early extinguishment of debt, resulting in a net gain on the early extinguishment of debt of $4.6 million for the year ended December 31, 2009. Since there are no funds held in escrow, there are no amounts remaining for us to borrow and no amounts remaining for Thoratec to convert into shares of HeartWare common stock. Therefore, Thoratec's conversion rights, and thus the derivative, have been eliminated.

Other, net

Other, net consists of gains and losses on the disposal of fixed assets. For the year ended December 31, 2009, we incurred a loss on the disposal of fixed assets of approximately $25,000 primarily in connection with the termination of our lease for administrative offices in Australia. For the year ended December 31, 2008, we incurred a loss on the disposal of fixed assets of approximately $188,000 primarily in connection with the termination of our lease for our prior manufacturing facility in Florida.

Income Taxes

We are subject to taxation in the United States and Australia. We have incurred losses since inception in both jurisdictions. Changes in share ownership, as well as other factors, may limit our ability to utilize any net operating loss carry-forwards, and as such a 100% valuation allowance has been recorded against our net deferred tax assets.

As of December 31, 2009, we did not have revenues or profit which would be sufficient to allow any portion of our deferred tax assets to be recorded. We intend to monitor closely the question of whether to record a deferred tax asset as we expand the commercialization of our products.

Liquidity and Capital Resources

As of December 31, 2010, our cash and cash equivalents were approximately $192.1 million as compared to $50.8 million at December 31, 2009. The increase is primarily a result of the cash proceeds from the issuance of convertible notes in December 2010, the issuance of common stock in February 2010 and the exercise of stock options, partially offset by cash used to support our operating and investing activities.

Following is a summary of our cash flow activities:

	Years Ended December 31,	
	2010	2009
	(in thousands)	
Net cash used in operating activities	$ (27,635)	$ (29,542)
Net cash used in investing activities	(32,132)	(1,473)
Net cash provided by financing activities	200,926	60,257
Effect of exchange rate changes on cash and cash equivalents	155	789
Net increase in cash and cash equivalents	$ 141,314	$ 30,031

Cash Used in Operating Activities

Cash used in operating activities for the year ended December 31, 2010 was approximately $27.6 million as compared to approximately $29.5 million for the same period in the prior year. For 2010, this amount included a net loss of approximately $29.4 million and non-cash adjustments to net loss in a total amount of approximately $13.6 million, which primarily consisted of $10.6 million of share-based compensation, and $1.5 million of depreciation and amortization. Also included in cash used in operating activities in 2010 is approximately $8.2 million related to an increase in accounts receivable and $6.7 million for the purchase and manufacture of inventories offset by cash provided by the increase of accrued expenses and other current liabilities of approximately $3.0 million. We expect increases in accounts receivable and inventory purchases to continue to be a significant use of cash throughout 2011 in support of our U.S. clinical trials and international commercial sales.

Cash used in operating activities for the year ended December 31, 2009 was approximately $29.5 million. For 2009, this amount included a net loss of approximately $20.9 million and non-cash adjustments to net loss in a total amount of approximately $5.1 million, which primarily consisted of approximately $4.6 million for the gain on early extinguishment of debt, $4.1 million of share-based compensation, $3.9 million for the change in fair value of a derivative and $1.6 million of depreciation and amortization. Included in cash used in operating activities in 2009 is approximately $11.1 million related to an increase in accounts receivable and $5.4 million for the purchase and manufacture of inventories offset by cash provided related to an increase in accounts payable of $2.5 million.

Cash Used in Investing Activities

Investing activities used cash of approximately $32.1 million and $1.5 million for the years ended December 31, 2010 and 2009, respectively. In 2010, cash used in investing activities included $25.8 million for the purchase of available-for-sale securities, $5.1 million to acquire property, plant and equipment and capitalized patent costs and $1.25 million of cash paid for a security deposit on a new facility lease. In 2009, cash used in investing activities primarily consisted of the costs to acquire property, plant and equipment and capitalized patent costs.

Cash Provided by Financing Activities

Cash provided by financing activities for the years ended December 31, 2010 and 2009 was approximately $200.9 million and $60.3 million, respectively. During 2010, these amounts were primarily the result of the net cash proceeds from the issuance of convertible senior notes and capital raises through the issuance of common stock.

In December 2010, we issued Convertible Senior Notes with an aggregate principal amount of $143.75 million pursuant to the terms of an Indenture dated as of December 15, 2010, and received net cash proceeds of approximately $139.0 million. The Convertible Senior Notes are senior unsecured obligations of the Company. The Convertible Senior 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, beginning on June 15, 2011. The Convertible Senior Notes will mature on December 15, 2017, unless earlier repurchased by the Company or converted.

In February 2010, we closed a public offering, under a shelf registration on Form S-3 filed with the Securities and Exchange Commission on December 24, 2009, of approximately 1.77 million shares of our common stock at an offering price of $35.50 per share for aggregate gross proceeds of approximately $62.8 million. This amount includes the underwriter's exercise of their over-allotment option to purchase an additional 230,595 shares of our common stock at the offering price. In 2010, we also received approximately $3.6 million from the exercise of stock options.

In 2009, we completed a private placement for the sale of approximately 2.74 million shares of our common stock at an issue price of $22.00 per share for aggregate gross proceeds of approximately $60.2 million. Related costs of approximately $1.5 million were paid in 2009. In 2009, we also received approximately $1.5 million from the exercise of stock options. Financing activities in 2009 reflect the borrowing and repayment of an aggregate of $20.0 million under a loan agreement. This loan agreement is discussed in the Note 6 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Operating Capital and Capital Expenditure Requirements

We have incurred operating losses to date and anticipate that we will continue to incur substantial net losses as we expand our sales and marketing capabilities, develop new products and seek regulatory approvals for the HeartWare System in the U.S. In 2011, 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, continuing implants under a CAP, and enrolling patients in our U.S. destination therapy clinical study, continued product development, regulatory and other compliance functions as well as for general working capital. We expect to experience increased cash requirements for inventory and property related to the expansion of our manufacturing capabilities to support continued growth.

We believe cash on hand and investment balances as of December 31, 2010 is sufficient to support our planned operations throughout 2011 and 2012.

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

- commercial acceptance of our products,
- costs to manufacture our products,
- expenses required to operate multiple clinical trials,
- further product research and development for next generation products and peripherals and efforts to sustain and maintain incremental improvements to existing products,
- expanding our sales and marketing capabilities on a global basis, including building a team to support U.S. commercialization should the FDA approve our device for marketing in the U.S.,
- 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 both the United States and Australia.

Contractual Obligations

At December 31, 2010, our contractual financial obligations and commitments by due dates were as follows:

	Total	Less than 1 year	1-3 years	3-5 years	Thereafter
Convertible senior notes	$ 178,969	$ 5,031	$ 10,063	$ 10,063	$ 153,812
Operating lease obligations	17,188	983	1,952	1,863	12,390
Purchase obligations	13,631	11,855	274	574	928
Total	$ 209,788	$ 17,869	$ 12,289	$ 12,500	$ 167,130

On January 24, 2011, the University of Michigan Cardiovascular Center and the University of Pittsburgh announced that they have been awarded grants from the National Heart, Lung and Blood Institute and the Company to conduct a study exploring the potential benefits of LVADs in patients who will be given earlier access to these devices. In the study, called REVIVE-IT, researchers will compare whether non-transplant eligible patients with heart failure less advanced than that of current LVAD recipients do better with implanted devices than with current medical therapy. This future financial commitment is not included in the above table. Our financial commitment for the study is up to $9.6 million of actual costs over the five-year trial period. The terms and conditions of the financial commitment are subject to completion of a definitive agreement.

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. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize 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.

Our convertible notes do not bear interest rate risk as the notes were issued with a fixed interest rate of 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 revenues 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 substantial portion of our revenues 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 impact our financial results and our overall cash position. These foreign currency transaction 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.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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. and subsidiaries (the Company) as of December 31, 2010 and 2009, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2010. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

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, 2010 and 2009, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2010 in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), HeartWare International, Inc. and subsidiaries' internal control over financial reporting as of December 31, 2010, based on criteria established in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated February 24, 2011 expressed an unqualified opinion.

/s/ Grant Thornton LLP

Fort Lauderdale, Florida

February 24, 2011

HEARTWARE INTERNATIONAL, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 192,148,312	$ 50,834,714
Short-term investments, net	21,330,110	—
Accounts receivable, net	19,052,672	11,384,647
Inventories, net	15,076,590	8,870,903
Prepaid expenses and other current assets	2,406,505	1,663,157
Total current assets	250,014,189	72,753,421
Property, plant and equipment, net	7,484,022	3,719,415
Long-term investments, net	4,005,659	—
Other intangible assets, net	1,595,456	1,191,917
Deferred financing costs, net	2,939,149	—
Restricted cash	1,538,429	288,429
Total assets	$ 267,576,904	$ 77,953,182
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,889,643	$ 3,122,131
Accrued expenses and other current liabilities	7,001,350	3,848,086
Total current liabilities	10,890,993	6,970,217
Convertible senior notes, net	88,921,557	—
Commitments and contingencies — See Note 15		
Stockholders' equity:		
Preferred stock — $.001 par value; 5,000,000 shares authorized; no shares issued and outstanding at December 31, 2010 and 2009, respectively	—	—
Common stock — $.001 par value; 25,000,000 shares authorized; 13,878,686 and 11,786,173 shares issued and outstanding at December 31, 2010 and 2009, respectively	13,879	11,786
Additional paid-in capital	302,533,344	176,698,329
Accumulated deficit	(127,268,545)	(97,871,645)
Accumulated other comprehensive loss:		
Cumulative translation adjustments	(7,548,706)	(7,855,505)
Unrealized gain on investments	34,382	—
Total accumulated other comprehensive loss	(7,514,324)	(7,855,505)
Total stockholders' equity	167,764,354	70,982,965
Total liabilities and stockholders' equity	$ 267,576,904	$ 77,953,182

The accompanying notes are an integral part of these financial statements.

HEARTWARE INTERNATIONAL, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2010	2009	2008
Revenues, net	$ 55,164,423	$ 24,171,783	$ 331,799
Cost of revenues	24,441,425	13,210,742	77,632
Gross profit	30,722,998	10,961,041	254,167
Operating expenses:			
Selling, general and administrative	26,642,279	16,444,202	10,981,131
Research and development	33,107,978	15,067,033	18,643,557
Total operating expenses	59,750,257	31,511,235	29,624,688
Loss from operations	(29,027,259)	(20,550,194)	(29,370,521)
Other income (expense):			
Foreign exchange gain (loss)	(502,339)	(284,985)	4,550,193
Interest expense	(431,308)	(819,944)	(17,555)
Interest income, net	564,006	100,549	1,262,695
Change in fair value of derivative instrument	—	(3,934,710)	—
Gain on early extinguishment of debt, net	—	4,605,613	—
Other, net	—	(25,187)	(188,433)
Loss before income taxes	(29,396,900)	(20,908,858)	(23,763,621)
Provision for income taxes	—	—	—
Net loss	$ (29,396,900)	$ (20,908,858)	$ (23,763,621)
Net loss per common share — basic and diluted	$ (2.17)	$ (2.15)	$ (3.00)
Weighted average shares outstanding — basic and diluted	13,569,876	9,713,925	7,929,054

The accompanying notes are an integral part of these financial statements.

HEARTWARE INTERNATIONAL, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Years Ended December 31,		
	2010	**2009**	**2008**
Net loss	$ (29,396,900)	$ (20,908,858)	$ (23,763,621)
Foreign currency translation adjustments	306,799	835,662	(9,302,940)
Unrealized gain on investments	34,382	—	—
Comprehensive loss	$ (29,055,719)	$ (20,073,196)	$ (33,066,561)

The accompanying notes are an integral part of these financial statements.

HEARTWARE INTERNATIONAL, INC.

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

	Common Shares, $.001 Par Value Per Share		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	Shares Issued	Amount				
Balance, December 31, 2007	7,088,572	$ 7,089	$ 81,852,174	$ (53,199,166)	$ 611,773	$ 29,271,870
Issuance of shares pursuant to capital raise, net of offering costs	1,778,130	1,778	29,396,849	—	—	29,398,627
Share-based compensation	—	—	1,151,619	—	—	1,151,619
Net loss	—	—	—	(23,763,621)	—	(23,763,621)
Other comprehensive loss:						
Foreign currency translation adjustment	—	—	—	—	(9,302,940)	(9,302,940)
Balance, December 31, 2008	8,866,702	8,867	112,400,642	(76,962,787)	(8,691,167)	26,755,555
Issuance of common stock pursuant to private placement, net of offering costs	2,737,273	2,737	58,619,272	—	—	58,622,009
Issuance of common stock pursuant to share-based awards	182,198	182	1,546,267	—	—	1,546,449
Share-based compensation	—	—	4,132,148	—	—	4,132,148
Net loss	—	—	—	(20,908,858)	—	(20,908,858)
Other comprehensive loss:						
Foreign currency translation adjustment	—	—	—	—	835,662	835,662
Balance, December 31, 2009	11,786,173	11,786	176,698,329	(97,871,645)	(7,855,505)	70,982,965
Issuance of common stock pursuant to public offering, net of offering costs	1,767,900	1,768	58,487,069	—	—	58,488,837
Issuance of common stock pursuant to share-based awards	324,613	325	3,556,106	—	—	3,556,431
Allocation of fair value of equity component of convertible notes	—	—	55,037,913	—	—	55,037,913
Allocation of a portion of convertible notes issuance costs to equity component of convertible notes	—	—	(1,830,820)	—	—	(1,830,820)
Share-based compensation	—	—	10,584,747	—	—	10,584,747
Net loss	—	—	—	(29,396,900)	—	(29,396,900)
Other comprehensive loss:						
Foreign currency translation adjustment	—	—	—	—	306,799	306,799
Unrealized gain on investments	—	—	—	—	34,382	34,382
Balance, December 31, 2010	13,878,686	$ 13,879	$302,533,344	$(127,268,545)	$ (7,514,324)	$167,764,354

The accompanying notes are an integral part of these financial statements.

HEARTWARE INTERNATIONAL, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2010	2009	2008
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$ (29,396,900)	$ (20,908,858)	$ (23,763,621)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation of property, plant and equipment	1,390,159	894,928	663,894
Amortization of intangible assets	101,500	75,871	41,187
Share-based compensation expense	10,584,747	4,132,148	1,151,619
Bad debt expense	600,000	—	—
Amortization of premium on investments	500,764	—	—
Amortization of discount on convertible notes	209,470	—	—
Amortization of deferred financing costs	11,231	670,903	—
Change in fair value of derivative instrument	—	3,934,710	—
Gain on early extinguishment of debt, net	—	(4,605,613)	—
Accrued interest on convertible note	209,635	—	(81,633)
Loss on disposal of assets	—	25,187	189,380
Change in operating assets and liabilities:			
Accounts receivable	(8,155,864)	(11,140,449)	(244,198)
Inventories, net	(6,740,688)	(5,362,838)	(3,508,065)
Prepaid expenses and other current assets	(732,783)	(643,939)	(229,815)
Accounts payable	765,787	2,523,508	59,906
Accrued expenses and other current liabilities	3,018,346	862,533	1,660,070
Net cash used in operating activities	(27,634,596)	(29,541,909)	(24,061,276)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of investments	(25,802,150)	—	—
Additions to property, plant and equipment	(4,575,416)	(1,030,945)	(1,490,248)
Additions to patents	(505,039)	(444,294)	(546,471)
Cash paid for security deposits	(1,250,000)	—	(288,429)
Proceeds from dispositions of assets	—	1,973	—
Net cash used in investing activities	(32,132,605)	(1,473,266)	(2,325,148)
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from issuance of common stock	62,760,450	60,220,006	30,239,247
Payment of common stock issuance costs	(4,359,934)	(1,509,675)	(840,620)
Proceeds from issuance of convertible debt	143,750,000	20,000,000	—
Repayment of convertible debt	—	(20,000,000)	(1,360,929)
Payment of convertible debt issuance costs	(4,781,201)	—	—
Proceeds from exercise of stock options	3,556,431	1,546,449	—
Net cash provided by financing activities	200,925,746	60,256,780	28,037,698
Effect of exchange rate changes on cash	155,053	789,453	(9,124,006)
CHANGE IN CASH AND CASH EQUIVALENTS	141,313,598	30,031,058	(7,472,732)
CASH AND CASH EQUIVALENTS — BEGINNING OF PERIOD	50,834,714	20,803,656	28,276,388
CASH AND CASH EQUIVALENTS — END OF PERIOD	$ 192,148,312	$ 50,834,714	$ 20,803,656
Supplemental disclosure of cash flow information:			
Interest paid	$ —	$ 149,041	$ 88,870
Supplemental disclosure of non-cash investing and financing activities:			
Transfers of equipment from inventory to property, plant and equipment	$ 535,000	$ —	$ —
Recognition of fair value of derivative instrument	$ —	$ 3,891,109	$ —

The accompanying notes are an integral part of these financial statements.

HEARTWARE INTERNATIONAL, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
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Note 1. Description of Business

HeartWare International, Inc., referred to in these notes collectively with its subsidiaries HeartWare Pty. Limited, HeartWare, Inc., HeartWare (UK) Limited and HeartWare GmbH as "we," "our," "HeartWare" or the "Company", is a medical device company that develops and manufactures small implantable heart pumps, or ventricular assist devices, which are used by physicians and hospitals for the treatment of advanced heart failure.

The HeartWare Ventricular Assist System (the "HeartWare System"), which includes a left ventricular assist device ("LVAD"), patient accessories and surgical tools, is designed to provide circulatory support for patients with advanced heart failure. The core of the HeartWare 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.

In January 2009, the HeartWare System received Conformite Europenne ("CE") Marking approval, which allows us to market and sell the device in Europe. Our first commercial sale in Europe occurred in March 2009. The HeartWare System is also sold to customers located in the U.S. through our clinical trials and under special access in other countries.

In April 2008, we received conditional Investigational Device Exemption ("IDE") approval from the United States Food & Drug Administration ("FDA") to enroll 150 patients in a bridge-to-transplant clinical study in the United States (called "ADVANCE"). Full IDE approval for the HeartWare System was received from the FDA in September 2008 and, in October 2009 we received FDA approval to expand the number of participating sites from 28 to 40 centers. In February 2010, we completed enrollment in this trial with 140 patients receiving the HeartWare System. The remaining 10 patients were enrolled but did not receive an implant of the HeartWare System because they failed to meet the trial's inclusion and exclusion criteria after being enrolled.

We continue to enroll patients in our ADVANCE trial under a Continued Access Protocol ("CAP"). The CAP makes the HeartWare System available to patients and clinicians while also providing additional data for the FDA to evaluate prior to determining whether or not to approve the HeartWare System. The CAP patients will be enrolled and followed under a modified protocol of the ADVANCE trial. The FDA grants approval to enroll under CAP for specific patient cohorts, the most recent being a third allotment of 94 patients, approved in January 2011.

In June 2010, we received conditional IDE approval from the FDA to begin enrollment in our destination therapy clinical study for the HeartWare System. Designed to enroll up to 450 patients at 50 U.S. hospitals, the non-inferiority study, which is named "ENDURANCE," is a randomized, controlled, unblinded, multi-center clinical trial to evaluate the use of the HeartWare System as a destination therapy in advanced heart failure patients. The study population will be selected from patients with end-stage heart failure who have not responded to standard medical management and who are ineligible for cardiac transplantation. Patients in the study will be randomly selected to receive either the HeartWare System or, as part of a control group they will be implanted with any alternative LVAD approved by the FDA for destination therapy, in a 2:1 ratio. Each patient receiving the HeartWare System or control LVAD will be followed to the primary endpoint at two years, with a subsequent follow-up period extending to five years post implant. In August 2010, our first patient was implanted as part of the ENDURANCE trial and we received full IDE approval from the FDA in September 2010.

Beyond the HeartWare System, we are also evaluating our next generation device, the Miniaturized Ventricular Assist Device ("MVAD"). The MVAD is based on the same technology platform as the HeartWare System but adopts an axial flow, rather than a centrifugal flow, configuration and is being developed in multiple configurations. The MVAD designs are currently at the preclinical stage and undergoing animal studies focused on less invasive implantation techniques. Each of the MVAD configurations is approximately one-third the size of the HVAD Pump. We believe that the MVAD designs will be implantable by surgical techniques that are even less invasive than those required to implant the HVAD Pump.

We are headquartered in Framingham, Massachusetts. We have an operations and manufacturing facility in Miami Lakes, Florida, a small development and operations facility in Sydney, Australia and a small distribution and customer service facility in Hannover, Germany.

HEARTWARE INTERNATIONAL, INC.
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Basis of Presentation

Effective November 13, 2008, we redomiciled from Australia to the United States. Pursuant to a court approved scheme of arrangement under Australian law, all ordinary shares of HeartWare Limited, a company incorporated in Australia, were transferred by court order to HeartWare International, Inc., a Delaware corporation, in exchange for shares of common stock of HeartWare International, Inc. Holders received common stock in a ratio of 35 HeartWare Limited ordinary shares to 1 share of HeartWare International, Inc. common stock. All outstanding equity awards of HeartWare Limited were assumed by HeartWare International, Inc. at historical cost. All share-based awards were assumed by HeartWare International, Inc. and equitably adjusted to reflect the reincorporation. Throughout these financial statements, all share information, including related per share data, has been adjusted to give retroactive effect to the reincorporation for all periods presented.

HeartWare International, Inc. shares trade on the NASDAQ Stock Market under the symbol of "HTWR". The Company's shares also trade on the Australian Securities Exchange ("ASX") in the form of CHESS Depositary Interests ("CDIs") under the symbol of "HIN". Each CDI represents 1/35th of a share of common stock.

Note 2. Liquidity

At December 31, 2010, we had approximately $217.5 million of cash, cash equivalents and investments. The accompanying 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 sustained substantial losses from operations since our inception, and such losses have continued through December 31, 2010. At December 31, 2010, we had an accumulated deficit of approximately $127.3 million.

We have financed our operations primarily through the issuance of shares of our common stock and the issuance of convertible notes. Most recently, in December 2010, we consummated the issuance and sale of $143.75 million aggregate principal amount of convertible notes. The convertible notes are the senior unsecured obligations of the Company. The convertible 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, beginning on June 15, 2011. The convertible notes will mature on December 15, 2017, unless earlier repurchased or converted. The convertible notes will be convertible at an initial conversion rate of 10 shares of common stock per $1,000 principal amount of convertible notes, which corresponds to an initial conversion price of $100.00 per share of common stock.

In 2011, our cash, cash equivalents and investments are expected to primarily be used to fund our ongoing operations including expanding our sales and marketing capabilities on a global basis, continuing our ENDURANCE trial for destination therapy, enrolling additional patients in our ADVANCE trial under a CAP, continued product development, regulatory and other compliance functions as well as for general working capital. We believe our cash, cash equivalent and investment balances are sufficient to support our planned operations through 2012.

Note 3. Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of HeartWare International, Inc., and its subsidiaries described in Note 1. All inter-company balances and transactions have been eliminated in consolidation.

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 revenues and expenses during the reporting periods. Actual results could differ from those estimates.

HEARTWARE INTERNATIONAL, INC.
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Cash and Cash Equivalents

Cash and cash equivalents are recorded in the consolidated balance sheets at cost, which approximates fair value. All highly liquid investments purchased with an original maturity of three months or less 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 is beyond three months. Investments with maturities beyond one year 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 interest income, net. Premiums paid on our short-term investments are amortized over the remaining term of the investment and are included in Interest income, net.

Receivables

Accounts receivable consists of amounts due from the sale of our HeartWare System to our customers, which are primarily hospitals and health research institutions. As of December 31, 2010, one customer had an accounts receivable balance greater than 10% of total accounts receivable representing approximately 13% of our total accounts receivable. As of December 31, 2009, one customer had an accounts receivable balance representing approximately 16% of our total accounts receivable.

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. Prior to 2010, we did not maintain an allowance for doubtful accounts and as of December 31, 2010 and 2009 we did not have an allowance for returns.

The following table summarizes the change in our allowance for doubtful accounts for the year ended December 31, 2010:

	2010
Beginning balance	$ —
Additions (bad debt expense)	600,000
Deductions (charge-offs)	—
Ending balance	$ 600,000

Inventories, net

Components of Inventories, net are as follows:

	December 31,	
	2010	2009
Raw material	$ 4,279,170	$ 2,984,486
Work-in-process	2,708,840	1,497,591
Finished goods	8,088,580	4,388,826
	$ 15,076,590	$ 8,870,903

Finished goods inventories includes inventory held on consignment at customer sites of $4.7 million and $3.8 million, at December 31, 2010 and 2009, respectively.

HEARTWARE INTERNATIONAL, INC.
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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 includes direct and indirect labor and manufacturing overhead. Finished goods includes 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 inventory and write-down obsolete or otherwise unmarketable inventory to its estimated net realizable value.

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 at December 31:

	Estimated Useful Lives	December 31, 2010	December 31, 2009
Property, plant and equipment			
Machinery and equipment	1.5 to 7 years	$ 8,966,747	$ 5,295,217
Leasehold improvements	3 to 7 years	282,483	210,570
Office equipment, furniture and fixtures	5 to 7 years	450,849	278,587
Purchased software	5 to 7 years	1,741,132	487,388
		11,441,211	6,271,762
Less: accumulated depreciation		(3,957,189)	(2,552,347)
		$ 7,484,022	$ 3,719,415

Depreciation expense was $1,390,159, $894,928 and $663,894 for the years ended December 31, 2010, 2009 and 2008, respectively.

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 revenues 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 HeartWare 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 revenues and is computed using the straight-line method based on the estimated useful life of one and one half years.

The net carrying value of equipment subject to the agreements discussed above was approximately $520,000 as of December 31, 2010.

Deferred Financing Costs

Costs incurred in connection with the issuance of our convertible senior notes have been allocated between the liability component and the equity component as further discussed in Note 8. The liability component of the issuance costs incurred was capitalized and is included in Deferred financing costs, net on the consolidated balance sheets. These costs are amortized using the effective interest method until December 15, 2017, the maturity date of the notes, and such amortization expense is reflected in Interest expense on our consolidated statements of operations. The amount of amortization for the year ended December 31, 2010 was approximately $11,000.

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Other Intangible Assets, net

The gross carrying amount of intangible assets and the related accumulated amortization for intangible assets subject to amortization at December 31 are as follows:

		2010		2009	
Amortizable Intangible Assets	Weighted Average Life (Years)	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Patents	15	$ 1,861,684	$ (266,228)	$ 1,356,645	$ (164,728)

Amortization expense for the years ended December 31, 2010, 2009 and 2008 was $101,500, $75,871 and $41,187, respectively.

Estimated amortization expense for each of the five succeeding fiscal years based upon our intangible asset portfolio at December 31, 2010 is approximately $124,000.

Revenue Recognition

We recognize revenue from product sales in accordance with FASB ASC 605 — *Revenue Recognition*. Pursuant to agreements or orders from customers, we ship product to our customers. Revenue from product sales is only recognized when substantially all the risks and rewards of ownership have transferred to our customers, the selling price is fixed and collection is reasonably assured. A majority of product sales are made on a consignment basis and as such, pursuant to the terms of the consignment arrangements, revenue is recognized on the date the consigned product is implanted or otherwise consumed. Revenue from product sales not sold on a consignment basis is recognized upon customer receipt and acceptance of the product. Shipping fees billed to customers are included in revenues and the related shipping costs are included in cost of revenues. 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 Revenues, net. Revenue recognized to date is from sales of our devices in connection with our U.S. clinical trials, as commercial products to customers in Europe and under special access in countries.

Product Warranty

Certain patient accessories sold with the HeartWare 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 revenues 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 amount of the liability recorded is equal to the estimated costs to repair or otherwise satisfy claims made by customers. Accrued warranty expense is included as a component of Accrued expenses and other current liabilities on the consolidated balance sheets. Prior to 2009, we did not maintain an accrual for product warranty as revenue was minimal.

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 revenues and are not included in product warranty liability.

The following table summarizes the change in our warranty liability for the years ended December 31, 2010 and 2009:

	2010	2009
Beginning balance	$ 99,169	$ —
Accrual for warranties	311,920	99,169
Warranty costs incurred during the period	(120,198)	—
Ending balance	$ 290,891	$ 99,169

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Share-Based Payments

We recognize share-based compensation expense in connection with our share-based awards, net of an estimated forfeiture rate and therefore only recognize compensation cost for those awards expected to vest over the service period of the award. We value Restricted Stock Units ("RSU's") at their intrinsic value on the date of grant. We use a Black-Scholes option pricing model to estimate the fair value of our stock options. Calculating share-based compensation expense requires the input of highly subjective judgment and assumptions, including estimates of expected life of the award, stock price volatility, forfeiture rates 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.

When appropriate, we estimate the expected life of an option by averaging the contractual term of the stock option grants (up to 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 forfeiture rate based on our historical experience of forfeitures and our employee retention rate. If our actual forfeiture rate is materially different from our estimate, the share-based compensation expense could be significantly different from what we have recorded in the current period. We estimate the risk-free interest rate based on rates in effect for United States government bonds with similar lives, 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. If ultimately performance goals are not met, for any awards where vesting was previously deemed probable, previously recognized compensation cost will be reversed.

Impairment of Long-Lived Assets

We review our long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable from future undiscounted cash flows. Impairment losses are recorded for the excess, if any, of the carrying value over the fair value of the long-lived assets. As of December 31, 2010, none of our long-lived assets were impaired.

Income Taxes

We account for income taxes in accordance with 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 — *Income Taxes*.

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.

Translation of Foreign Currency

Assets and liabilities of our non-U.S. entities are translated at the period-end exchange rate and revenues 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.

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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.

The exchange rate between the U.S. and Australian dollar has fluctuated substantially in the past. This fluctuation resulted in significant changes in the cumulative translation adjustment and foreign exchange gains during the year ended December 31, 2008. During that period of time, our Australian subsidiary, HeartWare Pty. Limited, which operates in a functional currency of Australian dollars, held significant U.S. dollar cash accounts. Exchange rate fluctuations affect the value of these accounts and result in foreign currency gains and losses. Such gains and 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, 2010, 2009 and 2008.

Fair Value Measurements

The carrying amounts reported in the consolidated balance sheets for cash and cash equivalents, accounts receivable, accounts payable and accrued expenses and other current liabilities approximate their fair value based on the short-term maturity of these instruments. Investments are considered available-for-sale as of December 31, 2010 and are carried at fair value. Our convertible senior notes were recorded at fair value on the issuance date. See Note 5, "Fair Value Measurements" and Note 8, "Debt" for more information.

Vendor Concentration

For the years ended December 31, 2010, 2009 and 2008, we purchased approximately 66%, 60% and 58%, 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, 2010 and 2009, the amounts due to these vendors totaled approximately $902,000 and $846,000, 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 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.

Concentration of credit risk with respect to our trade accounts receivable from our customers is primarily limited to hospitals and health research institutions. Credit is extended to our customers, based on an evaluation of a customer's financial condition and collateral is not required. To date, we have not experienced any credit losses, but have established an allowance for doubtful accounts of $600,000 at December 31, 2010.

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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, the ability to achieve widespread acceptance of our product, 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 October 2009, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2009-14, *Software (Topic 985): Certain Revenue Arrangements That Include Software Elements (a consensus of the FASB Emerging Issues Task Force).* ASU No. 2009-14 amends ASC 985-605, *Software: Revenue Recognition*, such that tangible products, containing both software and non-software components that function together to deliver the tangible product's essential functionality, are no longer within the scope of ASC 985-605. It also amends the determination of how arrangement consideration should be allocated to deliverables in a multiple-deliverable revenue arrangement. ASU No. 2009-14 will become effective for us for revenue arrangements entered into or materially modified after our fiscal year ending December 31, 2010. Earlier application is permitted with required transition disclosures based on the period of adoption. Adoption of the provisions of ASU No. 2009-14 is not expected to have a material effect on our consolidated financial position, results of operations or cash flows.

In January 2010, the FASB issued ASU No. 2010-6, *Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements*. This update requires new disclosures for fair value measurements and provides clarification for existing disclosures requirements. The majority of the new disclosure requirements became effective for us on January 1, 2010. Certain of the disclosure requirements will be effective for us on January 1, 2011. As ASU No. 2010-6 only requires enhanced disclosures, the adoption of ASU No. 2010-6 did not have a material effect on our consolidated financial position, results of operations or cash flows and did not materially expand our financial statement footnote disclosures.

In April 2010, the FASB issued ASU No. 2010-13, *Compensation-Stock Compensation (Topic 718): Effect of Denominating the Exercise Price of a Share-Based Payment Award in the Currency of the Market in Which the Underlying Equity Security Trades*. ASU No. 2010-13 clarifies that an employee share-based payment award with an exercise price denominated in the currency of a market in which a substantial portion of the entity's equity securities trades should not be considered to contain a condition that is not a market, performance, or service condition. Therefore, an entity would not classify such an award as a liability if it otherwise qualifies as equity. The provisions of ASU No. 2010-13 will be effective for us on January 1, 2011. Early adoption is permitted. Adoption of the provisions of ASU No. 2010-13 is not expected to have a material effect on our consolidated financial position, results of operations or cash flows.

Note 4. Investments

We have cash investment policies that limit investments to investment grade securities. At December 31, 2010, all of our investments were classified as available-for-sale and carried at fair value. Our short-term investments had maturity dates of less than twenty-four months, while our long-term investments matured beyond twenty-four months, but within thirty months of the date of this report. Such investments consist of corporate debt, a portion of which is guaranteed by foreign governments, and U.S. government agency debt securities. At December 31, 2009, we did not hold any investments.

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The amortized cost and fair value of our investments, with gross unrealized gains and losses, at December 31, 2010 is as follows:

	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value
Short-term investments:				
Corporate debt	$ 21,294,673	$ 35,437	$ —	$ 21,330,110
Total short-term investments	$ 21,294,673	$ 35,437	$ —	$ 21,330,110
Long-term investments:				
U.S. government agency debt	$ 4,006,714	$ —	$ (1,055)	$ 4,005,659
Total long-term investments	$ 4,006,714	$ —	$ (1,055)	$ 4,005,659

In the year ended December 31, 2010 we did not have any realized gains or losses on our investments.

Note 5. 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 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.

The following table represents 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.

	Carrying Value	Fair Value	Fair Value Measurements at the Reporting Date Using		
			Level 1	Level 2	Level 3
Assets					
Short-term investments	$ 21,330,110	$ 21,330,110	$ —	$ 21,330,110	$ —
Long-term investments	$ 4,005,659	$ 4,005,659	$ —	$ 4,005,659	$ —
Liabilities					
Convertible senior notes	$ 89,921,557(1)	$ 160,693,813	$ —	$ 160,693,813	$ —

(1) The carrying amount of our convertible senior notes is net of unamortized discount. See Note 8, "Debt" for more information.

The fair value of our investments and convertible senior notes was determined using quoted prices for the instruments in markets that are not active. The fair value of our convertible senior notes is presented for disclosure purposes only.

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Note 6. Other Balance Sheet Information

Accrued expenses and other current liabilities consist of the following at December 31:

	December 31,	
	2010	2009
Accrued payroll and other employee costs	$ 4,152,833	$ 2,487,066
Accrued research and development costs	671,928	344,256
Accrued VAT	647,525	42,256
Accrued professional fees	577,237	347,063
Accrued material purchases	255,679	370,226
Other accrued expenses	696,148	257,219
	$ 7,001,350	$ 3,848,086

Accrued payroll and other employee costs included year-end employee bonuses of approximately $3.1 million and $1.7 million at December 31, 2010 and 2009, respectively.

Note 7. Exchange of Equity Interests Among Entities Under Common Control

On November 13, 2008, the Company completed an Australian court approved redomiciliation transaction whereby HeartWare International, Inc., a Delaware Corporation, replaced HeartWare Limited, an Australian public company as the ultimate parent company of the HeartWare Group. The transaction was accounted for as an exchange of equity interests among entities under common control. All assets and liabilities of HeartWare Limited were assumed by HeartWare International, Inc. and were accounted for at historical cost.

Note 8. Debt

Convertible Senior Notes

On December 15, 2010, we consummated the issuance and sale of $143.75 million aggregate principal amount of 3.5% convertible senior notes due 2017 (the "Convertible Notes") pursuant to the terms of an Indenture dated December 15, 2010. The Convertible Notes are the senior unsecured obligations of the Company. The Convertible 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, beginning on June 15, 2011. The Convertible Notes will mature on December 15, 2017, unless earlier repurchased by us or converted.

The Convertible Notes will be convertible at an initial conversion rate of 10 shares of our common stock per $1,000 principal amount of Convertible Notes, which corresponds to an initial conversion price of $100.00 per share of our common stock, representing a conversion premium of approximately 23% based on the closing price of $81.31 per share of our common stock on December 9, 2010. 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 Convertible Notes at their option only upon satisfaction of one or more 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. On or after June 15, 2017 until the close of business of the business day immediately preceding the date the Convertible Notes mature, holders may convert their Convertible Notes at any time, regardless of whether any of the foregoing conditions have been met. As of the date of the filing, none of the events that would allow holders to convert their Convertible Notes have occurred. 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 Convertible Notes prior to maturity. Holders of the Convertible Notes may require us to purchase for cash all or a part of their Convertible Notes at a repurchase price equal to 100% of the principal amount of the Convertible 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 payments of dividends, the incurrence of indebtedness or the issuance or repurchase of securities by us or any of our subsidiaries.

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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 Convertible 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 Convertible 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 Convertible Notes will automatically become due and payable. Upon such a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately. 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 Convertible Notes.

In accordance with ASC 470-20, *Debt*, 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 Convertible 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 measurement of fair value required the Company to make estimates and assumptions to determine the present value of the cash flows of the Convertible Notes, absent the conversion feature. This treatment increased interest expense associated with our Convertible Notes by adding a non-cash component to amortize 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 Convertible Notes using the effective interest method and is included in interest expense on the consolidated statements of operations. Additionally, we allocated the costs related to issuance of the Convertible 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 Convertible Notes using the effective interest method and such amortization is included in interest expense on the consolidated statements of operations

The Convertible Notes and the equity component, which is recorded in additional paid-in-capital, consisted of the following at December 31, 2010:

Principal amount	$	143,750,000
Unamortized discount		(54,828,443)
Net carrying amount	$	88,921,557
Equity component	$	55,037,913

Based on the initial conversion rate of 10 shares of our common stock per $1,000 principal amount of Convertible 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 Convertible Notes is 1,437,500. The value of these shares, based on the closing price of our common stock on December 31, 2010 of $87.57, was approximately $125.9 million. The fair value of our Convertible Notes as presented in Note 5 was $160.7 million at December 31, 2010.

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 year ended December 31, 2010, interest expense related to the Convertible Notes was as follows:

Stated amount at 3.5% coupon rate	$	209,636
Amortization of discount		209,470
Amortization of deferred financing costs		11,231
	$	430,337

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Thoratec Loan Agreement

On February 12, 2009, we entered into an Agreement and Plan of Merger ("Merger Agreement") with Thoratec Corporation ("Thoratec"). Concurrent with the Merger Agreement, and as described in a Current Report on Form 8-K filed with the SEC on February 13, 2009, we entered into a loan agreement ("Loan Agreement") with Thoratec, pursuant to which Thoratec committed to loan us up to $28.0 million through one or more term loans subject to the terms and conditions set forth in the Loan Agreement. On July 31, 2009, HeartWare and Thoratec agreed to terminate the Merger Agreement pursuant to Section 8.01 (a) of the agreement. The Loan Agreement survived the termination of the Merger Agreement and as of July 31, 2009, the date the Merger Agreement was terminated, we were able to borrow up to $20.0 million under the Loan Agreement.

Any loans to us under the Loan Agreement, at Thoratec's option, could have been converted in whole or in part into shares of HeartWare common stock prior to the maturity date of the loans The number of shares to be issued was determined by dividing the outstanding principal amount of the loans, including any accrued and unpaid interest, or funds held in escrow by the U.S. dollar equivalent of AU$35.00 at the time of the conversion. The conversion price was subject to customary adjustment provisions as defined in the Loan Agreement.

As of December 31, 2009, the entire $20.0 million commitment under the Loan Agreement had been borrowed and repaid and was no longer available to us. In addition, since there are no funds held in escrow, there are no amounts for Thoratec to convert into shares of HeartWare common stock, thereby eliminating entirely Thoratec's conversion rights. The amount of interest expense incurred and paid on amounts borrowed under the Loan Agreement during the year ended December 31, 2009 was approximately $149,000.

Beginning July 31, 2009, the date the Merger Agreement was terminated, Thoratec became entitled to convert any escrow funds in whole or in part into shares of HeartWare International common stock at any time prior to termination of the Loan Agreement. The terms and conditions of this conversion provision were evaluated and determined to result in an embedded derivative within the host contract Loan Agreement. We computed the fair value of the embedded derivative to be approximately $3.9 million at July 31, 2009, the initial measurement date. Fair value was determined using a valuation model with observable market inputs to determine relevant assumptions including interest rates and stock and foreign currency volatilities. The initial fair value was capitalized as deferred financing costs and was being amortized over the contractual term of the Loan Agreement. The amount of amortization for the year ended December 31, 2009 was approximately $671,000 and is included in Interest expense on our consolidated statements of operations. Due to the repayment of all amounts borrowed under the Loan Agreement and our inability to re-borrow amounts repaid, the proportionate amount of the unamortized balance of the deferred financing costs at the repayment dates were recorded as an expense. These amounts aggregating approximately $3.2 million are included in the line item Gain on early extinguishment of debt, net on our consolidated statements of operations.

The change in the fair value of the derivative instrument during the period of time it remained outstanding resulted in an expense aggregating approximately $3.9 million. This amount is presented as a separate line item on our consolidated statements of operations. Due to the repayment of all amounts borrowed under the Loan Agreement, our inability to re-borrow amounts repaid and Thoratec's inability to convert any repaid amounts into our common stock, the proportionate amount of the fair value of the derivative at the repayment dates, aggregating to $7.8 million, as well as the unamortized balance of deferred financing costs of $3.2 million, was recorded as a gain on the extinguishment of debt. The net amount of $4.6 million is shown on the line item Gain on early extinguishment of debt, net on our consolidated statements of operations.

Note 9. Leases

On September 30, 2010, we amended and renewed our lease for our facility in Miami Lakes, Florida. This facility contains our domestic operations and manufacturing. Under the amended lease we will maintain our existing space of approximately 59,000 square feet, extend the lease term by approximately two years to expire on June 30, 2013 and pay a base rent of $9.00 per square foot starting in June 2011, subject to a 3% annual escalation thereafter. Under the amended lease, we have an option to renew for two additional three-year periods.

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On August 16, 2010, we amended and renewed our lease for our headquarters in Framingham, Massachusetts. Under the amended lease we began occupying additional space in the fourth quarter of 2010, increasing our total square footage from 7,040 to approximately 15,000. Base rent obligations will increase to approximately $275,000 per year. The lease term expires on December 31, 2014 and we have an option to renew for an additional four-year period at fair market value, as defined in the lease agreement. We also have an option to expand with an additional 3,002 square foot space in the building.

On December 9, 2010, we signed a lease for a new facility in Miami Lakes, Florida as part of our planned expansion to support our efforts to prepare for U.S. commercialization. The facility will be used primarily for manufacturing, research and development and administrative functions. Under the lease, we will rent approximately 131,000 square feet for a period ending February 28, 2022, with an option to renew for two five-year terms. The landlord will provide up to $1.75 million towards capital improvements. Base rent will be $9.00 per square foot, payable starting March 2012 and subject to a 3% annual escalation thereafter. A security deposit of $1.25 million was provided 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 Restricted cash on our consolidated balance sheet as of December 31, 2010.

In addition to the leases discussed above, we have entered into various operating lease agreements for miscellaneous office space and equipment. The duration of these agreements is typically twenty-four to thirty-six months from origination. The aggregate base annual rental payment on these leases is less than $100,000.

We recognize rent expense on a straight-line basis over the term of the lease. Any scheduled rent increases, rent holidays and other related incentives are recognized on a straight-line basis over the term of the lease. Rent expense was approximately $931,000, $879,000 and $967,000 in 2010, 2009 and 2008, respectively. Future minimum rental commitments under non-cancelable operating lease agreements with remaining terms of at least one year as of December 31, 2010 are as follows:

	Operating Leases
Year Ending December 31,	
2011	$ 983,323
2012	1,951,893
2013	1,862,645
2014	1,607,997
2015	1,371,313
After 2015	9,410,565
Total minimum lease payments	$ 17,187,736

Note 10. 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 25,000,000 shares of common stock, $.001 par value per share. As of December 31, 2010, we had 13,878,686 shares outstanding. Holders are entitled to one vote for each share of common stock (or its equivalent).

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Shares of our common stock reserved at December 31, 2010, for possible future issuance are as follows:

Convertible senior notes	1,767,923
Equity award plans	949,231
	2,717,154

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

2010 Public Offering

In February 2010, we completed a public offering of approximately 1.77 million shares of our common stock, including the underwriter's exercise of their overallotment to purchase 230,595 shares, at an offering price of $35.50 per share for aggregate gross proceeds of approximately $62.8 million. The underwriters for the transaction received a fee of 6% of the gross proceeds. After fees and related expenses, net proceeds from the offering were approximately $58.5 million.

The offering was completed pursuant to a prospectus supplement, dated January 27, 2010, to a shelf registration statement on Form S-3 that was previously filed with the SEC and which was declared effective on January 20, 2010. 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 of the securities described in the prospectus, up to an aggregate amount of $100 million.

2009 Private Placement

In August and September 2009, we entered into Purchase Agreements separately with a number of institutional and accredited investors for the private placement of approximately 2.74 million shares of our common stock at an issue price of $22.00 per share for aggregate gross proceeds of approximately $60.2 million. The placement agent for the transaction received a placement fee in aggregate of approximately 2% of the gross proceeds.

The issuance of approximately 1.4 million shares of the total number of shares sold to the investors in the Private Placement was subject to approval by our stockholders in accordance with NASDAQ Stock Market Rules and Australian Securities Exchange Listing Rules and, as a result, approximately $30.7 million of the proceeds from the Private Placement were held in escrow by an independent third party. Such proceeds were released to us and the 1.4 million shares were issued following stockholder approval which was obtained at a special meeting of stockholders held on October 26, 2009.

2008 Private Placement

In July 2008, we completed a private placement of approximately 1.78 million shares of our common stock for gross proceeds of approximately $29.9 million. After fees and expenses, net proceeds were approximately $29.4 million.

The Company's issuance and sale of its shares of common stock in this private placement were exempt from SEC registration pursuant to Regulation S under the Securities Act of 1933, as amended (the "Act") with respect to Australian investors, and pursuant to Regulation D under the Act with respect to United States investors.

Note 11. Share-Based Compensation

We recognize share-based compensation expense for the portion of awards that are ultimately expected to vest using an accelerated accrual method over the vesting period from the date of grant. We estimate forfeitures at the time of grant. We have applied a forfeiture rate of approximately 12.5% to all unvested share-based awards as of December 31, 2010, which represents the portion that we expect will be forfeited over the vesting period. We reevaluate this analysis periodically and adjust the forfeiture rate as necessary. Vesting of share-based awards issued with performance-based vesting criteria must be "probable" before we begin recording share-based compensation expense. At each reporting period, we review the likelihood that these awards will vest and if vesting is deemed probable, we begin to recognize compensation expense at that time. If ultimately performance goals are not met, for any awards where vesting was previously deemed probable, previously recognized compensation cost will be reversed.

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We allocate share-based compensation expense to cost of revenues, selling, general and administrative expense and research and development expense based on the award holders' employment function. For the years ended December 31, 2010, 2009 and 2008, we recorded share-based compensation expenses as follows:

	2010	2009	2008
Cost of revenues	$ 937,388	$ 805,387	$ 37,405
General and administrative	7,629,282	2,006,709	1,025,548
Research and development	2,018,077	1,320,052	88,666
	$ 10,584,747	$ 4,132,148	$ 1,151,619

For the years ended December 31, 2010 and 2009, we experienced a significant increase in share-based compensation expense due primarily to an annual grant of equity awards to a large group of our employees in September 2009. A portion of this grant was subject to stockholder approval. Upon receipt of stockholder approval at our annual meeting of stockholders in the second quarter of 2010, we recorded a true-up of share-based compensation expense to coincide with the award's vesting period of approximately $1.2 million.

No deferred tax benefits were attributed to our share-based compensation expense recorded 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.

On August 5, 2008, we adopted the HeartWare International, Inc. 2008 Stock Incentive Plan ("2008 SIP"). The 2008 SIP allows for the issuance of share-based awards to employees, directors and consultants. We have issued options and restricted stock units ("RSU's") to employees and directors under the 2008 SIP. The plan allows for the issuance of share-based awards representing up to 13% of the prior fiscal year's weighted average shares outstanding, less share-based awards outstanding under our other equity plans. At December 31, 2010, there were no shares available for future awards under the 2008 SIP. Under the terms of the 2008 SIP, the shares available for future issuance are adjusted on January 1st of each year based on the prior year's weighted average shares outstanding. As of January 1, 2011, the shares available for future issuance were approximately 671,000. Future share-based awards will only be made from the 2008 SIP.

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 fair market value 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.

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In 2007 and 2008, we granted options with performance-based vesting criteria. These performance-based options vest in four equal tranches contingent upon the achievement of pre-determined corporate milestones related primarily to the development of our products and the achievement of certain prescribed clinical and regulatory objectives. Any performance-based options that have not vested after five years from the date of grant automatically expire.

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 the periods noted.

	Years Ended December 31,		
	2010	2009	2008
Dividend yield	0.00%	0.00%	0.00%
Expected volatility	60.94%	60.50%	58.23%
Risk-free interest rate	2.71%	2.80%	6.22%
Estimated holding period (years)	6.25	6.25	6.22

Information related to options granted under all of our plans at December 31, 2010 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):

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2009	520,835	$ 27.96		
Granted	34,250	48.57		
Exercised	(131,405)	27.06		
Forfeited	(9,751)	27.14		
Expired	(9,563)	43.29		
Outstanding at December 31, 2010	404,366	$ 32.87	6.70	$ 22,119,299
Exercisable at December 31, 2010	256,118	$ 34.35	5.91	$ 13,630,658

The aggregate intrinsic values at December 31, 2010 noted in the table above represent the closing price of our common stock traded on NASDAQ, less the weighted average exercise price at period end multiplied by the number of options outstanding and exercisable.

At December 31, 2010, 34,283 of the 148,248 options outstanding that are not yet exercisable are subject to performance-based vesting criteria as described above.

The weighted average grant date fair value per share of options granted during the years ended December 31, 2010, 2009 and 2008 was $28.62, $16.50 and $9.37, respectively.

The total intrinsic value of options exercised during the years ended December 31, 2010 and 2009 was approximately $4.0 million and $2.9 million, respectively. There were no options exercised during the year ended December 31, 2008. Cash received from option exercises for the year ended December 31, 2010 was approximately $3.6 million.

At December 31, 2010, there was approximately $1.3 million of unrecognized compensation cost related to non-vested option awards, including performance-based options not yet deemed probable of vesting. The expense is expected to be recognized over a weighted average period of 1.5 years.

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Restricted Stock Units

RSU's issued under the plans 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 RSU's with performance-based vesting criteria vest in tranches contingent upon the achievement of pre-determined corporate milestones. RSU's with performance-based vesting criteria not vested after five years from the date of grant automatically expire. There is no consideration payable on the vesting or exercise of RSU's issued under the plans. Upon vesting, the RSU's are exercised automatically and settled in one share of our common stock.

Information related to RSU's at December 31, 2010 and activity during the year then ended is as follows:

	Number of Units	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2009	413,135		
Granted	331,425		
Vested/Exercised	(193,208)		
Forfeited	(6,487)		
Expired	—		
Outstanding at December 31, 2010	544,865	8.97	$ 47,713,828
Exercisable at December 31, 2010	—	—	$ —

The aggregate intrinsic value at December 31, 2010 noted in the table above represents the closing price of our common stock traded on NASDAQ, multiplied by the number of RSU's outstanding.

At December 31, 2010, 58,580 of the 544,865 RSU's outstanding that are not yet exercisable are subject to performance-based vesting criteria as described above.

The total intrinsic value of RSU's vested during the years ended December 31, 2010 and 2009 was approximately $11.6 million and $512,000, respectively. No RSU's vested during the year ended December 31, 2008.

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 RSU's granted during the years ended December 31, 2010, 2009 and 2008 was $73.87, $27.21 and $14.40, respectively.

At December 31, 2010, we had approximately $15.7 million of unrecognized compensation cost related to non-vested RSU awards, including awards not yet deemed probable of vesting. The expense is expected to be recognized over a weighted average period of 1.6 years.

Note 12. Income Taxes

At December 31, 2010 and 2009, we had gross deferred tax assets in excess of deferred tax liabilities of $24.7 million and $32.8 million, respectively. We determined that it is not "more likely than not" that such assets will be realized, and as such have applied a valuation allowance of $24.7 million and $32.8 million as of December 31, 2010 and 2009, respectively. We evaluate our ability to realize our deferred tax assets each period and adjust the amount of our valuation allowance, if necessary. If there is an ownership change, as defined under Internal Revenue Code Section 382, the use of operating loss and credit carry-forwards may be subject to limitation on use. 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.

FASB ASC 740 — *Income Taxes* requires that a valuation allowance be established 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 our current and past performance, the market environment in which we operate, the utilization of past tax credits and length of carry-back and carry-forward periods. Forming a conclusion that a valuation allowance is not needed is difficult when there is negative objective evidence such as cumulative losses in recent years. Cumulative losses weigh heavily in the overall assessment. We have applied a 100% valuation allowance against our net deferred tax assets as of December 31, 2010 and 2009.

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The United States and foreign components of loss before income taxes were as follows:

	Years Ended December 31,		
	2010	2009	2008
United States	$ (29,512,066)	$ (20,204,552)	$ (24,679,024)
Non-U.S.	115,166	(704,306)	915,403
	$ (29,396,900)	$ (20,908,858)	$ (23,763,621)

The effective tax rate of 0% differs from the statutory United States federal income tax rate of 35% for all periods presented due primarily to the valuation allowance. The valuation allowance decreased by approximately $8.1 million for the year ended December 31, 2010 and increased by approximately $6.4 million and $8.8 million for the years ended December 31, 2009 and 2008, respectively.

The primary components of net deferred tax assets are as follows:

	At December 31,	
	2010	2009
Net operating loss and other carryforwards		
United States	$ 38,168,532	$ 30,009,853
Non-U.S.	2,906,860	2,276,745
Total net operating losses	41,075,392	32,286,598
Deferred tax asset — equity awards	3,880,553	2,664,116
Deferred tax liability — convertible notes	(20,736,885)	—
Other deferred tax assets	516,459	241,930
Valuation allowance	(24,735,519)	(35,192,644)
Net deferred tax assets	$ —	$ —

At December 31, 2010, we had net operating loss carryforwards of approximately $116.2 million for U.S. federal income tax purposes and $9.7 million for non-U.S. (primarily Australia) income tax purposes. Non-U.S. losses have an unlimited carry forward period and the U.S. operating losses expire as follows:

Year of Expiration	Year Generated	U.S. Losses	Foreign Losses
Unlimited	2006	—	$ (3,968,169)
Unlimited	2007	—	(3,864,254)
Unlimited	2009	—	(1,829,362)
2025	2005	(10,975,294)	—
2026	2006	(13,460,082)	—
2027	2007	(17,344,349)	—
2028	2008	(23,928,792)	—
2029	2009	(20,543,508)	—
2030	2010	(29,962,300)	—
		$ (116,214,325)	$ (9,661,785)

Uncertain tax positions

The amount of unrecognized tax benefits as of December 31, 2010 and December 31, 2009 was $0. There have been no material changes in unrecognized tax benefits through December 31, 2010. The fiscal years 2005 through 2010 are considered open tax years in U.S. federal and state and Australian tax jurisdictions. In addition, 2010 is considered an open tax year for German and United Kingdom jurisdictions. We currently do not have any audit investigations in any jurisdiction.

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Note 13. Net Loss Per Common Share

Basic loss per common share is computed by dividing net loss for the period by the weighted-average number of common shares outstanding during the period. Diluted loss per common share adjusts basic loss per share for the dilutive effects of convertible securities, options and other potentially dilutive instruments only in the periods in which such 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 have been excluded from the calculation of diluted loss per share, as their effect would be anti-dilutive.

Common shares issuable upon:	2010	2009	2008
Conversion of convertible notes	1,767,923	—	—
Exercise of share-based awards	949,231	933,970	841,220

Note 14. 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 sold to customers located in the United States through our clinical trials, 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 are as follows:

	Years Ended December 31,	
(In thousands)	2010	2009
Domestic	$ 14,998	$ 9,967
Germany	25,103	8,550
International, excluding Germany	15,063	5,655
	$ 55,164	$ 24,172

For the year ended December 31, 2010, one customer exceeded 10% of product sales individually and accounted for approximately 16% of product sales in the aggregate. For the year ended December 31, 2009, two customers exceeded 10% of product sales individually and accounted for approximately 22% of product sales in the aggregate. As the majority 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.

The percentage of our revenue generated in the U.S. was lower in 2010 compared to 2009 due to the acceleration of our commercial efforts in Europe and the completion of enrollment in our ADVANCE trial in the U.S. in February 2010. While the FDA approved an Investigational Device Exemption Supplement that allowed us to enroll additional patients in our ADVANCE trial under a Continued Access Protocol, we experienced periods of inactivity while we awaited approval. In August 2010, we commenced enrollment in our ENDURANCE destination therapy clinical trial in the U.S. However, the revenue impact in the year ended December 31, 2010 was not significant as it can take several months to reach a level of enrollment that will have a significant impact on domestic and total revenue.

Note 15. Commitments and Contingencies

The following contingent liabilities resulting from the 2003 acquisition by HeartWare, Inc. of a business that previously held our technology existed as of December 31, 2010:

- a milestone payment of $1.25 million due within 6 months of the date when the first circulatory assist device is approved for sale in the United States, provided that we have at least $25 million in cash on hand and, if we do not have $25 million at that time, then the payment is deferred until such time that we have $25 million in cash on hand; and
- a special payment of up to $500,000 upon a sale of our HeartWare, Inc. subsidiary if such sale generates proceeds in excess of the aggregate liquidation preferences of all of HeartWare, Inc.'s then outstanding preferred stock.

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We will record the effect of these payment obligations when and if these events occur or are deemed probable of occurring.

During 2009, we paid $750,000 as a result of our receipt of approval to sell our first circulatory assist device in Europe. This represented the first milestone payment resulting from the acquisition noted above and is included in research and development expense.

At December 31, 2010, we had purchase order commitments of approximately $11.9 million related to product costs and property, plant and equipment purchases. Many of our materials and supplies require long lead times and as such 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, including our Chief Executive Officer and our Chief Financial Officer who is also our Chief Operating Officer. 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.

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.

From time to time we may be involved in litigation arising out of claims in the ordinary course of business. Except as set forth below, and based on the information presently available, management believes that there are no claims or actions pending or threatened against us, the ultimate resolution of which will have a material adverse effect on our financial position, liquidity or results of operations, although the results of litigation are inherently uncertain and adverse outcomes are possible.

We received a letter from Abiomed, Inc. in September 2009 in which Abiomed suggested that we "may be interested in licensing Abiomed's technology" as it relates to an Abiomed patent concerning bearingless blood pumps. Further, in a subsequent letter received in February 2010, it was stated that Abiomed was "concerned that HeartWare's left ventricular assist rotary blood pump infringes one or more claims" of an Abiomed patent. We have had communications with Abiomed, Inc. since receipt of the initial letter. The patent referenced by these letters relates to technology that is potentially material to our business and any litigation in this regard, irrespective of the outcome, may have a material adverse effect on our financial position, liquidity or results of operations. We believe the HeartWare System does not infringe this patent.

On February 24, 2010 we received a letter from two holders of Series A Preferred Stock in HeartWare, Inc., an indirect subsidiary of HeartWare International, Inc., requesting various financial and other information regarding HeartWare, Inc. for the purposes of determining the Company's compliance with their rights as holders of Series A Preferred Stock, including whether a liquidation event has occurred since inception in 2003. HeartWare, Inc. issued Series A-1 and Series A-2 Preferred Stock to certain creditors of Kriton Medical, Inc. when HeartWare, Inc. purchased substantially all of the assets of Kriton in July 2003. The Series A-1 and Series A-2 Preferred Stock do not have voting or dividend rights but entitle the holders thereof to receive, upon certain liquidation events of HeartWare, Inc. (but not the liquidation of or change of control of HeartWare International, Inc.), an amount equal to $10 per share of Series A-1 and an amount equal to $21 per share of Series A-2, which currently represent an aggregate liquidation preference of approximately $15 million. We do not believe we have abrogated the rights, or in any way failed to satisfy obligations owed to any of our stockholders, including holders of Series A Preferred Stock in HeartWare, Inc. There have been no further communications.

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There can be no certainty that litigation will not arise in relation to the above matters or, if it does arise, whether or not it will be determined in a manner which is favorable to us. As at the date of this report, we are not able to determine the amount, if any, of costs or damages that could be associated with either of the above matters.

Note 16. Guarantees

On December 16, 2008, we entered into a Deed of Cross Guarantee (the "Deed") by and among the Group's 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 provides 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 17. Retirement Savings Plan

We have established a 401(k) plan in which substantially all of our 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 $276,000 for 2010. We did not make any contributions to the plan in 2009 and 2008.

Note 18. 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 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			
(In thousands, except per share data)	**March 31**	**June 30**	**September 30**	**December 31**
2010				
Revenues, net	$ 10,703	$ 9,757	$ 13,817	$ 20,887
Gross profit	5,023	5,464	7,814	12,422
Net loss	(4,544)	(9,982)	(7,844)	(7,027)
Net loss per common share — basic and diluted (1)	$ (0.35)	$ (0.73)	$ (0.57)	$ (0.51)
Weighted average shares outstanding — basic and diluted	12,958	13,683	13,753	13,874
2009				
Revenues, net	$ 1,478	$ 2,968	$ 7,506	$ 12,220
Gross profit	759	1,389	3,403	5,410
Net loss	(6,233)	(6,891)	(5,874)	(1,911)
Net loss per common share — basic and diluted (1)	$ (0.70)	$ (0.78)	$ (0.60)	$ (0.17)
Weighted average shares outstanding — basic and diluted	8,867	8,876	9,716	11,369

(1) Net 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 loss per common share may not equal the full-year earnings per share.

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Significant amounts in per quarter information listed above include:

- Net loss for the quarters ended March 31, June 30, September 30 and December 31, 2010 include approximately $1.7 million, $4.3 million, $2.6 million and $2.0 million, respectively, of share-based compensation expense.
- Net loss for the quarter ended March 31, 2009 includes $750,000 related to the commitment discussed in Note 15 above and approximately $693,000 of foreign currency exchange gains arising from the appreciation in value of our cash holdings, which were denominated in foreign currencies, namely Australian dollars.
- Net loss for the quarter ended June 30, 2009 includes $1.1 million of foreign currency exchange losses arising from the depreciation in value of our cash holdings, which were denominated in foreign currencies, namely Australian dollars.
- Net loss for the quarters ended March 31, 2009 and June 30, 2009 include $1.9 million and $2.4 million, respectively, of expenses related to the proposed acquisition by Thoratec.
- Net loss for the quarter ended September 30, 2009 includes $2.2 million related to the change in fair value of a derivative instrument.
- Net loss for the quarter ended December 31, 2009 includes $4.6 million related to the net gain on the early extinguishment of debt related to the borrowing and repayment of all amounts under the Thoratec Loan Agreement.

Note 19. Subsequent Events

We have evaluated events and transactions that occurred subsequent to December 31, 2010 through the date the financial statements were issued, for potential recognition or disclosure in the accompanying consolidated financial statements.

On January 24, 2011, the University of Michigan Cardiovascular Center and the University of Pittsburgh announced that they have been awarded grants from the National Heart, Lung and Blood Institute and the Company to conduct a study exploring the potential benefits of LVADs in patients who will be given earlier access to these devices. In the study, called REVIVE-IT, researchers will compare whether non-transplant eligible patients with heart failure less advanced than that of current LVAD recipients do better with implanted devices than with current medical therapy. Our financial commitment for the study is up to $9.6 million of actual costs over the five-year trial period. The terms and conditions of the financial commitment are subject to completion of a definitive agreement.

Except as disclosed above, we did not identify any events or transactions that should be recognized or disclosed in the accompanying consolidated financial statements.

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 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, 2010. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2010, 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, 2010 based on the framework in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and in accordance with the interpretive guidance issued by the SEC in Release No. 34-55929. Based on that evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2010.

Our independent registered public accounting firm, Grant Thornton LLP, has issued a report on our internal control over financial reporting, which is presented below.

Attestation Report of Independent Registered Public Accounting Firm

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
HeartWare International, Inc.

We have audited HeartWare International, Inc. and subsidiaries' (the Company) internal control over financial reporting as of December 31, 2010, based on criteria established in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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

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 Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2010, based on criteria established in *Internal Control-Integrated Framework* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of the Company as of December 31, 2010 and 2009, and the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2010 and our report dated February 24, 2011 expressed an unqualified opinion.

/s/ Grant Thornton LLP

Fort Lauderdale, Florida

February 24, 2011

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, 2010, 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 are as follows:

Name	Age	Position
Douglas Godshall	46	Managing Director [(1)], President and Chief Executive Officer
David McIntyre	40	Executive Vice President, Chief Financial Officer and Chief Operating Officer
Jeffrey LaRose	49	Executive Vice President and Chief Scientific Officer
David Hathaway	63	Chief Medical Officer
Lauren Farrell	43	Vice President, Finance and Chief Accounting Officer
Jeffrey Held	42	Vice President, General Counsel and Secretary
Ramon Paz	53	Senior Vice President, Quality Assurance
James Schuermann	42	Senior Vice President, Sales and Marketing

(1) The term "Managing Director" with respect to Mr. Godshall is a job title given to him by the Company.

Biographical Summaries

Douglas Godshall. Mr. Godshall has been President and Chief Executive Officer since September 2006 and became a director in 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. Prior thereto, Mr. Godshall spent 5 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 has a Bachelor of Arts in Business from Lafayette College and Masters of Business Administration from Northeastern University in Boston, Massachusetts.

David McIntyre. Mr. McIntyre has been our Chief Financial Officer and Company Secretary since February 2005. In addition, in 2008, Mr. McIntyre assumed the role of Chief Operating Officer. From November 2003 to February 2005, Mr. McIntyre was Chief Financial Officer and General Counsel with Unilife Medical Solutions Limited. Mr. McIntyre was also a senior attorney in private practice specializing in corporate, mergers and acquisitions and capital markets with Baker & McKenzie and KPMG Legal. Mr. McIntyre has also held senior financial reporting roles in multinational companies, among them Coal & Allied Limited, an ASX-listed subsidiary of the Rio Tinto group of companies. Mr. McIntyre holds a Bachelor of Economics (in Accounting) from the University of Sydney (in Australia) as well as a Bachelor of Law from the University of Technology, Sydney (in Australia). He is a Certified Practising Accountant (CPA), is admitted as a Legal Practitioner of the Supreme Court of New South Wales (in Australia) and is a member of the Law Society of New South Wales.

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 HeartWare LVAD 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. David Hathaway. Dr. Hathaway joined HeartWare in June 2008 as our Chief Medical Officer responsible for all medical and clinical affairs, including the design and execution of HeartWare's clinical trial program. Prior to joining HeartWare, Dr. Hathaway served as a private consultant in the biotechnology and medical device industry from October 2006 to June 2008. From June 2003 to September 2006, Dr. Hathaway was the Chief Medical Officer of Arginox Pharmaceuticals. Prior to joining Arginox, Dr. Hathaway was Vice President, Clinical Development at Restoragen from May 2001 to February 2003. Dr. Hathaway was previously Vice President of Medical Affairs with Knoll Pharmaceutical Company until it was acquired by Abbott Laboratories. He oversaw the Medical Affairs Department and was responsible for clinical research, regulatory affairs, medical information and drug advocacy. Prior to joining Knoll, Dr. Hathaway was Vice President, Cardiovascular Drug Discovery at Bristol-Myers Squibb, where he managed a team of 90 scientists. Before transitioning to a corporate career, he was Division Chief and Director of the Krannert Institute of Cardiology at the Indiana University School of Medicine, where he practiced for more than 14 years. He also served as a Clinical Associate and Cardiology Fellow at the National Institutes of Health in Bethesda, Md. Dr. Hathaway has been section editor (Cardiovascular Diseases) of Kelley's Textbook of Medicine and a member of the editorial boards of the Journal of Clinical Investigation, the Journal of the American College of Cardiology and Circulation. He has authored over 80 scientific and medical publications and is an inventor on 13 U.S. patents and 8 pending U.S. patent applications. He is a member of the Association of American Physicians, the American College of Physicians and the American Society for Clinical Investigation and is a fellow in the American College of Cardiology. He earned his medical degree from the Indiana University School of Medicine.

Lauren Farrell. Ms. Farrell joined HeartWare in November 2006 as Group Director, Finance and was promoted to Vice President, Finance in August 2008. Reporting to the Chief Financial Officer, Ms. Farrell has overall responsibility for the Company's accounting and finance activities. Ms. Farrell has over 20 years accounting and finance experience including roles in public accounting, financial management and reporting with private and public companies. Prior to joining HeartWare, Ms. Farrell was Chief Financial Officer of Ambient Corporation from March 2005 to January 2006. From January 2001 to July 2004, Ms. Farrell served as Vice President at Bingham Strategic Advisors, a strategic consulting firm. Ms. Farrell is a Certified Public Accountant and holds a Bachelors of Science in Accounting and a Masters of Business Administration from Bentley College.

Jeffrey Held. Mr. Held has been our Vice President, General Counsel since July 2010 and Secretary since September 2010. Mr. Held directs our legal function. Prior to joining HeartWare, Mr. Held was at 3Com Corporation (sold to Hewlett-Packard Company) from February 2006 to May 2010, where he served in increasingly senior legal positions including, most recently, as Vice President, Deputy General Counsel and Assistant Secretary. At 3Com, Mr. Held was responsible for a wide range of legal functions, including securities, mergers and acquisitions, finance, corporate governance and strategic transactions, as well as Board support duties. Prior to 3Com, Mr. Held practiced at several leading law firms in Boston and New York where he counseled growth companies in the life sciences and high technology sectors. Mr. Held has a B.A. from Tufts University and earned his law degree from Fordham University School of Law.

Ramon Paz. Mr. Paz joined HeartWare as Director of Quality Assurance in October 2004 and was promoted to Vice President, Quality Assurance in July 2007. He has primary responsibility for establishing and managing the company's Quality Management System. Mr. Paz has over 23 years of multifunctional experience in the medical device industry across Quality, Manufacturing, Engineering, Regulatory and Clinical organizations. He began his career with Cordis Corporation, where he spent 15 years in a range of progressively more senior positions across the Quality, Manufacturing and Product Development groups. In 1998, Mr. Paz joined World Medical, a start-up company which was later acquired by MedtronicAVE, where he was Head of Quality, with expanded responsibility for managing the regulatory and clinical groups responsible for the clinical study of the TALENT stent graft.

James Schuermann. Mr. Schuermann joined HeartWare in September 2007. He has overall responsibility for HeartWare's sales and marketing activities across all markets. Mr. Schuermann has over 15 years sales and marketing experience in the medical device arena. Prior to joining HeartWare, he spent nine years in sales and marketing at Boston Scientific Corporation. Over this time he progressed from sales through product management until being appointed Director of Marketing in 2005. Before joining Boston Scientific, he spent 5 years in medical sales and sales management at Sherwood Davis & Geck. 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.

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 on our website at www.heartware.com.

The other information required by this Item 10 is incorporated herein by reference to the applicable information in our definitive proxy statement for our 2011 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 2011 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 2011 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.

The information required by this Item 12 is included in our 2011 Proxy Statement and is incorporated herein by reference.

Australian Disclosure Requirements

In addition to our primary listing on NASDAQ, we are also listed for quotation in the form of CHESS Depositary Interests ("CDIs") on the Australian Securities Exchange ("ASX") and trade under the symbol "HIN". As part of our ASX listing, we are required to comply with various disclosure requirements as set out in the ASX Listing Rules. The following information is intended to comply with the ASX Listing Rules and is not intended to fulfill information required by Part III of this Annual Report on Form 10-K.

Substantial Shareholders

The number of CDIs held by our substantial shareholders (being shareholders who, together with their associates, have a relevant interest in at least 5% of our voting shares) should their stockholdings be converted from common stock into CDIs as at 31 December 2010 are set out below:

	Number of Ordinary CDIs	Percentage %
FMR LLC and FIL Limited	72,814,875	15.0
Apple Tree Partners	58,588,670	12.1
Wellington Asset Management	51,115,225	10.5
Mr. Muneer A. Satter	36,872,500	7.6
T. Rowe Price Associates, Inc.	29,553,405	6.1

The above amounts are based solely upon information furnished to us or contained in reports filed with the Securities and Exchange Commission.

Distribution of equity security holders as at 31 January 2011

As of 31 January 2011, there were 13,891,230 shares of our common stock outstanding, a portion of which were held as CDI's. The table below presents the number of shares of common stock and the number of CDI's held.

	Common Stock		CDIs*		Options (unlisted)		RSU's (unlisted)	
	Number of holders	Number of Shares	Number of holders	Number of CDIs	Number of holders	Number of options	Number of holders	Number of RSU's
1 – 1,000	5	2,890	120	74,907	39	24,670	22	15,031
1,001 – 5,000	5	12,687	184	578,911	30	77,303	61	132,948
5,001 – 10,000	1	5,190	157	1,335,681	11	63,675	12	70,586
10,001 – 100,000	2	109,259	248	8,383,981	3	76,148	6	212,943
100,001 – and over	3	12,094,828	56	47,949,680	1	149,464	1	112,857
	16	12,224,854	765	58,323,160	84	391,260	102	544,365

* Holders of CDI's may receive 1 share of common stock for 35 CDI's. The common stock equivalent of the number of CDI's outstanding at 31 January 2011 was 1,666,376 shares.

Unmarketable parcels

As at 31 January 2011, the number of shareholders holding less than a marketable parcel (for the purposes of the ASX Listing Rules) was 19.

Top 20 Stockholders

No.	Holder	Number of CDIs held	% of CDIs Outstanding
1.	J P Morgan Nominees Australia Limited	9,314,710	16.00
2.	Phillip Asset Management Ltd. <IB AUS Bioscience Fund I A/C>	8,119,625	13.94
3.	HSBC Custody Nominees (Australia) Limited	5,740,686	9.86
4.	Warman Investments Pty. Ltd.	4,749,990	8.16
5.	National Nominees Limited	1,990,379	3.42
6.	Warman Investments Pty. Ltd.	1,477,067	2.54
7.	Nickeli Holdings Pty. Limited <Wade Family S/Fund A/C>	1,451,310	2.49
8.	Mr. Robert Thomas and Mrs. Kyrenia Thomas <Rob Thomas Super Fund A/C>	1,447,950	2.49
9.	National Australia Trustees Limited <Hayberry Investments P/L A/C>	1,206,941	2.07
10.	MAN Holdings Pty. Limited <Nelson Hybrid A/C>	816,655	1.40
11.	JP Morgan Nominees Australia Limited <Cash Income A/C>	755,587	1.30
12.	Viking Management Services Pty. Ltd. <VHK Superannuation Fund A/C>	727,265	1.25
13.	Asia Union Investments Pty. Ltd.	500,000	0.86
14.	Mrs. Kyrenia Thomas	500,000	0.86
15.	Spectrok Pty. Ltd. <Hedley Family A/C>	499,975	0.86
16.	Mr. Robert B. Stockman	499,975	0.86
17.	CS Fourth Nominees Pty. Ltd.	487,474	0.84
18.	Citicorp Nominees Pty. Limited	457,656	0.79
19.	PBC Investments Pty. Limited <PBC Super Fund A/C>	412,000	0.71
20.	Mr. Alex Proimos	357,740	0.61
Total CDIs held by top 20 shareholders		41,512,985	71.29
Total CDIs held by all other shareholders		16,715,150	28.71

Two individuals, Todd Frazier and Stephen Boyce, own 100% of the Company's options issued outside employee incentive plans, with each owning options for 2,285 and 2,857 shares, respectively.

Voting Rights

HeartWare International's by-laws provide that each stockholder has one vote for every share of common stock entitled to vote held of record by such stockholder and a proportionate vote for each fractional share of stock entitled to vote so held, unless otherwise provided by Delaware General Corporation Law or in the certificate of incorporation.

Holders of CDIs have one vote for every 35 CDIs held of record by such stockholder.

If holders of CDIs wish to attend HeartWare International general meetings, they will be able to do so. Under the ASX Listing Rules, HeartWare International, as an issuer of CDIs, must allow CDI holders to attend any meeting of the holders of the underlying securities unless relevant U.S. law at the time of the meeting prevents CDI holders from attending those meetings.

In order to vote at such meetings, CDI holders have the following options:

(a) instructing CDN, as the legal owner, to vote the HeartWare International shares of common stock underlying their CDIs in a particular manner. The instruction form must be completed and returned to HeartWare International's share registry prior to the meeting;

(b) informing HeartWare International that they wish to nominate themselves or another person to be appointed as CDN's proxy for the purposes of attending and voting at the general meeting;

(c) converting their CDIs into a holding of HeartWare International shares of common stock and voting these at the meeting (however, if thereafter the former CDI holder wishes to sell their investment on ASX, it would be necessary to convert HeartWare International shares of common stock back to CDIs). This must be done prior to the record date for the meeting. See section 7 below for further information regarding the conversion process.

As holders of CDIs will not appear on HeartWare International's share register as the legal holders of HeartWare International shares of common stock, they will not be entitled to vote at HeartWare International shareholder meetings unless one of the above steps is undertaken.

Proxy forms and details of these alternatives will be included in each notice of meeting sent to CDI holders by HeartWare International.

Holders of options and restricted stock units are not entitled to vote.

Required Statements

The Company makes the following disclosures:

(a) There is no current on-market buy-back of the Company's securities.

(b) HeartWare International, Inc. was incorporated in the state of Delaware in the United States of America.

(c) The Company is not subject to Chapters 6, 6A, 6B or 6C of the Corporations Act 2001 (Cth) dealing with the acquisitions of shares (ie, substantial shareholdings and takeovers).

(d) Under the Delaware General Corporation Law, shares are generally freely transferable subject to restrictions imposed by U.S. federal or state securities laws, by the certificate of incorporation or by-laws of the Company or by an agreement signed with the holders of the shares at issue. The Company's certificate of incorporation and by-laws do not impose any specific restrictions on transfer.

General Information

The name of the Company Secretary is Mr. Jeffrey Held.

The address of the principal registered office in Australia is Unit 2, 3 Marshall Road, Kirrawee, NSW 2232 (02) 8078 6164.

Registers of securities are held at Computershare Investor Services Pty. Limited, Level 3, 60 Carrington Street, SYDNEY NSW 2000, Investor Enquiries: 1300 855 080.

Quotation has been granted for the Company's CDIs on ASX Limited. In addition, the Company's common stock became listed for quotation on NASDAQ on 24 February 2009.

Australian Corporate Governance Statement

The Board of Directors and employees of HeartWare International, Inc. ("HeartWare" or "the Company") are committed to developing, promoting and maintaining a strong culture of good corporate governance and ethical conduct.

The Board of Directors is pleased to confirm that the Company's corporate governance framework is generally consistent with the Australian Securities Exchange's ("ASX") Corporate Governance Council's "Corporate Governance Principles and Recommendations with 2010 amendments (2nd Edition)" ("ASX Governance Recommendations"), other than as set out below. To this end, the Company provides below a review of its corporate governance framework using the same numbering as adopted for the Principles as set out in the ASX Governance Recommendations.

Copies of the Company's codes and policies may be downloaded from the corporate governance section of the HeartWare website (www.heartware.com).

It should be noted that the Company redomiciled to the United States in November 2008 and listed on NASDAQ in late February 2009. As a result and to meet NASDAQ listing requirements, the policies and practices adopted by the Company have been adopted to be consistent with U.S. listing standards.

Principle 1 — Lay solid foundations for management and oversight

Recommendation 1.1 — Establish the functions reserved to the Board of Directors and those delegated to senior executives and disclose those functions

The primary responsibility of:

(a) the Board of Directors is to provide effective governance over the business and affairs of HeartWare and its controlled entities ("the HeartWare Group") so that the interests of all stakeholders are protected; and

(b) the Chief Executive Officer is to oversee the day-to-day performance of the HeartWare Group (pursuant to Board delegated powers).

The Board's responsibilities are recognized and documented on an aggregated basis via the Charter of the Board of Directors and via Letters of Appointment for each individual director. A copy of the Charter of the Board of Directors is available on the corporate governance section of the Company's website.

While day-to-day management has been delegated to the Chief Executive Officer, it is noted that the following matters are specifically reserved for the attention of the Board:

(a) decisions about corporate strategy and policies as well as commitments over prescribed limits;

(b) setting major capital expenditure, acquisitions, divestments and funding arrangements;

(c) setting the various internal controls and reporting framework for the management of the risks inherent in the operations of the HeartWare Group;

(d) setting of discretionary financial and related operating limits for management; and

(e) establishing and determining the powers and functions of the committees of the Board.

Recommendation 1.2 — Disclose the process for evaluating the performance of senior executives

The Company's 2010 definitive proxy statement filed with the Securities and Exchange Commission included extensive discussions in relation to the mechanics concerning the evaluation of performance of the Company's senior executives, including relevant benchmarking activities. Information regarding executive compensation for the year ended 31 December 2010, as required by Item 11, is incorporated by reference to the applicable information in our definitive proxy statement for our 2011 annual meeting of stockholders to be filed with the Securities and Exchange Commission, including the information set forth under the captions "Executive Compensation," "Compensation of Directors" and "Compensation Committee Interlocks and Insider Participation," 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.

Recommendation 1.3 — Disclosure of information indicated in the guide to reporting on Principle 1of the ASX Governance Recommendations

Reporting Requirement

The Company fully complied with Recommendation 1.1 to 1.3 during the year ended 31 December 2010.

Principle 2 — Structure the Board to add value

Recommendation 2.1 — A majority of the Board of Directors should be independent

Recommendation 2.2 — The Chair should be an independent director

Recommendation 2.3 — The roles of Chairman and Chief Executive Officer should not be exercised by the same individual

The Board of Directors presently comprises eight (8) directors. The eight (8) directors encompass six (6) independent non-executive directors (including the Chairman of the Board), one (1) executive director (being the Chief Executive Officer) and one (1) non-independent, non-executive director (being the Deputy Chairman).

The current composition of the Board and length of tenure of each member of the Board is as follows:

Name	Position	Date Appointed	Tenure*	Independent
Rob Thomas	Non-executive director	26 Nov 2004	6.1 years	Yes
Seth Harrison	Non-executive Deputy Chairman	26 Nov 2004	6.1 years	No
Denis Wade	Non-executive director	15 Dec 2004	6.0 years	Yes
Christine Bennett	Non-executive director	15 Dec 2004	6.0 years	Yes
Bob Stockman	Non-executive director	11 Dec 2006	4.1 years	Yes
Ray Larkin Jr	Non-executive Chairman	3 Oct 2009	2.2 years	Yes
Tim Barberich	Non-executive director	29 Apr 2009	2.7 years	Yes
Doug Godshall	Chief Executive Officer / President / Executive Director	28 Oct 2006	4.2 years	No

* Calculated as at 31 December 2010.

Independent advice

At the Company's expense, the Board collectively or directors (acting as individuals) are entitled to seek advice from independent external advisers in relation to any matter which is considered necessary to fulfill their relevant duties and responsibilities.

Individual directors seeking such advice must obtain the approval of the Chairman (which may not be unreasonably withheld). Any advice so obtained will be made available to all Board members.

Recommendation 2.4 — The Board should establish a Nomination Committee

The members of the Nominating and Governance Committee are Mr. Barberich, Mr. Larkin (Chair) and Mr. Thomas. A copy of the Nominating and Governance Committee Charter is available on the corporate governance section of the Company's website. The Nominating and Governance Committee met once during 2010 with each of Mr. Barberich, Mr. Larkin and Mr. Thomas attending.

Reporting Requirement

The Company fully complied with Recommendation 2.1 to 2.4 during the year ended 31 December 2010.

Recommendation 2.5 — Disclose the process for evaluating the performance of the Board, its committees and individual directors

Reporting Requirement

The Company has not undertaken a formal review of the performance of the Board, its committees and individual directors. The Company has not therefore complied with Recommendation 2.5 during the year ended 31 December 2010.

Recommendation 2.6 — Disclosure of information indicated in the guide to reporting on Principle 2 of the ASX Governance Recommendations

Reporting Requirement

Information regarding Directors, including biographical information, key attributes, experience and skills as required by Item 12, is incorporated herein by reference to the applicable information in our definitive proxy statement for our 2011 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 and Related Stockholder Matters," 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.

The Company has fully complied with Recommendation 2.6 during the year ended 31 December 2010.

Principle 3 — Promote ethical and responsible decision-making

Recommendation 3.1 — Establish a Code of Conduct and disclose it

The Company has adopted a Code of Business Conduct and Ethics, a copy of which is available on the corporate governance section of the Company's website.

The Company fully complied with Recommendation 3.1 during the year ended 31 December 2010.

Principle 4 — Safeguard integrity in financial reporting

Recommendation 4.1 — The Board should establish an Audit Committee

Recommendation 4.2 — The Audit Committee should: (a) consist of non-executive directors only; (b) consist of a majority of independent directors; (c) be chaired by an independent chair who is not chair of the Board; and (d) have at least three members

Recommendation 4.3 — The Audit Committee should have a formal charter

The members of the Audit Committee are Dr. Bennett, Mr. Stockman (Chair), Mr. Thomas and Dr. Wade all of whom are independent non-executive directors. The Audit Committee met five times during 2010 with each of Dr. Bennett, Mr. Thomas and Dr. Wade attending on all occasions. Mr. Stockman (Chair) attended on four occasions.

A copy of the Audit Committee Charter is available on the corporate governance section of the Company's website.

Reporting Requirement

The Company fully complied with Recommendation 4.1 to 4.3 during the year ended 31 December 2010.

Recommendation 4.4 — Disclosure of information indicated in the guide to reporting on Principle 4 of the ASX Governance Recommendations

Reporting Requirement

Information regarding the skills, experience and expertise of directors, including audit committee members, in accordance with U.S. disclosure requirements is included by reference to the applicable information in our definitive proxy statement for our 2011 annual meeting of stockholders to be filed with the Securities and Exchange Commission. To the extent these disclosures are not specifically restated within in this Corporate Governance Statement then the Company has not complied with the requirement to include this information within the Corporate Governance Statement.

In Item 9A of this Annual Report on Form 10-K, we have disclosed information regarding the Company's Controls and Procedures, including management's evaluation of the effectiveness of our disclosure controls and procedures and management's evaluation of the effectiveness of our internal control over financial reporting. To the extent these disclosures are not specifically restated within in this Corporate Governance Statement then the Company has not complied with the requirement to include this information within the Corporate Governance Statement.

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 9A of this Annual Report on Form 10-K.

The Company has not disclosed its policy for selection and appointment of the Company's external auditor or for the rotation of external audit engagement partners.

In all other respects, the Company fully complied with Recommendation 4.4 during the year ended 31 December 2010.

Principle 5 — Make timely and balanced disclosure

Recommendation 5.1 — Establish written policies designed to ensure compliance with ASX Listing Rule disclosure requirements and to ensure accountability at a senior executive level for that compliance and disclose those policies

Recommendation 5.2 — Disclosure of information indicated in the guide to reporting on Principle 5 of the ASX Governance Recommendations

HeartWare is committed to providing timely and balanced disclosure to the market and, in consequence, to meeting its continuous disclosure requirements. In accordance with its commitment to fully comply with its continuous disclosure requirements, the Company has adopted a Continuous Disclosure Policy, together with other internal mechanisms and reporting requirements.

A copy of the Continuous Disclosure Policy is available on the corporate governance section of the Company's website. In addition, a copy of all of the Company's ASX announcements, financial reports and related public information are also available on the Company's website.

Reporting Requirement

The Company fully complied with Recommendation 5.1 and 5.2 during the year ended 31 December 2010.

Principle 6 — Respect the rights of shareholders

Recommendation 6.1 — Design a communications policy for promoting effective communication with shareholders and encourage their participation at general meetings and disclose those policies

Recommendation 6.2 — Disclosure of information indicated in the guide to reporting on Principle 6 of the ASX Governance Recommendations

The Company has implemented a number of measures so as to facilitate what it believes to be the effective and efficient exercise of the rights of shareholders. The Company communicates information to shareholders through a range of media including annual reports, public (ASX) announcements and via the Company's website including advance notification of investor presentations and results announcements. Key financial information and stock performance are also available on the Company's website. Shareholders can raise questions with the Company by contacting the Company via telephone, facsimile, post or email, with relevant contact details being available on the Company's website.

All shareholders are invited to attend the Company's Annual General Meeting, either in person or by proxy. The Board regards the Annual General Meeting as an excellent forum in which to discuss issues relevant to the Company and thereby encourages full participation by shareholders. Shareholders have an opportunity to submit questions to the Board and the Company's auditors. The meeting is also webcast to provide access to those shareholders who are unable to attend the Annual General Meeting.

Reporting requirement

The Company fully complied with Recommendation 6.1 and 6.2 for the year ended 31 December 2010.

Principle 7 — Recognise and manage risk

Recommendation 7.1 — Establish policies for the oversight and management of material business risks and disclose it

The risks that the Company faces are continually changing in line with the development of the Company. The primary risks faced by the Company during 2010 included liquidity or funding risk, operational risks associated with the manufacture of an implantable medical device, ongoing risks of the Company's human clinical trials and achieving relevant regulatory hurdles which will unlock key markets for the Company's products together with growing revenue and inventory management.

The above is set in an environment where the Company must actively manage fundamental risks such as the integrity of the Company's intellectual property portfolio, disaster management, exchange rate risk and the risk of losing key management personnel.

In simple terms, risk is inherent in all activities undertaken by HeartWare. Unfortunately, many of these risks are beyond the control of the Company and, as such, it is important that risk be mitigated on a continuous basis, particularly if the Company is to preserve shareholder value.

The Board of Directors has approved a Risk Management Policy, a copy of which is available on the corporate governance page of the Company's website. In summary, the Risk Management Policy is designed to ensure that risks including, amongst others, technology risks, economic risks, financial risks and other operational risks are identified, evaluated and mitigated to enable the achievement of the Company's goals.

It would be remiss of the Board not to acknowledge that no risk management system can provide total assurance that HeartWare's risks will be fully mitigated. This is particularly the case in organizations such as HeartWare where its pre-revenue status means that limited resources can be applied to the risk management process. HeartWare's approach is therefore not to eliminate risk, rather to utilize available resources as effectively as possible in order to manage the risks inevitably involved in many corporate activities.

Reporting requirement

The Company fully complied with Recommendation 7.1 for the year ended 31 December 2010.

Recommendation 7.2 — Require management to design and implement the risk management and internal control system to manage the Company's material business risks and report to it whether those risks are being managed effectively (and makes disclosures therein); Disclose that management has reported to the Board as to the effectiveness of the Company's management of its material business risks

Management provides the Board with frequent (i.e. generally monthly) updates on the state of the Company's business, including the risks that the Company faces from time-to-time. This update includes up-to-date financial information, operational activity, clinical status and competitor updates. These updates are founded on internal communications that are fostered internally through weekly management meetings and other internal communications. These processes operate in addition to the Company's system of internal controls over financial reporting, its Quality System, complaint handling processes, employee policies and standard operating procedures.

In addition, the Board of Directors holds regular meetings at the Company's facility in Miami Lakes for the purposes of discussing and reviewing operational developments.

The Company fully complied with Recommendation 7.2 for the year ended 31 December 2010.

Recommendation 7.3 — Disclose whether the Board has received assurance from the Chief Executive Officer and the Chief Financial Officer that the declaration under Section 295A of the Corporations Act is founded on a sound system of risk management and internal control and is operating effectively in all material respects in relation to financial reporting risks

Reporting requirement

As the Company prepares and files its financial statements under U.S. accounting practices and laws, management is required to provide representations to the Board on a wide range of issues, including in relation to the effectiveness of the Company's disclosure controls and procedures as well as the design or operation of internal control over financial reporting.

Notwithstanding the above and in consequence of its dual listed status and various waivers granted by the ASX and the Australian Securities and Investments Commission, no declaration is required under Section 295A of the Corporations Act. To this end, shareholders' attention is drawn to Item 9A of this Annual Report on Form 10-K and the certifications provided by the Chief Executive Officer and the Chief Financial Officer at the end of the Form 10-K. As stated above, Item 9A of this Annual Report on Form 10-K discloses information regarding the Company's controls and procedures, including management's evaluation of the effectiveness of our disclosure controls and procedures and management's evaluation of the effectiveness of our internal control over financial reporting.

For the reasons stated above, the Company has not complied with Recommendation 7.3 for the year ended 31 December 2010.

Recommendation 7.4 — Disclosure of information indicated in the guide to reporting on Principle 7of the ASX Governance Recommendations

Reporting requirement

Except as disclosed above, the Company believes that the aforementioned reporting meets, or otherwise exceeds, the requirements of Recommendation 7.2 to 7.4 for the year ended 31 December 2010.

Principle 8 — Remunerate fairly and responsibly

Recommendation 8.1 — Establish a Remuneration Committee

Recommendation 8.2 — The Remuneration Committee should be structured so that it: (a) consist of a majority of independent directors; (b) is chaired by an independent chair; and (c) has at least three members The members of the Compensation Committee are Mr. Barberich (Chair), Mr. Thomas, Dr. Bennett and Dr. Wade all of whom are independent non-executive directors. A copy of the Compensation Committee Charter is available on the corporate governance section of the Company's website. The Compensation Committee met four times during 2010 with each of Mr. Barberich, Mr. Thomas, Dr. Bennett and Dr. Wade attending on all occasions.

Recommendation 8.3 — Clearly distinguish the structure of non-executive directors' remuneration from that of executive directors and senior executives

As noted above in the discussion regarding Recommendation 1.2, the definitive proxy statement for the Company's 2011 annual meeting of stockholders includes extensive discussions in relation to the mechanics concerning the evaluation of performance of the Company's senior executives. Information is also included in relation to the Company's remuneration practices and policies, including its annual performance review process, its external benchmarking review and its meritorious approach to employee performance.

Reporting requirement

As previously disclosed no review or other form of assessment has been undertaken in relation to the non-executive directors.

Recommendation 8.4 — Disclosure of information indicated in the guide to reporting on Principle 8 of the ASX Governance Recommendations

Reporting requirement

With the exception noted above, the Company complied with Recommendation 8.1 to 8.3 during the year ended 31 December 2010.

This report is made in accordance with a resolution of the Board of Directors.

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 2011 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 2011 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 24, 2011

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 24, 2011
/s/ David McIntyre David McIntyre	Chief Financial Officer and Chief Operating Officer (Principal Financial Officer)	February 24, 2011
/s/ Lauren Farrell Lauren Farrell	Vice President, Finance (Principal Accounting Officer)	February 24, 2011
/s/ C. Raymond Larkin, Jr. C. Raymond Larkin, Jr.	Chairman and Director	February 24, 2011
Timothy J. Barberich	Director	
/s/ Christine Bennett Christine Bennett	Director	February 24, 2011
/s/ Seth Harrison Seth Harrison	Director	February 24, 2011
/s/ Robert Stockman Robert Stockman	Director	February 24, 2011
/s/ Robert Thomas Robert Thomas	Director	February 24, 2011
/s/ Denis Wade Denis Wade	Director	February 24, 2011

Exhibit Index

Exhibit No.	Description
2.1	Implementation Agreement, dated as of August 5, 2008, between HeartWare International, Inc. and HeartWare Limited. (13)
2.2	Agreement and Plan of Merger, dated as of February 12, 2009, among HeartWare International, Inc., Thoratec Corporation, Thomas Merger Sub I, Inc. and Thomas Merger Sub II, Inc. (14)
3.1	Certificate of Incorporation of HeartWare International, Inc.(4)
3.2	Bylaws of HeartWare International, Inc. (4)
10.01	Securities Exchange Agreement between Apple Tree Partners I, L.P., Anthony Low-Beer, Edward Nerssissian, Garrett and Carol Thunen, HeartWare, Inc. and HeartWare Limited dated December 13, 2004 (1)
10.02	Amended and Restated Employment Agreement, dated as of December 16, 2009, by and between HeartWare International, Inc. and Douglas Godshall (11) +
10.03	Amended and Restated Employment Agreement, dated as of December 16, 2009, by and between HeartWare International, Inc and David McIntyre (19)+
10.04	Amended and Restated Employment Agreement, dated as of December 16, 2009, by and between HeartWare International, Inc. and Jeffrey LaRose (20)+
10.05	Employment Agreement, dated as of December 5, 2008, between HeartWare International, Inc. and James Schuermann (5) +
10.06	Employment Agreement, dated as of December 5, 2008, between HeartWare International, Inc. and Ramon Paz (5) +
10.07	Employment Agreement, dated as of December 5, 2008 between HeartWare Inc. and David R. Hathaway, M.D. (12) +
10.08	Form of Amendment to Employment Agreement (for Section 16 officers), dated December 2010*+
10.09	Form of Deed of Indemnity, Access and Insurance Agreement for directors and executive officers (1) +
10.10	Letter of Appointment as a Director of the Company dated December 1, 2006 between HeartWare Limited and Robert Stockman (1) +
10.11	Letter of Appointment as a Director of the Company dated December 15, 2004 between HeartWare Limited and Robert Thomas (1) +
10.12	Letter of Appointment as a Director of the Company dated December 15, 2004 between HeartWare Limited and Christine Bennett (1) +
10.13	Letter of Appointment as a Director of the Company dated December 15, 2004 between HeartWare Limited and Denis Wade (1) +
10.14	Letter of Appointment as a Director of the Company dated September 3, 2008 between HeartWare International, Inc. and Ray Larkin (15) +
10.15	Letter of Appointment as a Director of the Company dated April 16, 2008 between HeartWare International, Inc. and Timothy J. Barberich (16) +
10.16	HeartWare Limited Employee Share Option Plan Rules (1) +
10.17	HeartWare Limited Share Performance Rights Plan — Plan Rules (3) +
10.18	HeartWare International, Inc. 2008 Stock Incentive Plan (6) +
10.19	HeartWare International, Inc. Employee Stock Option Plan (7) +
10.20	HeartWare International, Inc. Restricted Stock Unit Plan (8) +
10.21	Form of HeartWare International, Inc. Incentive Option Terms (9) +
10.22	Nonstatutory Stock Option Notice and Agreement to 2008 Stock Incentive Plan (24) +
10.23	Restricted Stock Units Notice and Agreement to 2008 Stock Incentive Plan (25) +

Exhibit No.	Description
10.24	Lease Agreement, dated as of April 17, 2008, between JDRP Associates No. 1, Ltd. and HeartWare, Inc. ("Lease")(10)
10.25	First Amendment to Lease dated September 30, 2010 (2)
10.26	Business Lease, dated December 27, 2006, between HeartWare, Inc. and Atlantic-Philadelphia Realty LLC (17)
10.27	First Amendment to Business Lease, dated August 19, 2008, between HeartWare, Inc. and Atlantic-Philadelphia Realty LLC ("Business Lease") (18)
10.28	Second Amendment to Business Lease, dated August 9, 2010 (26)
10.29	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*
10.30	Loan Agreement, dated as of February 12, 2009, among HeartWare International, Inc., the Guarantors thereto and Thoratec Corporation (14)
10.31	Investor's Rights Agreement, dated as of February 12, 2009, between HeartWare International, Inc. and Thoratec Corporation (14)
10.32	Indenture dated as of December 15, 2010 between the Company and Wilmington Trust FSB, as trustee (21)
10.33	First Supplemental Indenture dated as of December 15, 2010 between the Company and Wilmington Trust FSB, as trustee (22)
10.34	Form of 3.50% Convertible Senior Notes due 2017 (23)
21.1	List of Subsidiaries *
23.1	Consent of Independent Registered Public Accounting Firm *
31.1	Certificate pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 of Chief Executive Officer *
31.2	Certificate pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 of Chief Financial Officer *
32.1	Certificate pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, of Chief Executive Officer **
32.2	Certificate pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, of Chief Financial Officer **

(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 September 30, 2010.

(3) Incorporated by reference to Exhibit 99.1 to the Company's Registration Statement on Form S-8 (File No. 333-147506) filed with the Securities and Exchange Commission on November 19, 2007.

(4) 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.

(5) 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.

(6) 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.

(7) 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.

(8) 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.

(9) 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.

(10) Incorporated by reference to Exhibit 10.01 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 18, 2008.

(11) 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.

(12) Incorporated by reference to Exhibit 10.13 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 Appendix 1 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.

(14) 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 February 13, 2009.

(15) 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.

(16) 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.

(17) Incorporated by reference to Exhibit 10.40 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 28, 2008.

(18) 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 23, 2010.

(19) Incorporated by reference to Exhibit 10.5 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 23, 2010.

(20) 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.

(21) 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.

(22) 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.

(23) 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.

(24) 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.

(25) 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.

(26) 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 August 19, 2010.

* Filed herewith

** Furnished herewith

\+ Management contract or compensatory plan or arrangement.

Exhibit 10.08

December ___, *2010*

We would like to clarify certain terms of the employment letter (the "Agreement"), between you and HeartWare, Inc. (the "Company"), to reflect the parties' original intent to comply with the requirements of section 409A of the Internal Revenue Code of 1986, as amended ("Section 409A") and one additional matter concerning indemnification, as follows:

1. Timing of Severance Pay After Execution of a Release. If under the terms of the Agreement the execution of a general release of claims is a condition to your receiving severance or other benefits under the Agreement, the Company will provide you with the form of release agreement within seven days after your separation from service. To be entitled to the severance or other benefits, you must execute and deliver to the Company the release agreement on or before the last day of the minimum required waiver consideration period provided under the Age Discrimination in Employment Act or other applicable law. If you timely deliver an executed release agreement to the Company, and you do not revoke the release agreement during the minimum revocation period required under applicable law, the severance or other benefits shall be paid or commence being paid, as specified in the Agreement, on the date the release agreement becomes effective. If, however, the period during which you have discretion to execute or revoke the release agreement straddles two calendar years, the severance or other benefits shall be paid or commence being paid, as applicable, as soon as practicable in the second of the two calendar years, regardless of within which calendar year you actually deliver the executed release agreement to the Company, subject to the release agreement first becoming effective. Consistent with Section 409A, you may not, directly or indirectly, designate the calendar year of payment. Nothing in this letter agreement shall be construed to alter the terms of the Agreement that condition your entitlement to any severance or other benefits upon your compliance with the restrictive covenants and any other terms and conditions specified in the Agreement.

2. Indemnification. Except in the case of negligence, fraud, embezzlement or misrepresentation the Company hereby agrees to indemnify and hold harmless Executive to the fullest extent permitted by Section 145 of the Delaware General Corporation Law and to cause any parent or subsidiary of the Company (including, without limitation, the Parent) to indemnify and hold you harmless to the fullest extent permitted by the provisions of the laws of the jurisdiction of its incorporation against any liability, loss or expense (including reasonable attorney's fees and costs incurred in defense of such claims) incurred in connection with the your services as an officer or director of the Company or any of its subsidiaries or affiliates, including the Parent, if in each of the foregoing cases, (i) you acted in good faith and in a manner you believed to be in, or not opposed to, the best interests of the Company, and, with respect to any criminal proceeding, had no reasonable cause to believe your conduct was unlawful, and (ii) your conduct did not constitute gross negligence or willful or wanton misconduct. Without limitation of the foregoing, this paragraph shall be deemed to grant to the you the rights to indemnification provided by the Company's and the Parent's certificate of incorporation and by-laws, as currently constituted, regardless of any subsequent amendment or modification of the applicable provisions of such instruments, with such provisions being deemed incorporated herein by reference. The Company shall advance or cause its subsidiaries to advance all expenses (including all reasonable legal fees and expenses) reasonably incurred by you in defending any such claim, action or proceeding, whether civil, administrative, criminal or otherwise, brought against you in your capacity as an officer of director of the Company or any of its subsidiaries or affiliates, including the Parent, to the fullest extent permitted under applicable law, provided Executive provides an undertaking pursuant to which he agrees to repay all such advances if it is ultimately determined that you are not entitled to indemnification under the circumstances. Notwithstanding anything else contained in this letter agreement or the Agreement, the above shall not apply where the liability, loss or expense (including reasonable attorney's fees and costs incurred in defense of such claims) incurred by you arise as a result, directly or indirectly, of any claim or action taken against you by the Company, the Parent or any of their respective subsidiaries or affiliates.

3. Relocation Benefit. You shall be entitled to reimbursement of the relocation costs specified in Clause 5 of the Agreement only to the extent such costs are incurred no later than the end of the second calendar year after the calendar year in which your separation from service occurs. To the extent incurred, those relocation costs shall be reimbursed by the Company within 30 days after receipt of appropriate documentation and in no event later than the end of the third calendar year after the calendar year of your separation from service. In addition, any payment due under Clause 5(b) of the Agreement shall be made as soon as practicable after your separation from service, but in all events within 30 days after such separation. [*THIS SECTION 3 APPLIES TO MR. MCINTYRE ONLY*]

4. No Other Changes. You agree that the terms and conditions of the Agreement, to the extent not modified hereby, will continue to apply as specified in the Agreement.

* * * *

To indicate your acceptance of these updated terms and conditions of your employment, please sign and return one copy of this letter to me by no later than December 31, 2010.

Sincerely,

HEARTWARE, INC.

By: _____

Name:
Title:

Agreed to and accepted:

_____

Write Name:

Exhibit 10.29

STANDARD LEASE

THIS LEASE AGREEMENT (the "**Lease**") is made and entered into as of the 8th day of December, 2010, by and between MCP EWE LLC, a Delaware limited liability company ("**Landlord**"), whose address for purposes hereof is 10165 N W. 19th Street, Miami, Florida 33172, and HEARTWARE, INC., a Delaware corporation ("**Tenant**"), whose address for purposes hereof is _____ and is guaranteed by HEARTWARE INTERNATIONAL INC., a Delaware corporation (the "**Guarantor**") pursuant to that certain Guaranty of Lease attached as Schedule A hereto (the "**Guaranty**").

W I T N E S S E T H:

In consideration of the payments of rents and other charges provided for in this Lease, the covenants and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant hereby covenant and agree as follows:

1. PREMISES: Landlord hereby leases to Tenant and Tenant hereby leases from Landlord, upon the terms and conditions hereinafter set forth, the three (3) industrial warehouse/office facility buildings containing a total of approximately 130,952 square feet located at 14400, 14420 and 14440 NW 60th Avenue, Miami Lakes, Florida and described as Buildings "7A", "7B" and "7C" (collectively, the "**Building**"). The Building constitutes a portion of the real property described on Exhibit A attached hereto and made a part hereof (the "**Land**"). The Building is included in a multiple-building business and industrial park located at 14300 to 14560 NW 60th Avenue, Miami Lakes, Florida (the "**Project**"). A sketch of the Project is attached hereto and made a part hereof as Exhibit A-1. The Building and the portion of the Land on which the Building is located as shown on Exhibit A-1 shall hereinafter be collectively referred to as the "**Premises**".

Tenant and its employees and customers will have the nonexclusive right during the Term of this Lease to use the parking areas, streets, driveways, aisles, sidewalks, curbs, delivery passages, loading areas, lighting facilities, and all other areas situated on or in the Project which are designated by Landlord, from time to time, for use by all tenants of the Project (collectively, the "**Common Areas**"), in common with Landlord, other tenants of the Project and other persons reasonably designated by Landlord, subject to the rules and regulations promulgated by Landlord from time to time, which rules and regulations shall be applied in a nondiscriminatory fashion. In the event of any conflict between the rules and regulations and this Lease, this Lease shall control.

Tenant accepts the Premises and the Project in their "as is" condition on the Commencement Date.

2. TERM: The term ("**Term**") of this Lease shall commence on the Delivery Date, as hereinafter defined, (the "**Commencement Date**") and shall expire on February 28, 2022 (the "**Expiration Date**"). Tenant's obligation to pay Rent hereunder shall not commence until March 1, 2012, subject to Landlord Delays (the "**Rent Commencement Date**"). The first "Lease Year" shall begin on the date hereof and shall extend through the last day of the twelfth (12th) full calendar month after the Commencement Date. Thereafter, each "Lease Year" shall commence on the day following the expiration of the preceding Lease Year and shall end at the expiration of twelve (12) calendar months thereafter; provided, however, that the last "Lease Year" shall end on the Expiration Date.

If Landlord fails to deliver possession of the Premises to Tenant on or before the Commencement Date for any reason other than a Force Majeure Event, the Rent Commencement Date shall be delayed one day for each day after the Commencement Date until the date that Landlord actually delivers possession of the Premises to Tenant. Notwithstanding the foregoing, in the event Landlord has not delivered possession of the Premises to Tenant within two (2) months after the Commencement Date for any reason other than a Force Majeure Event, (the "**Extended Delivery Date**"), the Rent Commencement Date shall be delayed by two (2) days for each day after the Extended Delivery Date until the date that Landlord actually delivers possession of the Premises to Tenant. In addition, in the event Landlord has not delivered possession of the Premises to Tenant within three (3) months after the Commencement Date for any reason other than a Force Majeure Event, Tenant shall have the right to terminate this Lease upon written notice to Landlord at any time but prior to the date that Landlord actually delivers possession of the Premises to Tenant, whereupon the parties shall have no further obligations to each other except those expressly set to survive termination of this Lease. Tenant's termination of the Lease in accordance with the terms provided in this paragraph, if applicable, will constitute full settlement of all claims which Tenant might otherwise have against Landlord by reason of any delay in the delivery of Premises to Tenant. For purposes of this Lease, a "Force Majeure Event" shall mean fire, earthquake, weather delays or other acts of God, strikes, boycotts, war, riot, insurrection, embargoes, shortages of equipment, labor or materials, delays in issuance of governmental permits or approvals, or any other cause beyond the reasonable control of either party, provided, however, that a Force Majeure Event shall be inapplicable to any payments of money due under this Lease or to lack of funds for Landlord to fund the Tenant Improvement Allowance. Landlord and Tenant acknowledge and agree that any delay due to a Force Majeure Event referenced in this Section 2 shall be taken into account for only up to thirty (30) days in the aggregate for any or all Force Majeure Events, and any delay referenced in this Section 2 due to Force Majeure Events which shall exceed thirty (30) days in the aggregate shall constitute a delay for purposes hereof and shall not be subtracted from the total number of days of delay of Landlord.

3. SECURITY DEPOSIT: Tenant shall deliver to Landlord, upon Tenant's execution of this Lease, a Letter of Credit (as hereinafter defined) in the amount of $1,250,000.00, as a guaranty for the faithful performance and observance by Tenant of the terms, covenants and conditions of this Lease. The letter of credit shall be in the form of a clean, irrevocable, non-documentary and unconditional stand-by letter of credit (the "**Letter of Credit**") issued by and drawable upon a commercial bank, trust company, national banking association or savings and loan association with an AM Best's Financial Strength Rating equal to or better than "aa" (or such other rating service which would be equivalent thereto) which is reasonably acceptable to Landlord and which has offices for banking purposes in the City of Miami, Florida (the "**Issuing Bank**"). The Letter of Credit shall (a) name Landlord as beneficiary, (b) have a term of not less than one year, (c) permit multiple drawings, (d) be fully transferable by Landlord without the payment of any fees or charges by Landlord, and (e) otherwise be in form and content reasonably satisfactory to Landlord. If upon any

transfer of the Letter of Credit any fees or charges shall be so imposed, then such fees or charges shall be payable solely by Tenant and the Letter of Credit shall specify that it is transferable without charge to Landlord. If Landlord pays any such fees or charges, Tenant shall reimburse Landlord therefor upon demand. The Letter of Credit shall provide that it shall be automatically renewed, without amendment or need for any other action, for consecutive periods of one year each thereafter during the Term of this Lease, as the same may be extended (and in no event shall the Letter of Credit expire prior to the 45th day following the expiration date of this Lease) unless the Issuing Bank sends notice (the "**Non-Renewal Notice**") to Landlord by certified mail, return receipt requested, not less than 45 days next preceding the then expiration date of the Letter of Credit stating that the Issuing Bank has elected not to renew the Letter of Credit. The Issuing Bank shall agree with all beneficiaries, drawers, endorsers, transferees and bona fide holders that drafts drawn under and in compliance with the terms of the Letter of Credit will be duly honored upon presentation to the Issuing Bank at an office location in Miami, Florida. The Letter of Credit shall be subject in all respects to the International Standby Practices 1998, International Chamber of Commerce Publication No. 590.

If (a) an Event of Default by Tenant occurs in the payment or performance of any of the terms, covenants or conditions of this Lease, including the payment of Rent, (b) Landlord receives a Non-Renewal Notice, or (c) Tenant fails to increase the Letter of Credit as required herein, Landlord shall have the right by sight draft to draw, at its election, all or a portion of the proceeds of the Letter of Credit and thereafter hold, use, apply, or retain the whole or any part of such proceeds, (x) to the extent required for the payment of any Rent or any other sum as to which Tenant is in default including (i) any sum which Landlord may expend or may be required to expend by reason of Tenant's default, and/or (ii) any damages to which Landlord is entitled pursuant to this Lease, whether such damages accrue before or after summary proceedings or other reentry by Landlord and/or (y) as cash proceeds to guaranty Tenant's obligations hereunder, unless and until Tenant delivers to Landlord a substitute Letter of Credit which meets the requirements of this Section 3, provided at such time no default or Event of Default by Tenant has occurred and is continuing, in which event Landlord shall have no obligation to accept such substitute Letter of Credit and shall have the right to retain the cash proceeds. If Landlord applies any part of the cash proceeds of the Letter of Credit, Tenant shall promptly thereafter amend the Letter of Credit to increase the amount thereof by the amount so applied or provide Landlord with an additional Letter of Credit in the amount so applied so that Landlord shall have the full amount thereof on hand at all times during the Term. If Tenant shall comply with all of the terms, covenants and conditions of this Lease, the Letter of Credit or the cash proceeds thereof, as the case may be, shall be returned to Tenant after the Expiration Date and after delivery of possession of the Premises to Landlord in the manner required by this Lease, including without limitation, Section 25 of this Lease and Landlord shall execute such documents as are required to terminate the Letter of Credit. Tenant shall have the right to replace the Letter of Credit with other collateral acceptable to Landlord in Landlord's reasonable determination.

Upon a sale or other transfer of the Premises or the Project, Landlord shall transfer the Letter of Credit or the cash proceeds to its transferee. With respect to the Letter of Credit, within 5 days after notice of such transfer, Tenant, at its sole cost, shall (if required by Landlord) arrange for the transfer of the Letter of Credit to the new landlord, as designated by Landlord in the foregoing notice or have the Letter of Credit reissued in the name of the new landlord. Upon such transfer, Tenant shall look solely to the new landlord for the return of the Letter of Credit or the cash proceeds and thereupon Landlord shall without any further agreement between the parties be released by Tenant from all liability therefor, and it is agreed that the provisions hereof shall apply to every transfer or assignment made of the Letter of Credit or the cash proceeds to a new landlord. Tenant shall not assign or encumber or attempt to assign or encumber the Letter of Credit or the cash proceeds and neither Landlord nor its successors or assigns shall be bound by any such action or attempted assignment, or encumbrance.

Notwithstanding anything to the contrary contained in this Section 3, if Tenant has not provided Landlord with reasonable documentation as may be requested by Landlord to confirm that the Tenant has received U.S. Food and Drug Administration approval of Tenant's premarket approval application for the HeartWare Ventricular Assist System for a bridge-to-transplant indication (the "**FDA Approval**") on or before January 1, 2012, or if prior to January 1, 2012, Tenant's liquid net worth drops below $50,000,000.00, then Tenant shall be required to promptly amend the Letter of Credit to increase the amount of the Letter of Credit by $750,000.00. In the event that Tenant has increased the amount of the Letter of Credit by $750,000.00, and Tenant subsequently obtains the FDA Approval, Landlord agrees that Tenant may amend the Letter of Credit to decrease the amount of the Letter of Credit to $1,250,000.00 and notwithstanding that Tenant's liquid net worth may be less than $50,000,000.00. In addition, commencing on the sixth (6^{th}) anniversary of the Rent Commencement Date, and provided that (i) Tenant has not previously defaulted in its obligation to pay Rent to Landlord within the time periods set forth in this Lease (subject to the notice and cure periods provided for in this Lease),(ii) no Event of Default then exists and (iii) Tenant has had at least four (4) consecutive quarters of profitability, Landlord agrees that Tenant may amend the Letter of Credit to decrease the amount of the Letter of Credit to $750,000.00. Tenant shall provide Landlord with such reasonable documentation as may be requested by Landlord to confirm that the Tenant has received the FDA Approval or to confirm that Tenant has had at least four (4) consecutive quarters of profitability. In the event that Tenant is required to increase the amount of the Letter of Credit in accordance with this Section 3 or permitted to decrease the amount of the Letter of Credit in accordance with this Section 3, Tenant shall either (x) deliver to Landlord a consent to an amendment to the Letter of Credit (which amendment must be reasonably acceptable to Landlord and the Issuing Bank in all respects), increasing or reducing, as applicable, the amount of the Letter of Credit by the amount of the permitted increase or reduction, and Landlord shall execute such consent and such other documents as are reasonably necessary to increase or reduce the amount of the Letter of Credit in accordance with the terms hereof, or (y) deliver a substitute Letter of Credit in compliance with this Section 3 which Landlord will simultaneously exchange for the existing Letter of Credit and Landlord shall consent to the cancellation of such existing Letter of Credit. If Tenant delivers to Landlord a consent to an amendment to the Letter of Credit in accordance with the terms hereof, Landlord shall, within 10 business days after delivery of such consent, either (1) provide its reasonable objections to such amendment or (2) execute such consent in accordance with the terms hereof.

4. BASE RENT:

A. Base Rent: Commencing on the Rent Commencement Date, Tenant agrees to pay Landlord, in monthly installments in advance, "Base Rent" of Ninety Eight Thousand Two Hundred Fourteen and No/100 Dollars ($98,214.00) for the first Lease Year. Monthly Base Rental installments of Ninety Eight Thousand Two Hundred Fourteen and No/100 Dollars ($98,214.00) shall be payable on the first day of each month during the Term of this Lease commencing on the Rent Commencement Date and continuing on the first day of each month thereafter throughout the Term. Each payment is to be made by Tenant without any offset or deduction whatsoever, except as expressly provided herein, in lawful money of the United States of America, at Landlord's address above specified or elsewhere as designated from time to time by Landlord's written notice to Tenant.

Beginning on the first anniversary of the Rent Commencement Date and on each anniversary thereafter during the Term of this Lease, the Base Rent due from Tenant hereunder shall be increased by an amount equal to three percent (3%) of the total Base Rent for the immediately preceding Lease Year (i.e. 2nd Lease Year = $1,213,925.00-; 3rd Lease Year = $1,250,343.00; etc.).

B. Additional Rent: For purposes of this Lease, the following definitions shall apply:

(i) Additional Rent shall equal the product of Tenant's Pro-Rata Share Percentage (as defined below) multiplied by the sum of all of the Landlord's Operating Expenses (as hereinafter defined) for the applicable Lease Year.

(ii) "Operating Expenses" shall mean (without duplication of any costs and expenses for which Tenant is responsible to pay directly as set forth in this Lease): (a) all of the costs and expenses Landlord incurs, pays or becomes obligated to pay in connection with operating, managing (including management fees not to exceed three percent (3 %) per month), maintaining, repairing and insuring the Premises or the Common Areas for the particular Lease Year or portion thereof as reasonably determined by Landlord in accordance with generally accepted accounting practices, (b) all other costs and expenses incurred by Landlord which would generally be regarded as operating, maintenance, repair, insurance and management costs and expenses relating to the Premises and the Common Areas.

Operating Expenses shall not include *(a)* any expenditures for capital repairs, replacements and improvements, all of which shall be the sole responsibility of Landlord and none of the foregoing shall be included in Operating Expenses and Tenant shall not be required to reimburse Landlord for any of the foregoing; *(b)* expenses actually paid to Landlord by proceeds of insurance, or condemnation proceeds (including deed or other transfer in lieu of condemnation), or under warranties or service contracts, or for which Landlord is otherwise reimbursed; *(c)* alterations and leasehold improvements attributable solely to tenants of the Project other than Tenant; *(d)* interest, amortization, principal, or other payments on loans to Landlord whether secured or unsecured (except that interest payments on loans obtained by Landlord to finance expenditures that otherwise qualify as Operating Expenses may be included, and principal payments on such loans may also be included if the underlying expenditure

was not included in Operating Expenses when made); *(e)* depreciation of the Building and other applicable property on the Project**;** *(f)* leasing commissions and legal fees incurred in connection with leasing space in the Project; *(g)* legal fees, space planners' fees, real estate brokers' leasing commissions and advertising expenses incurred in connection with the original or future leasing of space in the Project or legal fees incurred in connection with tenant disputes; *(h)* costs and expenses of alterations to the premises of other individual tenants or occupants of space in the Project, including tenant build out, renovating or otherwise improving or decorating, painting or redecorating space; *(i)* costs of correcting defects in, or inadequacy of, the design or construction of the Building and other buildings on the Project or the materials used in the construction of the Building and other buildings on the Project or the equipment or appurtenances thereto; *(j)* costs and expenses associated with the operation of the business of the person or entity which constitutes Landlord, such as Landlord's general corporate overhead, as the same are distinguished from the costs of operation of the Property, including accounting and legal matters, costs of defending any lawsuits with any mortgagee, and costs of selling or financing any of Landlord s interest in the Building or the Project; *(k)* costs and expenses directly resulting from the gross negligence or willful misconduct of Landlord or its agents; *(l)* expenses in connection with services or other benefits of a type which are not generally available to all tenants of the Project; *(m)* overhead and profit increments and any other costs for services and materials paid to subsidiaries or other affiliates of Landlord for services on or to the Building or the Project (or any portion thereof), to the extent that the costs of such services exceed competitive costs of such services were they not so rendered by a subsidiary or other affiliate of Landlord; *(n)* payments of rental concessions or negative cash flow guarantees, and rental payments under any ground or underlying lease or leases; *(o)* any compensation paid to clerks, attendants or other persons in commercial concessions operated by Landlord; *(p)* any costs, fines or penalties incurred due to violations by Landlord of any Applicable Laws or for late payment (and provided that Tenant has timely made its payments of the Additional Rent as required under this Lease); *(q)* costs for sculptures, paintings or other art; *(r)* the cost of repairs or restoration incurred by reason of fire or other casualty or condemnation to the extent that either (i) Landlord is compensated therefor through the receipt of proceeds of insurance or condemnation awards; or (ii) Landlord failed to obtain insurance against such fire or casualty, if such insurance was available at commercially reasonable rates; or (iii) Landlord is not fully compensated therefor due to the co-insurance provisions of its insurance policies on account of Landlord's failure to obtain a commercially reasonable and sufficient amount of coverage against such risk; provided, however, in no event shall the foregoing operate to exclude from Operating Expenses the commercially reasonable deductible amounts under insurance policies maintained by Landlord; *(s)* electricity or other costs charged separately to other tenants, *(t)* any costs arising from correcting violations of any Applicable Laws, including without limitation the Americans With Disabilities Act (the "**ADA**"), which were

in effect as of the date that actual possession of the Premises is delivered to Tenant (but specifically excluding any violations of Applicable Laws related to Tenant's Compliance Obligations); (u) so-called "administrative charges" or other add-ons to the total of Operating Expenses; *(v*) expenses related to vacant space, including utility costs, security and renovation; (*w*) costs related to investigation of, testing for, removal and/or clean up of Hazardous Materials; *(x)* the cost of overtime or other expense to Landlord in curing its defaults; *(y)* that proportionate portion of salaries and other employment costs of any employee (i) to the extent such employee is engaged in activities other than the direct operation or maintenance of the Common Areas, or (ii) whose position is at or above the level of property manager; or *(z)* the costs and expenses of Landlord not allowed to be passed through as Operating Expenses pursuant to the terms of Section 12 of this Lease.

(iii) "Tenant's Pro-Rata Share Percentage" shall mean one hundred (100%) percent with respect to the Building and thirty three and twenty two hundreths (33.22%) percent with respect to the Project. The total square footage of the Project on the Commencement Date is 394,211. If the rentable square footage in the Project or the Premises changes after the Commencement Date of this Lease (because for example, a portion of the Project is sold by the Landlord, or because Tenant leases additional space in the Project), Tenant's Pro Rata Share Percentage of the Project shall be appropriately adjusted to be equal to the ratio of the total square footage of the Premises over the total square footage of the Project.

In addition to the Base Rent, commencing on the Rent Commencement Date, Tenant shall pay to Landlord the Additional Rent, in each calendar year or partial calendar year, payable in monthly installments as hereinafter provided. On or prior to the Rent Commencement Date and at least thirty (30) days prior to the commencement of each calendar year thereafter, Landlord shall give Tenant written notice of Tenant's estimated Additional Rent for the applicable calendar year and the amount of the monthly installment due for each month during such year. Tenant shall pay to Landlord on the Rent Commencement Date and on the first day of each month thereafter the amount of the applicable monthly installment of Additional Rent, without notice, demand, offset or deduction (except as otherwise expressly set forth in this Lease), provided, however, that if the applicable installment covers a partial month, then such installment shall be prorated on a daily basis. If Landlord fails to give Tenant notice of its estimated payments of Additional Rent in accordance with this subsection for any calendar year, then Tenant shall continue making monthly estimated payments in accordance with the estimate for the previous calendar year until a new estimate is provided by Landlord. If Landlord determines that, because of unexpected increases in Operating Expenses or other reasons, Landlord's estimate of Operating Expenses was too low, then Landlord shall have the right to give a new statement of the estimated Additional Rent due from Tenant for the applicable calendar year or the balance thereof and to bill Tenant for any deficiency which may have accrued during each calendar year or portion thereof, and Tenant shall thereafter pay monthly installments of Additional Rent based on such new statement. Within one hundred twenty (120) days after the end of each calendar year and the Expiration Date, Landlord shall prepare and deliver to Tenant a statement showing Tenant's actual Additional Rent for the applicable calendar year (the "**Statement**"), provided that with respect to the calendar year in which the Expiration Date occurs, (x) that calendar year shall be deemed to have commenced on January 1 of that year and ended on the Expiration Date (the "**Final Calendar Year**") and (y) Landlord shall have the right to reasonably estimate the actual Operating Expenses allocable to the Final Calendar Year. If Tenant's total monthly payments of Additional Rent for the applicable calendar year are more than Tenant's actual Additional Rent, then Landlord shall credit the amount of such overpayment to Tenant, provided, however, with respect to the Final Calendar Year, Landlord shall pay to Tenant the amount of such excess payments, less any additional amounts then owed to Landlord, within thirty (30) days after the Expiration Date. Any amount due Landlord as shown on any such statement shall be paid by Tenant within twenty (20) days after it is furnished to Tenant.

If Tenant disputes the amount set forth in the Statement, Tenant shall have the right, at Tenant's sole expense, not later than ninety (90) days following receipt of such Statement, to cause Landlord's books and records with respect to the calendar year which is the subject of the Statement to be audited by a certified public accountant mutually acceptable to Landlord and Tenant. The audit shall take place at the offices of Landlord where its books and records are located in Miami-Dade County, Florida, at a mutually convenient time during Landlord's regular business hours. At the conclusion of such audit, Tenant shall provide a copy of the audit to Landlord, including all supporting documentation reasonably requested by Landlord. If Tenant's audit indicates that Tenant made an overpayment to Landlord for such preceding year, Landlord shall credit such amount to Tenant's subsequent payments of rent, or if the Lease has terminated, remit the amount of such overpayment to Tenant within thirty (30) days after receipt of the audit from Tenant. If such audit reveals an underpayment by Tenant, Tenant will remit the amount of such underpayment within thirty (30) days of Tenant's delivery of the audit to Landlord. Should Landlord disagree with the results of Tenant's audit, Landlord and Tenant shall use good faith efforts to resolve such dispute within sixty (60) days. If Landlord and Tenant have not resolved their dispute in such sixty (60) day period, Landlord and Tenant shall refer the matter to a mutually acceptable independent certified public accountant, who shall work in good faith with Landlord and Tenant to resolve the discrepancy. The fees and costs of such independent accountant to which such dispute is referred shall be shared pro rata to the extent each party is unsuccessful as determined by such independent accountant, whose decision shall be final and binding. Tenant shall have no right to conduct an audit or to give Landlord notice that it desires to conduct an audit at any time Tenant is in default under the Lease. The accountant conducting the audit shall be compensated on an hourly basis and shall not be compensated based upon a percentage of overcharges it discovers. No subtenant shall have any right to conduct an audit, and no assignee shall conduct an audit for any period during which such assignee was not in possession of the Premises. Tenant's right to undertake an audit with respect to any calendar year shall expire ninety (90) days after Tenant's receipt of the Statement for such calendar year, and such Statement shall be final and binding upon Tenant and shall, as between the parties, be conclusively deemed correct, at the end of such ninety (90) day period, unless prior thereto Tenant shall have given Landlord written notice of its intention to audit Operating Expenses for the calendar year which is the subject of the Statement. If Tenant gives Landlord notice of its intention to audit Operating Expenses, it must commence such audit within sixty (60) days after such notice is delivered to Landlord, and the audit must be completed within one hundred twenty (120) days after such notice is delivered to Landlord. If Tenant does not commence and complete the audit within such periods, the Statement which Tenant elected to audit shall be deemed final and binding upon Tenant and shall, as between the parties, be conclusively deemed correct. Tenant agrees that the results of any Operating Expense audit shall be kept strictly confidential by Tenant and shall not be disclosed to any other person or entity (except as it may be otherwise required by law or court order or by discovery rules in any legal proceeding and provided that Tenant may share the results of any such audit with its attorneys). In the event that Tenant's audit reveals that the Operating Expenses have been overstated by 5% or more, Landlord shall pay the reasonable fees and expenses of the auditor, not to exceed $5,000.00.

C. Sales Tax: In addition to Rent, Tenant shall and hereby agrees to pay to Landlord each month a sum equal to any sales tax, tax on rentals, and any other similar charges, taxes and/or impositions now in existence (currently 7.0%) or hereafter imposed based upon the privilege of renting the space leased hereunder or upon the amount of Rent and any other charges collected therefor.

D. Late Fees: Tenant shall be required to pay Landlord a late fee equal to 5% together with default interest on any Rent due that remains unpaid for ten (10) days after its due date. Said default interest will be computed from the due date at a rate the lesser of: (i) fifteen (15%) percent per annum, or (ii) the highest rate permitted by law.

E. Definition of Rent. The term "Rent" as used in this Lease shall mean Base Rent, Additional Rent and all other charges and costs due by Tenant to Landlord under this Lease.

F. Rent Abatement. Notwithstanding anything to the contrary contained in this Lease, Tenant shall not be required to pay Base Rent or Additional Rent for the period from the Commencement Date until the Rent Commencement Date (the "Rent Abatement Period"). Tenant shall be required to transfer all utility accounts for the Premises into Tenant's name effective as of the date that actual possession of the Premises is delivered to Tenant, and Tenant shall be responsible to pay for all utilities used at the Premises beginning on the date that actual possession of the Premises is delivered to Tenant.

5. REAL PROPERTY TAXES/ASSESSMENTS:

Beginning on the Rent Commencement Date, Tenant shall be responsible for and shall pay before delinquency all real estate taxes or assessments, general, special, ordinary or extraordinary, improvement bond or bonds imposed on the Premises or any portion thereof by any authority having the direct or indirect power to tax, including any city, county, state or federal government, or any school, agricultural, sanitary, fire, street, drainage or other improvement district thereof, as against any legal or equitable interest of Landlord in the Premises or in any portion thereof (collectively "**Real Property Taxes**"), assessed from the Rent Commencement Date through the Expiration Date.

The foregoing notwithstanding, at Landlord's option, Tenant shall pay to Landlord, together with and in addition to each monthly installment of Additional Rent, an amount deemed sufficient by Landlord to provide Landlord with funds sufficient to pay the Real Property Taxes next due at least thirty (30) days before the date the same are due.

Notwithstanding the foregoing, Real Property Taxes will not include any income, excess profits, single business, inheritance, succession, transfer, franchise, capital or other tax or assessments upon Landlord or Landlord's interest in the Premises or the Project, or any fine, penalty, cost or interest for any Real Property Taxes Landlord failed to timely pay (provided that Tenant has timely paid the Additional Rent due hereunder).

Commencing with calendar year 2011, Landlord will file a contest of the amount or validity of Real Property Taxes for each tax fiscal year by appropriate administrative and legal proceedings, and Landlord shall proceed diligently to obtain a resolution of said contest.

6. PERSONAL PROPERTY TAXES: Beginning on the date that actual possession of the Premises is delivered to Tenant, Tenant shall pay prior to delinquency all taxes assessed against and levied upon trade fixtures, furnishings, equipment and all other personal property of Tenant contained in the Premises or related to Tenant's use of the Premises, assessed from the date that actual possession of the Premises is actually to Tenant through the Expiration Date. If any of Tenant's personal property shall be assessed with Landlord's real or personal property, Tenant shall pay to Landlord the taxes attributable to Tenant within thirty (30) days after receipt of a written statement from Landlord setting forth the taxes applicable to Tenant's property (accompanied by the document(s) from the taxing authorities which evidence such assessment).

7. UTILITIES: Tenant shall pay throughout the Term (prior to delinquency) all charges and expenses for all utilities servicing the Premises, including, but not limited to, charges for gas, telephone, electricity, storm water and water together with all connection charges. Tenant shall pay all charges for metered water, sewer service charges and other fees or charges lawfully imposed by any public authority upon or in connection with the Premises, if any. Landlord represents that all utilities (electric, water, gas, telephone, sanitary and storm sewer, including but not limited to all necessary lines and equipment) are installed and are available to the Premises so long as the use of the Premises is consistent with the use that was made by the former occupant of the Premises, and that there are no hook-up, impact or other similar fees to be paid for the current amounts of utility services available at the Premises. If Tenant changes the use of the Premises to a use that is not consistent with the use that was made by the former occupant of the Premises, Tenant shall be solely responsible for any hook-up, impact or other similar fees related to such change in use. Tenant shall also be responsible for any deposits required by any utility provider.

8. TIME OF PAYMENT: Tenant agrees that Tenant shall promptly pay said Rent at the times and place stated above; and Tenant shall promptly pay any other charges that accrue under this Lease.

9. USE: The Tenant will use and occupy the Premises for general office, administrative, laboratory, research and development, manufacturing, quality control, warehousing and distribution and related uses, and for no other use or purpose (the "**Permitted Use**") .

In the event that Tenant uses the Premises for purposes not expressly permitted herein, the Landlord may, in addition to all other remedies available to it, restrain said improper use by injunction.

10. QUIET ENJOYMENT: Upon payment by Tenant of the Rent herein provided, and upon the observance and performance of all terms and provisions, on Tenant's part to be observed and performed under this Lease, Tenant shall, subject to all of the terms and provisions of this Lease, peaceably and quietly hold and enjoy the Premises for the Term hereby demised.

11. COMPLIANCE WITH LAWS.

A Tenant will not make or permit any occupancy or use of any part of the Premises for any hazardous, offensive, dangerous, noxious or unlawful occupation, trade, business or purpose or any occupancy or use thereof which is contrary to any law, by-law, ordinance, rule, permit or license, and will not cause, maintain or permit any nuisance in, at or on the Premises; provided, however, that the Permitted Use, if conducted in conformance with the terms of this Lease, all Applicable Laws which relate to the Permitted Use, and reasonable and customary standards for general office, administrative, laboratory, research and development, manufacturing, quality control, warehousing and distribution space, shall not be deemed to be a hazardous, offensive, dangerous, or noxious occupation, trade, business or purpose or a nuisance, unless it adversely affects tenants or occupants outside the Premises in a significant manner. Tenant shall not place any loads upon the floors, walls, or ceiling which endanger the structure (but Tenant shall have the right to upgrade such floors, walls or ceiling to accommodate loads, if necessary, as an alteration to the Premises in accordance with the terms of Section 12 hereof), or place any harmful fluids or other materials in the drainage system of the Premises or Land (other than fluids or other materials in compliance with laws, regulations and codes applicable to the drainage system of the Premises), or overload existing electrical or other mechanical systems (but Tenant shall have the right to upgrade such floors, walls or ceiling to accommodate loads, if necessary, as an alteration to the Premises in accordance with the terms of Section 12 hereof). Tenant shall not use any machinery or equipment in the Premises that causes excessive noise or vibration perceptible from the exterior of the Premises, as reasonably determined by Landlord, or that unreasonably interferes with the use or enjoyment of the Project by other tenants or lawful occupants. No waste materials or refuse shall be dumped upon or permitted to remain outside of the Premises except in trash containers placed inside exterior enclosures designated by Landlord for that purpose. No materials, supplies, equipment, finished products or semi-finished products, raw materials or articles of any similar nature shall be permitted to remain outside the Premises or on any portion of the common areas (other than during construction of the Tenant Improvements) unless otherwise approved by Landlord in its sole discretion. Subject to the terms of Sections 50 and 52 of this Lease, no sign, antenna or other structure or thing shall be erected or placed on the Premises or any part of the exterior of any building or on the Land or erected so as to be visible from the exterior of the Building containing the Premises without first securing the written consent of the Landlord, which shall not be unreasonably withheld, conditioned or delayed.

Tenant will, at Tenant's sole cost and expense, comply with all Applicable Laws (including the ADA) which affect the carrying on of the business being conducted in the Premises, as distinguished from the physical facilities in which such business is being conducted. Landlord will bear the expense of any alterations or improvements or repairs to the Premises ordered by any governmental authority, unless such alterations or improvements or repairs (i) relate solely to the type of business conducted in the Premises by Tenant or the manner in which Tenant is conducting Tenant's business in the Premises, (ii) relate to the Tenant Improvements being constructed by Tenant pursuant to the Work Letter attached hereto as Exhibit B, or (iii) are required solely by virtue of any other

alterations undertaken by Tenant to the Premises (items (i) through (iii), "**Tenant's Compliance Obligations**"). Notwithstanding the same, if Landlord is required to bear the expense of operating, replacing, modifying and/or adding improvements or equipment mandated by any law, statute, regulation or directive of any governmental agency enacted on or after the date that actual possession of the Premises is delivered to Tenant, and any repairs or removals necessitated thereby (including, but not limited to, the cost of complying with the ADA and regulations of the Occupational Safety and Health Administration that may be enacted from and after the date that actual possession of the Premises is delivered to Tenant), the cost shall be amortized over the useful life of the improvement or equipment, as reasonably determined by Landlord, together with an interest factor on the unamortized cost of six percent (6%) per annum and passed through to Tenant as an Operating Expense in accordance with Section 4.B. of this Lease.

Notwithstanding anything to the contrary contained in the Lease, Landlord and Tenant agree that if necessary with regard to the Tenant Improvements or any other Alterations by Tenant that Landlord and Tenant (i) will split equally the cost for any abatement related to the presence of asbestos in the black a/c duct seam mastic material on the air ducts above the ceiling tiles within Building 7C and any other asbestos containing material identified within the Premises which requires abatement and (ii) will reasonably cooperate in approving any plan for such abatement and the contractor selected to complete such abatement. Tenant further agrees that it will use commercially reasonable efforts to minimize any disturbance of any asbestos containing material in connection with the Tenant Improvements or any other Alterations**.**

Landlord will, at Landlord's sole cost and expense (subject to Landlord's right to pass through such cost and expense as an Operating Expense in accordance with Section 4.B. of this Lease if any such Applicable Laws are enacted on or after the date that actual possession of the Premises is delivered to Tenant), take such action as may be necessary or appropriate to cause the Common Areas to comply with all applicable laws of all governmental authorities (the "**Applicable Laws**") throughout the Term.

Landlord represents that as of the date of this Lease, and except as specifically set forth in this Lease, Landlord has not received written notice from any governmental authority that either the Premises or the Project is not in substantial compliance, in all material respects, with Applicable Laws. In addition, Landlord represents that, as of the date of this Lease, Landlord has not received written notice from any governmental authority of any non-compliance issues with the ADA on or about the Premises or the Project.

B. Tenant agrees not to generate, store or use any Hazardous Materials (as hereinafter defined) on or about the Premises, except (a) those used by Tenant in its general office operations and janitorial services, in both cases limited to such Hazardous Materials in such amounts as are customarily used in general office uses and for janitorial service provided to general office uses, and (b) those used in connection with the Permitted Use, and in each case only in compliance with any and all applicable Environmental Laws (also as hereinafter defined). Tenant shall provide Landlord, upon Landlord's written request, with copies of all Material Safety Data Sheets ("**MSDS**") for Hazardous Materials used or stored in the Premises. Tenant agrees to notify Landlord prior to using any Hazardous Materials on the Premises which require special precautions or facilities. In all events, Tenant agrees not to release or to permit Tenant's contractors, subtenants, licensees, invitees, agents, servants or employees or others for whom Tenant is legally responsible (collectively, "**Tenant Responsible Parties**") to release any Hazardous Materials on the Premises in violation of or that requires reporting under any Environmental Law, and not to dispose of Hazardous Materials (a) on the Premises or (b) from the Land to any other location except a properly approved disposal facility and then only in compliance with any and all Environmental Laws regulating such activity, nor permit any Tenant Responsible Party to do so.

For purposes of this Lease, "Hazardous Materials" shall mean any substance regulated under any Environmental Law, including those substances defined in 42 U.S.C. Sec. 9601(14) or any related or applicable federal, state or local statute, law, regulation, or ordinance, pollutants or contaminants (as defined in 42 U.S.C. Sec. 9601(33), petroleum (including crude oil or any fraction thereof), any form of natural or synthetic gas, sludge (as defined in 42 U.S.C. Sec. 6903(26A), radioactive substances, hazardous waste (as defined in 42 U.S.C. Sec. 6903(27)) and any other hazardous wastes, hazardous substances, contaminants, pollutants or materials as defined, regulated or described in any of the Environmental Laws. As used in this Lease, "**Environmental Laws**" means all federal, state and local laws, as the same may be amended, relating to the protection of the environment or health and safety, and any rule or regulation promulgated thereunder and any order, standard, interim regulation, moratorium, policy or guideline of or pertaining to any federal, state or local government, department or agency, including but not limited to the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended, the Superfund Amendments and Reauthorization Act of 1986, the Clean Water Act, the Clean Air Act, the Toxic Substances Control Act, the Occupational Safety and Health Act, the Federal Insecticide, Fungicide and Rodenticide Act, the Marine Protection, Research, and Sanctuaries Act, the National Environmental Policy Act, the Noise Control Act, the Safe Drinking Water Act, the Resource Conservation and Recovery Act, as amended, the Hazardous Material Transportation Act, the Refuse Act, the Uranium Mill Tailings Radiation Control Act and the Atomic Energy Act and regulations of the Nuclear Regulatory Agency, Florida Statutes Chapters 369 through 380 and any other state and local counterparts or related statutes, laws, regulations, and order and treaties of the United States.

C. Tenant shall permit Landlord and Landlord's agents, representatives and employees, including, without limitation, legal counsel and environmental consultants and engineers, access to the Premises at any time during the Term upon at least 72 hours' prior written notice (which notice shall indicate where within the Premises Landlord intends to investigate, the reason for the investigation, and identifies, to the extent practicable, the persons conducting such investigation) for purposes of conducting environmental assessments; provided, however, that such assessments may only be conducted if (i) Landlord has reason to believe that there has been a release or a material threat of release of Hazardous Materials in a reportable quantity at the Premises or arising from Tenant's activities at the Premises or (ii) requested by an actual or prospective mortgage lender, purchaser or equity investor, and shall, to the extent practicable, be conducted at a time designed to minimize interference with Tenant's operations (Tenant acknowledging that, in the event of an emergency, it shall have no right to object to such timing). In addition to the written notice set forth in the immediately preceding sentence, Landlord shall endeavor to provide verbal notice to David McIntyre, the facilities manager, or such other employee of Tenant as Tenant may designate to Landlord from time to time for the purposes of conducting environmental assessments. Landlord shall permit Tenant or Tenant's representatives to be present during any such assessment, and any

investigation, testing or sampling, provided that Landlord shall not, except in the event of an emergency, be allowed access to the area designated by Tenant as the "clean rooms" without being accompanied by an authorized representative of Tenant, and Landlord shall comply with all of Tenant's commercially reasonable rules and regulations regarding access to the "clean rooms". Landlord shall avoid materially interfering with Tenant's use of the Premises during any entrance on to the Premises as permitted hereunder, and upon completion of Landlord's assessment, investigation, and sampling, shall promptly repair and restore the affected areas of the Premises from any damage caused by the assessment. Such assessment shall be at Landlord's expense, provided that if the assessment shows that a release of Hazardous Materials by Tenant or Tenant Responsible Parties in violation of this Lease has occurred, then Landlord's actual, reasonable, out-of-pocket costs relating to such assessment shall be reimbursed by Tenant. If Landlord collects any samples from the Premises in connection with any such assessment, Landlord shall give Tenant reasonable prior notice thereof and Tenant shall be permitted to collect split samples, and, if Tenant so requests, Landlord shall provide to Tenant a portion of any sample being tested to allow Tenant, if Tenant so chooses, to perform its own testing.

D. Tenant shall prepare a written environmental contingency plan sufficient to comply with Environmental Laws and good practice for first class laboratory space ("**Environmental Contingency Program**") and shall revise the same from time to time as reasonably necessary because of changes in operations within the Premises, changes in applicable Environmental Laws, and changes in customary practice for environmental contingencies in first class laboratory space. Landlord acknowledges that Tenant has delivered a copy to Landlord of Tenant's Environmental Contingency Program as existing on the date hereof and that as of the date hereof Tenant has complied with its obligation hereunder to prepare an Environmental Contingency Program. Tenant shall implement the Environmental Contingency Program as necessary in accordance with the approved plan (as it may be revised) and shall, within 14 days after Landlord's written request, provide Landlord with copies of all reports and documentation prepared in connection therewith. Within 14 days after Landlord's written request, Tenant shall provide Landlord with copies of any routine safety audits conducted by Tenant in the ordinary course of Tenant's business. Landlord may from time-to-time undertake an environmental audit in accordance with the terms of subsection C. above to assess the compliance of Tenant with applicable Environmental Laws if Landlord reasonably believes that Tenant is not then in compliance with such Environmental Laws or if there is any release of Hazardous Materials required to be reported under any Environmental Law that arises out of the use, operation, or occupancy of the Premises or Land by Tenant or any Tenant Responsible Parties during the Term of this Lease and any further period during which Tenant or any Tenant Responsible Party retains use, operation or occupancy of the Premises (a "**Tenant's Release**"). In addition, Tenant shall investigate, assess, monitor and report as required by applicable Environmental Law, at Tenant's sole cost and expense, any Tenant's Release. Further, Tenant shall remediate, in compliance with applicable Environmental Laws, at Tenant's sole cost and expense, any Tenant's Release requiring remediation in compliance with applicable Environmental Laws. Tenant shall submit to Landlord, for Landlord's prior approval, a work plan outlining in reasonable detail any Remedial Work to be performed by Tenant hereunder (the "**Remedial Work Plan**"). Landlord shall not unreasonably withhold or delay its approval of such Remedial Work Plan if (i) it complies with all applicable Environmental Laws; and (ii) the Remedial Work outlined therein reasonably appears sufficient to remediate the releases to the level provided for in this Section 11.D. If Tenant is obligated to remediate a Tenant's Release under this Lease, Tenant shall be obligated to remediate the Tenant's Release to a level that will permit the Premises to be used for first class

office, laboratory, and research and development uses under Applicable Laws. Notwithstanding the foregoing, Tenant's obligation to remediate in connection with a Tenant Release shall not require the Tenant to remediate the Premises to a level that would allow the Premises to be used for residential, school or day care purposes. Tenant shall provide to Landlord copies of any submittals to governmental authorities simultaneously with such submittal to the governmental authorities. Tenant or the Tenant Responsible Party, as appropriate, shall sign any manifests or other documents as the waste generator for any Hazardous Materials it disposes of or sends off site or otherwise arising from a Tenant's Release. This Subsection shall survive the Term of this Lease and shall be subject to the provisions of Section 26 of this Lease. Tenant's remediation obligation set forth in this Subsection shall not limit Landlord's right to damages, if any, which Landlord may incur due to any unremediated Hazardous Materials resulting from a Tenant's Release.

E. Tenant shall pay for all costs reasonably and actually incurred by Landlord, for independent consultants or otherwise, in connection with inspections, investigations, and/or response actions concerning a Tenant's Release or the threat of a Tenant's Release.

F. Tenant may require that any representative of Landlord entering into a secured portion of the Premises (which has been identified by Tenant to Landlord in advance as containing proprietary information) for the purposes set forth in this Section 11 execute a confidentiality agreement with respect to Tenant's proprietary information, provided, however, that such agreement is subject to Landlord's prior approval (not to be unreasonably withheld). Landlord agrees to hold any proprietary information identified by Tenant and supplied to Landlord pursuant to this Section 11.F. ("**Confidential Information**") in confidence, subject to disclosures to the extent that such disclosure is required by law or court order or by discovery rules in any legal proceeding. Notwithstanding the foregoing, Landlord may disclose such Confidential Information to its lenders, attorneys, and consultants in connection with the financing or sale of the Property or Landlord's review of such information.

G. Any inspections, testing, approvals, or requirements by Landlord with respect to Hazardous Materials which are Tenant's responsibility under this Lease shall be for the sole benefit of Landlord and Tenant shall have no right to rely on Landlord or its consultants with respect to matters relating to such Hazardous Materials, and Tenant shall be solely responsible therefor.

H. Landlord represents to Tenant that, except as set forth in Section I. below (the "**Disclosed Environmental Matter**"), Landlord has not received written notice from any governmental agency regarding the existence of any Hazardous Materials on or about the Premises, the presence of which violates any applicable Environmental Laws. Except in the event that Tenant uses the Premises for residential purposes, for a school or day care center, or if Tenant uses groundwater at the Premises for drinking purposes, Landlord shall indemnify, defend, and hold Tenant, and its employees, officers and directors harmless from all claims, liabilities, losses, costs and expenses (including reasonable attorney fees) arising out of Landlord's introduction of any Hazardous Materials on or about the Premises or out of the Disclosed Environmental Matter. In addition, and notwithstanding anything to the contrary contained in this Lease, Landlord acknowledges and agrees that Tenant shall have no responsibility to assess or remediate any Hazardous Materials that were not introduced to the Project or the Premises by Tenant or any Tenant Responsible Party, including but not limited to any Hazardous Materials related to the Disclosed Environmental Matter, or to indemnify Landlord for any claims, liabilities, losses, costs and expenses related to any Hazardous Materials that were not introduced to the Project or the Premises by Tenant or any Tenant Responsible Party, including but not limited to any Hazardous Materials related to the Disclosed Environmental Matter.

I. Tenant expressly acknowledges and agrees that in accordance with the terms of that certain Covenant Running with the Land in favor of Miami Dade County Florida, recorded in Official Records Book 26889, Page 3982 of the Public Records of Miami-Dade County, Florida (the "**Covenant**"), Landlord has disclosed to Tenant that a portion of the Project is the subject of a Miami-Dade County Department of Environmental Resource Management ("**DERM**") Risk Based Corrective Action Site Closure Permit, under that certain permit RBCA-026. Landlord agrees to forward to Tenant any notices of any planned inspections of the Premises pursuant to the terms of the Covenant received by Landlord from DERM promptly after Landlord's receipt thereof.

12. MAINTENANCE AND REPAIR OF PREMISES; ALTERATIONS:

A. Tenant, at Tenant's own expense will keep and maintain the Premises continuously in a neat and attractive manner, in good repair and in tenantable condition during the Term. Notwithstanding anything in the Lease to the contrary, the only maintenance and repair obligations Tenant shall have are to the interior non-structural portions of the Premises and to the HVAC system, plumbing, wiring and other utility facilities inside of the Premises which are located above the floor slab of the Premises and which are not otherwise required to be maintained or repaired by Landlord pursuant to the terms of this Lease.

Landlord shall, at its sole cost and expense, maintain, repair and replace all structural components of the Premises (including, but not limited to, the foundation, bearing walls and roof structure). Landlord acknowledges and agrees that Landlord shall not have the right to pass through the cost and expense to maintain, repair and replace structural components of the Premises as an Operating Expense in accordance with Section 4.B. of this Lease. Landlord shall, at its sole cost and expense(subject to Landlord's right to pass through such cost and expense as an Operating Expense in accordance with Section 4.B. of this Lease) maintain, repair and replace the exterior windows, the exterior walls, floor slab (and, to the extent repair is required due to the condition of the slab or conditions under the slab, the floor coverings), the sprinkler system, gutters, downspouts and canopies of the Premises, building systems, all plumbing, wiring and other utility facilities within or under the floor slab of the Premises, all plumbing, wiring and other utility facilities serving the Premises up to their points of connection with the meter for such utilities serving the Premises, as necessary to keep the same in good order, condition and repair, ordinary wear and tear and damage by casualty excepted. Subject to the terms of Section 23(C) herein, Landlord shall be responsible at its sole cost and expense (without the right to pass through any such expenses as Operating Expenses) to repair and replace all damage to the Premises caused by Landlord or any of its employees, partners, agents, invitees or contractors.

B. Tenant shall not, without Landlord's prior written consent, which may be given or withheld in Landlord's sole discretion, make any alterations, improvements, additions, utility installations or repairs (hereinafter collectively referred to as "**Alterations**") in, on or about the Premises or the Project. Alterations shall include, but shall not be limited to, the installation or alteration of security or fire protection systems, communication systems, electrical distribution systems, lighting fixtures, telephone or computer system wiring, HVAC and plumbing. The term "Alterations" expressly excludes any improvements made to the Premises by Tenant in accordance with the Work Letter. At the expiration of the Term, Landlord may require the removal of any Alterations installed by Tenant and the restoration of the Premises to their prior condition, at Tenant's expense, if Landlord advised Tenant at the time of its approval of such Alterations that such Alterations would be required to be removed at the end of the Term, and further provided that Tenant shall not have to remove any of the Tenant improvements installed pursuant to the terms of the Work Letter attached hereto as Exhibit B. Should Landlord permit Tenant to make its own Alterations, Tenant shall use only such general contractor, architect or engineer as have been expressly approved by Landlord, which approval shall not be unreasonably withheld, conditioned or delayed, and Landlord may require Tenant to provide to Landlord, at Tenant's sole cost and expense, for any Alterations that will exceed $1,000,000, a payment and performance bond in an amount equal to the estimated cost of such Alterations, to insure Landlord against any liability for mechanic's and materialmen's liens and to insure completion of the work. In addition, Tenant shall pay to Landlord a fee equal to the lower of two percent (2.0%) of the cost of the Alterations or $50,000.00 to compensate Landlord for the overhead and other costs it incurs in reviewing the plans for the Alterations and in monitoring the construction of the Alterations. Should Tenant make any Alterations without the prior approval of Landlord, or use a contractor, architect or engineer not expressly approved by Landlord, Landlord may, at any time during the Term of this Lease, require that Tenant remove all or part of the Alterations and return the Premises to the condition it was in prior to the making of the Alterations. In the event Tenant makes any Alterations, Tenant agrees to obtain or cause its contractor to obtain, prior to the commencement of any work, "builders risk" insurance in a reasonable amount and workers compensation insurance.

C. Any Alterations in or about the Premises that Tenant shall desire to make shall be presented to Landlord in written form, with plans and specifications which are sufficiently detailed to obtain a building permit (to the extent that a building permit is required therefor). If Landlord consents to an Alteration, the consent shall be deemed conditioned upon Tenant acquiring a building permit from the applicable governmental agencies (to the extent that a building permit is required therefor), furnishing a copy thereof to Landlord prior to the commencement of the work, and compliance by Tenant with all conditions of said permit in a prompt and expeditious manner. Tenant shall provide Landlord with as-built plans and specifications for any Alterations made to the Premises.

D. Notwithstanding anything to the contrary contained in this Section 12, for work which (i) will cost less than $50,000.00 on an annual basis, (ii) which does not affect the structure of the Building or any of the Building's systems, including without limitation, the electrical, plumbing, HVAC or mechanical systems, and (iii) which will not be visible from any Common Areas, Tenant shall not be required to obtain the prior written consent of Landlord or to pay any fee for monitoring the construction of any such Alterations, however, Landlord must receive no less than ten (10) business days written notice prior to the commencement of said decorative work and Tenant must otherwise comply with the terms of this Section 12.

13. MECHANICS LIENS: Tenant shall keep the Premises and all parts thereof at all times free of mechanic's liens and any other lien for labor, services, supplies, equipment or material purchased or procured, directly or indirectly, by or for Tenant. Tenant further agrees that Tenant will promptly pay and satisfy all liens of contractors, subcontractors, mechanics, laborers, materialmen, and other items of like character, and will indemnify Landlord against all expenses, costs and charges, including bond premiums for release of liens and attorneys fees and costs reasonably incurred in and about the defense of any suit in discharging the Premises, from any liens, judgments, or encumbrances caused or suffered by Tenant. In the event any such lien shall be made or filed, Tenant shall bond against or discharge the same within sixty (60) days after the same had been made or filed and Tenant has actual notice thereof. The foregoing notwithstanding, in the event Landlord should be in the process of either selling the Premises of refinancing the Premises then Tenant shall bond against or discharge an such lien within ten (10) days after the same had been made or filed and Tenant has actual notice thereof. It is understood and agreed between the parties hereto that the expenses, costs and charges above referred to shall be considered as Rent due and shall be included in any lien for Rent.

The Tenant herein shall not have any authority to create any liens for labor or material on the Landlord's interest in the Premises and all persons contracting with the Tenant for the construction or removal of any facilities or other improvements on or about the Premises, and all materialmen, contractors, mechanics, and laborers are hereby charged with notice that they must look only to the Tenant and to the Tenant's interests in the Premises to secure the payment of any bill for work done or material furnished at the request or instruction of Tenant.

In accordance with Florida Statutes 713.10, Landlord shall have the right to post on the Premises and to file and/or record in the Public Records or court registry, as applicable, notices of non-responsibility and such other notices as Landlord may reasonably deem proper for the protection of Landlord's interest in the Premises. Tenant shall, before the commencement of any work which might result in any lien on the Premises, give Landlord reasonable written notice under the circumstances of its intention to commence said work.

14. SUBORDINATION OF LEASE; ATTORNMENT: This Lease is subject and subordinate to any and all mortgages now or hereafter encumbering the Premises, and to any renewals, extensions and/or modifications thereof, on the condition that Tenant receives a commercially reasonable subordination, non-disturbance and attornment agreement (an "SNDA") from any such lienholders in form and substance reasonably acceptable to Tenant. Tenant agrees to use good faith and commercially reasonable efforts to execute and acknowledge any such SNDA as Landlord reasonably requests (provided same is in form and substance reasonably acceptable to Tenant) within ten (10) business days after Landlord's delivery of the same to Tenant. Tenant's failure to execute the SNDA within ten (10) business days after written demand shall constitute an Event of Default by Tenant hereunder. In the event Landlord's interest in the Premises is transferred by reason of foreclosure or other proceeding for enforcement of any such mortgage, Tenant agrees to attorn to and recognize the rights of the transferee of Landlord's interest in the Premises as if such transferee were the Landlord under this Lease, provided that Tenant's rights and interests under this Lease and its possession of the

Premises will not be disturbed or affected by the succession of such transferee to Landlord's interest in the Building or the Project. This provision shall be self-operative without the execution of any further instruments. At the option of the holder of any such mortgage, upon written notice to Tenant, Tenant will simultaneously give to such holder a copy of any and all default notices to Landlord and such holder shall have the right (but not the obligation) to cure or remedy any default of Landlord during the period that is permitted to Landlord hereunder plus an additional thirty (30) days, and Tenant will accept such curative or remedial action (if any) taken by Landlord's mortgagee with the same effect as if such action had been taken by Landlord. Tenant further agrees to execute any commercially reasonable modification(s) of this Lease requested by any mortgagee if such modification does not increase Tenant's obligations hereunder other than in an immaterial or *de minimis* manner or adversely affect Tenant's rights hereunder.

15. ASSIGNMENT AND SUBLETTING: Tenant shall not, directly or indirectly, assign, transfer, mortgage, pledge or otherwise encumber or dispose of this Lease or sublet the Premises or any part thereof or permit the Premises to be occupied by other persons. Any transfer of the majority control of the stock of Tenant shall be deemed an assignment hereunder, except that the existing stockholders or Tenant may freely transfer stock among themselves, without the consent of Landlord, and further provided that the foregoing portion of this sentence shall not apply to corporations whose stock is traded through a national or regional exchange or over-the-counter market. Any such transfer made in violation of the terms of this Lease shall be null and void and of no force and effect, and shall be deemed an Event of Default on the part of Tenant. Notwithstanding the foregoing:

(a) Tenant shall be entitled to assign this Lease to an Affiliate of Tenant provided that (i) Tenant delivers prior written notice to Landlord, (ii) the assignee executes an assumption of this Lease, (iii) Tenant shall not be released from any and all obligations hereunder and (iv) Guarantor shall not be released from any obligations under the Guaranty;

(b) Tenant shall be entitled to assign this Lease to an unaffiliated entity of Tenant provided that (i) Tenant delivers fifteen (15) days prior written notice to Landlord, (ii) the assignee executes an assumption of this Lease, (iii) Tenant delivers documentation and other evidence reasonably satisfactory to Landlord showing that such assignee's financial net worth is equal to or greater than that of Tenant, (iv) Tenant shall not be released from any and all obligations hereunder and (v) Guarantor shall not be released from any obligations under the Guaranty;

(c) Tenant shall be entitled to assign this Lease to an unaffiliated entity buying all or substantially all of the assets of Tenant provided that (i) Tenant delivers fifteen (15) days prior written notice to Landlord, (ii) the assignee executes an assumption of this Lease, (iii) Tenant delivers documentation reasonably satisfactory to Landlord evidencing such assignee's financial net worth, (iv) Tenant shall not be released from any and all obligations hereunder and (v) Guarantor shall not be released from any obligations under the Guaranty; and

(d) Tenant shall be entitled to sublet portions of the Premises, provided that: (i) Tenant shall remain fully liable for all obligations under this Lease, (ii) Tenant shall give written notice to Landlord of such subletting, (iii) such subtenant shall sublease the Premises subject to the terms and provisions of this Lease and (iv) Guarantor shall remain fully liable for all obligations under the Guaranty.

Notwithstanding the foregoing or anything in this Section to the contrary, Tenant may, without the consent of Landlord, assign or sublet all or any part of the Premises to (i) a subsidiary or Affiliate of Tenant, (ii) any entity that acquires substantially all of the assets or stock of Tenant, (iii) any entity into which Tenant is merged or with which it is consolidated (provided such merger, consolidation or transfer of assets or stock under subsections (ii) and (iii) hereof is not being consummated for the purposes of subverting the intent of this Section 15), (iv) a sublease of any or all of the warehouse space identified as part of the Premises, and/or (v) a transfer of any of the outstanding capital stock of Tenant through an "over the counter" market or any recognized national or overseas securities exchange, or in connection with an initial public offering. For purposes of this Section: (a) "Affiliate" shall mean any person or entity directly or indirectly controlling, controlled by, or under common control with, Tenant, and (b) "control" shall mean the possession, directly or indirectly, of the power to direct or cause the direction of management of that entity, whether through ownership, or by contract or otherwise. Tenant agrees to provide Landlord with at least ten (10) business days prior written notice of a transfer to an Affiliate in accordance with this Section 15. Tenant expressly acknowledges and agrees that no transfer of any interest in this Lease or sublease of the Premises, whether consented to by Landlord or not, shall release Tenant from Tenant's obligations hereunder or alter the primary liability of Tenant to pay the rent and other sums due Landlord hereunder and to perform all other obligations to be performed by Tenant hereunder or release the Guarantor from its obligations under its Guaranty unless otherwise expressly agreed to in writing by Landlord.

16. HOLD HARMLESS:

A. Except to the extent caused by the negligence or willful misconduct of an Indemnified Party and subject to the terms of Section 23(c) of this Lease, Tenant hereby agrees to indemnify, defend and hold harmless Landlord and its employees, partners, agents, contractors, lenders and ground lessors (said persons and entities are hereinafter collectively referred to as the "Indemnified Parties") from and against any and all liability, loss, cost, damage, claims, loss of rents, liens, judgments, penalties, fines, settlement costs, investigation costs, the cost of consultants and experts, attorneys fees, court costs and other legal expenses, insurance policy deductibles and other expenses (hereinafter collectively referred to as "Damages") arising out of or related to an "Indemnified Matter" (as defined below). For purposes of this Section 16, an "Indemnified Matter" shall mean any matter for which one or more of the Indemnified Parties incurs liability or Damages if the liability or Damages arise out of or involve, directly or indirectly, (a) Tenant's or its employees, agents, contractors or invitees (all of said persons or entities are hereinafter collectively referred to as "Tenant Parties") use or occupancy of the Premises or the Project, (b) any act, omission or neglect of a Tenant Party, or (c) any other matters for which Tenant has agreed to indemnify Landlord pursuant to any other provision of this Lease. Tenant's obligations hereunder shall include, but shall not be limited to (f) compensating the Indemnified Parties for Damages arising out of Indemnified Matters within ten (10) days after written demand from an Indemnified Party plus a reasonable period of time for Landlord's

investigation of the claim and (g) providing a defense, with counsel reasonably satisfactory to the Indemnified Party, at Tenant's sole expense, within ten (10) days after written demand from the Indemnified Party, of any claims, action or proceeding arising out of or relating to an Indemnified Matter whether the fees for such counsel arise because the claim is litigated or not, or whether reduced to judgment or whether or not well founded. If Tenant is obligated to compensate an Indemnified Party for Damages arising out of an Indemnified Matter in accordance with the terms of this Section 16, Landlord shall have the immediate and unconditional right, but not the obligation, to in good faith pay the damages and Tenant shall, upon thirty (30) days advance written notice from Landlord, reimburse Landlord for the costs incurred by Landlord. By way of example, and not limitation, Landlord shall have the immediate and unconditional right to cause any damages to the Common Areas, another tenant's premises or to any other part of the Project to be repaired and to compensate other tenants of the Project or other persons or entities for Damages arising out of an Indemnified Matter. This indemnity is intended to apply to the fullest extent permitted by applicable law. Tenant's obligations under this section shall survive the expiration or termination of this Lease unless specifically waived in writing by Landlord after said expiration or termination. Landlord hereby waives its right to recover consequential, special, indirect, exemplary or punitive damages (including but not limited to, lost profits) arising out of an Indemnified Matter or a Tenant default.

B. Tenant expressly acknowledges and agrees and that Landlord shall not be liable to Tenant for any damages, losses or injuries to the persons or property of Tenant which may be caused by the acts, neglect, omissions or faults of any persons, firms or corporations, except when such injury, loss or damage results from the negligence or willful misconduct of Landlord, its agents, invitees or employees. All personal property placed or moved into the Premises shall be at the risk of Tenant or the owner thereof, and Landlord shall not be liable to Tenant for any damage to said personal property, except when such damage results from the gross negligence or willful misconduct of Landlord, its agents, invitees or employees.

C. Except to the extent caused by the negligence or willful misconduct of a Tenant Indemnified Party and subject to the terms of Sections 16(b) and 23(c) of this Lease, Landlord hereby agrees to indemnify, defend and hold harmless Tenant and its employees, agents, and contractors (said persons and entities are hereinafter collectively referred to as the "Tenant Indemnified Parties") from and against any and all Damages that result from a Tenant Indemnified Matter. For purposes of this Section, a "Tenant Indemnified Matter" shall mean any matter for which one or more of the Tenant Indemnified Parties incurs liability or Damages if the liability or Damages arise out of or involve, directly or indirectly, (a) Landlord's or its employees, agents, contractors or invitees (all of said persons or entities are hereinafter collectively referred to as "Landlord Parties") negligence or willful misconduct, and (b) any other matters for which Landlord has agreed to indemnify Tenant pursuant to any other provision of this Lease. Landlord's obligations hereunder shall include, but shall not be limited to (i) compensating the Tenant Indemnified Parties for Damages arising out of Tenant Indemnified Matters within ten (10) days after written demand from a Tenant Indemnified Party plus a reasonable period of time for Landlord's investigation of the claim and (ii) providing a defense, with counsel reasonably satisfactory to the Tenant Indemnified Party, at Landlord's sole expense, within ten (10) days after written demand from the Tenant Indemnified Party, of any claims, action or proceeding arising out of or relating to an Tenant Indemnified Matter. This indemnity is intended to apply to the fullest extent permitted by applicable law. Landlord's obligations under this section shall survive the expiration or termination of this Lease unless specifically waived in writing by Tenant after said expiration or termination. Tenant hereby waives its right to recover consequential, special, indirect, exemplary or punitive damages (including but not limited to, lost profits) arising out of a Tenant Indemnified Matter.

17. CASUALTY LOSS: If the Premises shall be damaged by fire or other casualty and if such damage does not render all or a material portion of the Premises untenantable, then Landlord shall repair and restore the Premises to the extent of "available insurance proceeds". For purposes of this Lease, the term "available insurance proceeds" shall mean the portion of the insurance proceeds paid over to Landlord free and clear of any collection by mortgagees for the value of the damage, attorneys' fees and other reasonable costs of compromise, adjustment, settlement and collection of the insurance proceeds.

If any such damage renders all or a material portion of the Premises untenantable, or if "available insurance proceeds" are not made available to Landlord, then Landlord (a) shall have the right to terminate this Lease within sixty (60) days of the date of such damage, or (b) elect to restore the Premises. In the event Landlord elects not to rebuild, then Tenant shall have the right to terminate the Lease and Rent shall be abated from the date of the casualty. Unless this Lease is terminated as provided in the preceding sentences, Landlord shall proceed promptly to repair and restore (regardless of whether such damage is material) the Premises to substantially the same condition that existed prior to such damage and Tenant's Rent shall be abated from the date of the casualty until completion of the repair and restoration of the Premises. In this regard, Landlord shall commence such repair and/or restoration within ninety (90) days following the date of such damage. In the event Landlord elects to repair and does not complete restoration within six (6) months following receipt of the insurance proceeds or within nine (9) months following the date of such damage (and in either case subject to a Force Majeure Event), then Tenant shall have the option to terminate this Lease by written notice to Landlord given within no later than thirty (30) days following such time period, as applicable.

18. CONDEMNATION: In the event that the Premises or any material part thereof is taken for any public or quasi-public use by condemnation or by right of eminent domain, or purchase in avoidance or settlement of a condemnation or eminent domain proceeding, Landlord and Tenant agree that this Lease shall be canceled, and Rent shall abate as of the date of taking. In the event that a non-material portion of the Premises is taken for any public or quasi-public use by condemnation or by a right of eminent domain, or purchase in avoidance or settlement of a condemnation or eminent domain proceeding, then this Lease and all the covenants, conditions and provisions hereunder shall be and remain in full force and effect as to all the Premises not taken, except that Rent shall be paid in amounts reserved by this Lease to the date of said partial taking, Landlord shall do the work necessary to rebuild the shell portion of the Premises taken as a complete architectural unit and Tenant shall be responsible for any work necessary to rebuild the interior of the Premises for Tenant's Permitted Use , and after such date the Rent for the remainder of the Premises shall be equitably and justly reduced by such amount as may be reasonably determined by Landlord. Any and all condemnation awards shall be the property of the Landlord, except that Tenant shall have standing to seek a separate award or to challenge the taking, provided that such award does not reduce the amount of the award available to Landlord.

19. DEFAULT: If any one or more of the following events (herein sometimes called "Events of Default") shall happen:

(a) if default shall be made in the payment of any Rent or other charges herein reserved upon the date the same become due and payable and such default continues for a period of five (5) days after written notice of such due date (provided however that in no event shall Landlord be obligated to provide written notice more than twice in any twelve (12) month period); or

(b) if default shall be made by Tenant in the performance of or compliance with any of the other covenants, agreements, terms or conditions contained in this Lease (except failure to pay Rent as provided in subparagraph 19(a) above), and such default shall continue for a period of thirty (30) days after written notice thereof from Landlord to Tenant; provided, however, if such default cannot reasonably be cured within thirty (30) days, and Tenant, within said thirty (30) day period, shall have commenced and thereafter continued diligently to prosecute the cure of such default to completion, said default shall not constitute an Event of Default; or

(c) if Tenant shall file a voluntary petition in bankruptcy or shall be adjudicated a bankrupt or insolvent, or shall file any petition or answer seeking any reorganization, arrangement, composition, readjustment, liquidation, wage earner's plan, dissolution or similar relief under the present or any future federal bankruptcy act or any other present or future applicable federal, state or other debtor's relief statute or law, or shall seek or consent to or acquiesce in the appointment of any trustee, receiver or liquidator of Tenant or of all or any substantial part of Tenant's properties or of the Premises; or

(d) if within ninety (90) days after commencement of any proceeding against Tenant seeking any reorganization, arrangement, composition, readjustment, liquidation, dissolution or similar relief under the present or any future federal bankruptcy act or any other present or future applicable federal, state or other debtor's relief statute or law, such proceeding shall not have been dismissed, or stayed on appeal, or if, within ninety (90) days after the appointment, without the consent or acquiescence of Lessee, of any trustee, receiver or liquidator of Lessee or of all or any substantial part of Lessee's properties or of the Premises, such appointment shall not have been vacated or stayed on appeal or otherwise, or if, within ninety (90) days after the expiration of any such stay such appointment shall not have been vacated; or

(e) if the Premises shall be seized under any levy, execution, attachment or other process of court and the same shall not be promptly vacated or stayed on appeal or otherwise, or if the Tenant's interest in the Premises is sold by judicial sale and the sale is not promptly vacated or stayed on appeal or otherwise; or

(f) if Tenant should assign this Lease or sublet the Premises in violation of paragraph 15 of this Lease, or

(g) if Tenant should vacate, abandon, or desert the Premises, subject to closures for casualty, condemnation, repair and maintenance by Landlord or Tenant or a Force Majeure Event, and provided that Tenant shall not be in default hereunder so long as Tenant continues to pay Rent as provided for under the Lease and otherwise complies with the insurance, maintenance and other provisions of the Lease.

then in any such event Landlord may at any time thereafter terminate this Lease and retake possession, declare the balance of the entire Rent for the entire Term of this Lease to be immediately due and payable, in which event Landlord may then proceed to collect all of the unpaid Rent called for by this Lease by distress or otherwise), or pursue any other remedy afforded by law or equity, provided that such default and all other defaults at the time existing have not been fully cured, and all expenses and costs incurred by the Landlord, including reasonable attorneys' fees and court costs, at trial and all appellate levels, in connection with enforcing this Lease, shall not have been fully paid. Nothing herein contained shall be construed as precluding the Landlord from having such remedy as may be and become necessary in order to preserve the Landlord's right or the interest of the Landlord in the Premises and in this Lease, even before the expiration of the grace or notice periods provided for in this Lease, if under particular circumstances then existing the allowance of such grace or the giving of such notice will prejudice or will endanger the rights and estate of the Landlord in this Lease or in the Premises. All rights and remedies granted in this Lease to Landlord or available at law or equity shall be cumulative and not mutually exclusive. Landlord will use commercially reasonable efforts to mitigate its damages hereunder and to relet the Premises.

20. WAIVER OF LANDLORD'S LIEN. Landlord hereby waives any statutory liens and any rights of distress with respect to the personal property (trade fixtures, equipment and merchandise) of Tenant from time to time located within the Premises ("**Tenant's Property**"). This Lease does not grant a contractual lien or any other security interest to Landlord or in favor of Landlord with respect to Tenant's Property. Any language in the Lease granting Landlord a lien on Tenant's Property is hereby deleted.

21. WAIVER OF DEFAULT: Failure of Landlord to declare any default immediately upon occurrence thereof, or delay in taking any action in connection therewith, shall not waive such default, but Landlord shall have the right to declare any such default at any time and take such action as might be lawful or authorized hereunder, in law and/or in equity.

No waiver of any term, provision, condition or covenant of this Lease by Landlord shall be deemed to imply or constitute a further waiver by Landlord of any other term, provision, condition or covenant of this Lease and no acceptance of Rent or other payment shall be deemed a waiver of any default hereunder.

22. RIGHT OF ENTRY: Upon Forty Eight (48) hours prior verbal notice, Landlord, or any of its agents (provided said agents do not compete in any manner or engage in any business activity that competes with Tenant), shall have the right to enter the Premises during all reasonable business hours to examine the same, or to otherwise exhibit the Premises to third parties, including, without limitation, mortgagees, insurance examiners and building inspectors (provided that the Premises shall be exhibited to prospective tenants only during the last year of the Term). Said right of entry shall likewise exist for the purpose of removing placards, signs,

fixtures, alterations, or additions which do not conform to this Lease. Landlord shall not, except in the event of an emergency, be allowed access to the area designated by Tenant as the "clean rooms" without being accompanied by an authorized representative of Tenant, and Landlord shall comply with all of Tenant's commercially reasonable rules and regulations regarding access to the "clean rooms". Landlord shall use all commercially reasonable efforts to minimize interference with Tenant's operations during any such visits. Notwithstanding anything to the contrary contained in this Lease, in the event of an emergency or to conduct an Emergency Repair, Landlord may enter the Premises or any portion thereof without having to provide any prior advance notice to Tenant.

23. INSURANCE:

A. Tenant's Insurance: Tenant shall maintain at its expense throughout the Term of this Lease the following insurance coverages:

(i) commercial general liability, insurance for bodily injury, death and property damage to protect both Landlord and Tenant against damage, costs and attorneys' fees arising out of accidents occurring on or about the Premises with combined single limit liability coverage of not less than $5,000,000.00 for bodily injury and property damage coverage of not less than $2,000,000.00;

(ii) fire and extended casualty insurance with sufficient coverage (as reasonably determined by Landlord and Landlord's mortgagee) for full replacement costs of all of Tenant's improvements to the Premises (including the Tenant Improvements as defined in the Work Letter), and all of Tenant's fixtures, equipment, personal property and inventory;

(iii) appropriate workmen's compensation and any and all other insurance required by law; and

(iv) Landlord reserves the right to require that Tenant obtain additional types of insurance coverage or to increase the amount of coverage for any policy required to be obtained by Tenant hereunder so long as such additional insurance or increased amount is similar to that which other prudent landlords of buildings of like age, class and character in the Miami-Dade market require from their tenants.

All insurance shall be written by a company or companies qualified to do business in Florida and reasonably acceptable to Landlord and Landlord's mortgagee. A certificate or duplicate policies showing such insurance in force shall be delivered to Landlord prior to Tenant taking possession of the Premises, and such insurance and updated certificates or renewed policies shall be maintained with Landlord throughout the Term of this Lease.

All policies of insurance required by this sub-paragraph 23(A) shall: (i) indicate Tenant, Landlord and Landlord's mortgagee, if any, as named or additional insured; (ii) provide that no cancellation or termination shall be effective until at least thirty (30) days after written notice to the additional and named insured.

B. Landlord's Insurance: Landlord shall maintain at its expense (subject to the reimbursement provisions of Section 4(b) above) the following insurance coverages:

(i) comprehensive general and public liability, including contractual liability, insurance for bodily injury, death and property damage to protect both Landlord and Tenant against damage, costs and attorneys' fees arising out of accidents of any kind occurring on or about the Premises with combined single limit liability coverage of not less than $5,000,000.00 and property damage coverage of not less than $5,000,000.00;

(ii) fire and extended casualty insurance with sufficient coverage for full replacement cost of the Premises, the Building, all structures and all built in fixtures on the Premises;

(iii) complete rent loss insurance in favor of Landlord covering a period of one (1) year; and

(iv) Landlord reserves the right obtain additional types of insurance coverage or to increase the amount of coverage for any policy to be obtained hereunder so long as such additional insurance or increased amount is similar to that which other prudent landlords of buildings of like age, class and character in the Miami-Dade market require.

C. Waiver of Subrogation. All provisions of this Lease to the contrary notwithstanding, Landlord waives any and all rights of recovery against Tenant, and Tenant's employees, agents and contractors for or arising out of damage to, or destruction of, the Project, the Premises, and Landlord's personal property to the extent that such damage or destruction is covered by Landlord's insurance policies then in effect or the insurance policies Landlord is required to obtain by Section 23B (whether or not the insurance Landlord is required to obtain by Section 23B is then in force and effect), whichever is broader. Landlord's waiver shall not be limited by the amount of insurance then carried by Landlord or the deductibles applicable thereto.

Tenant waives any and all rights of recovery against Landlord, Landlord's employees, agents and contractors for loss or damage to the Premises, the Project and Tenant's personal property if such liability or damage is covered by Tenant's insurance policies then in force or the insurance policies Tenant is required to obtain by Section 23A (whether or not the insurance Tenant is required to obtain by Section 23A is then in force and effect), whichever is broader. Tenant's waiver shall not be limited by the amount of insurance then carried by Tenant or the deductibles applicable thereto.

Each party shall cause the property insurance policies it obtains in accordance with sections 23A and 23B to provide that the insurance company waives all right of recovery by subrogation against the other party in connection with any liability or damage covered by such insurance policies.

24. NOTICE: Any notice to be given Landlord as provided for in this Lease shall be in writing and shall be sent to Landlord by United States certified mail, postage prepaid, return receipt requested, addressed to Landlord at Landlord's office at the address set forth on page 1 hereof, or hand delivered to Landlord at such office, or delivered by a nationally recognized courier for overnight delivery. Any notice to be given Tenant under the terms of this Lease (other than as permitted under the terms of Section 22), shall be in writing and shall be sent by United States certified mail, postage prepaid, return receipt requested, or hand delivered to the Tenant at the Premises, Attention: David McIntyre (except that prior to commencement of the Rent Commencement Date, notices to Tenant shall be sent to the address set forth on page 1 thereof), with a copy to Akerman Senterfitt, One Southeast Third Avenue, Suite 2500, Miami, Florida 33131, Attention: Carol S. Faber, Esq. Either party, from time to time, by such notice, may specify another address to which subsequent notice shall be sent. Any notice given by certified mail shall be deemed given 3 days following the date of mailing and any notice given by overnight courier shall be deemed given when delivered.

25. CONDITION OF PREMISES ON TERMINATION OF LEASE.

A. Tenant agrees to surrender to Landlord, at the end of the Term of this Lease and/or upon any cancellation or early termination of this Lease, the Premises in as good condition as the Premises were at the beginning of the Term of this Lease, ordinary wear, tear, casualty and Landlord's maintenance and repair obligations excepted.

B. Prior to the expiration of this Lease (or within 30 days after any earlier termination), Tenant shall clean and otherwise decommission all interior surfaces (including floors, walls, ceilings, and counters), process piping, process supply lines, process waste lines and process plumbing in the Premises, and all exhaust or other ductwork in the Premises, in each case which has carried or released or been exposed to any Hazardous Materials (other than ordinary and customary office supplies and cleaning fluids) from the operations of Tenant or any person claiming by or through Tenant, and shall otherwise clean the Premises so that:

(i) the Hazardous Materials from Tenant's (or any person claiming by or through Tenant's) operations have been removed as necessary so that the interior surfaces (including floors, walls, ceilings, and counters), process piping, process supply lines, process waste lines and process plumbing, and all such exhaust or other ductwork, may be reused by a subsequent tenant or disposed of in compliance with applicable Environmental Laws without taking any special precautions for Hazardous Materials, without incurring special costs or undertaking special procedures for demolition, disposal, investigation, assessment, cleaning or removal of Hazardous Materials and without incurring regulatory compliance requirements or giving notice in connection with Hazardous Materials; and

(ii) the Premises may be reoccupied for office, laboratory or research and development use, demolished or renovated without taking any special precautions for Hazardous Materials, without incurring special costs or undertaking special procedures for disposal, investigation, assessment, cleaning or removal of Hazardous Materials and without incurring regulatory requirements or giving notice in connection with Hazardous Materials.

Further, for purposes of clauses (i) and (ii): (a) materials previously or hereafter generated from operations shall not be deemed part of the Premises, and (b) "special costs" or "special procedures" shall mean costs or procedures, as the case may be, that would not be incurred but for the nature of the Hazardous Materials as Hazardous Materials instead of non-Hazardous Materials. Prior to the expiration of this Lease (or within 30 days after any earlier termination), Tenant, at Tenant's expense, shall obtain for Landlord a report addressed to Landlord (and, at Tenant's election, Tenant) by a reputable licensed environmental engineer that is designated by Tenant and acceptable to Landlord in Landlord's reasonable discretion, which report shall be based on the environmental engineer's inspection of the Premises and shall confirm that Tenant has complied with the requirements of this Section 25.B. The report shall include reasonable detail concerning the clean-up location, the tests run and the analytic results.

C. If Tenant fails to perform its obligations under Section 25.B within ten (10) business days after the expiration or any earlier termination of the Term of this of the Lease, without limiting any other right or remedy, Landlord may, on five (5) business days prior written notice to Tenant perform such obligations at Tenant's expense, and Tenant shall promptly reimburse Landlord upon demand for all out-of-pocket costs and expenses incurred by Landlord in connection with such work. In addition, any such reimbursement shall include a ten percent (10%) administrative fee (but in no event less than $1,000) to cover Landlord's overhead in undertaking such work. The reimbursement and administrative fee shall be Additional Rent. Tenant's obligations under this Section 25 of this Lease shall survive the expiration or termination of this Lease.

26. HOLDING OVER: Tenant agrees that if Tenant does not surrender the Premises to Landlord at the end of the Term of this Lease in the condition as required under the Lease, then Tenant will pay to Landlord: (i) One Hundred Twenty Five percent (125%) of the Rent paid by Tenant for the last full month of the Term for the first month or portion thereof that Tenant holds over; (ii) One Hundred Fifty percent (150%) of the Rent paid by Tenant for the last full month of the Term for the second month or portion thereof that Tenant holds over; and (iii) beginning with the third month and continuing until Tenant surrenders to Landlord possession of the Premises, Two Hundred percent (200%) of the amount of the Rent paid by Tenant for the last full month of the Term for each month or portion thereof that Tenant holds over. At all times, Tenant will indemnify and save Landlord harmless from and against all claims made by any succeeding tenant of the Premises against Landlord on account of delay of Landlord in delivering possession of the Premises to the succeeding tenant so far as such delay is occasioned by failure of Tenant to so surrender the Premises in accordance herewith or otherwise.

No receipt of money by Landlord from Tenant after termination of this Lease or the service of any notice of commencement of any suit or final judgment for possession shall reinstate, continue or extend the Term of this Lease or affect any such notice, demand, suit or judgment.

No act or thing done by Landlord or its agents during the Term hereby granted shall be deemed an acceptance of a surrender of the Premises, and no agreement to accept a surrender of the Premises shall be valid unless it be made in writing and signed by a duly authorized officer or agent of Landlord.

27. ENVIRONMENTAL INDEMNITY:

Tenant shall indemnify, defend with counsel reasonably acceptable to the Landlord, and hold Landlord, Landlord's managing agent and any mortgagee of the Premises, fully harmless from and against any and all liability, loss, suits, claims, actions, causes of action, proceedings, demands, costs, penalties, damages, fines and expenses, including, without limitation, attorneys fees, consultants' fees, laboratory fees and clean up costs, and the costs and expenses of investigating and defending any claims or proceedings, resulting from, or attributable to (i) the presence of any Hazardous Materials on the Land or the Premises arising from the action or negligence of Tenant and/or the Tenant Responsible Parties, or arising out of the generation, storage, treatment, handling, transportation, disposal or release by Tenant and/or the Tenant Responsible Parties of any Hazardous Materials at or near the Land or the Premises in violation of Environmental Laws during the Term of the lease, (ii) any violation(s) by Tenant and/or the Tenant Responsible Parties of any Environmental Laws during the Term of the Lease, and (iii) any breach by Tenant and/or the Tenant Responsible Parties of the obligations set forth in Section 11(B)-(D) of this Lease. This hold harmless and indemnity shall survive the expiration or earlier termination of this Lease.

Notwithstanding the foregoing, Tenant shall not be liable to Landlord hereunder for any contamination, claim of contamination, injury, loss or damage arising in connection with Hazardous Materials to the extent the same is the result of (A) Hazardous Materials existing in the Premises or on or under or near the Land prior to the date hereof (including, without limitation, any Hazardous Materials related to the Disclosed Environmental Matter), (B) migration of Hazardous Materials from any site onto or under the Land not caused by Tenant or any Tenant Responsible Parties, (C) the use of any Hazardous Materials at the Project by Landlord, any other tenant or occupant, or any so-called "midnight dumpers," (D) any actions or releases by Landlord, Landlord's consultants or any other parties under Landlord's responsibility, or (E) the use by any party other than Tenant or any Tenant Responsible Parties of Hazardous Materials at the Premises or the Land after the date upon which Tenant has completely vacated the same, including removal of all of its property (to the extent permitted herein) and Hazardous Materials in compliance with the terms of this Lease.

28. TRIAL BY JURY: It is mutually agreed by and between Landlord and Tenant that the respective parties hereto shall and they hereby do waive trial by jury in any action, proceeding or counterclaim brought by either of the parties hereto against the other on any matters arising out of or in any way connected with this Lease, the relationship of Landlord and Tenant, and Tenant's use or occupancy of the Premises. Tenant further agrees that the provisions for payment of Rent herein are independent covenants of Tenant and Tenant shall not interpose any counterclaim or counterclaims in a summary proceeding or in any action based upon non-payment of Rent or any other payment required of Tenant hereunder.

29. INVALIDITY OF PROVISION: If any term or provision, of this Lease or the application thereof to any person or circumstance shall, to any extent, be invalid or unenforceable, the remainder of this Lease or the application of such term or provision, to persons or circumstances other than those as to which it is held invalid or unenforceable shall not be affected thereby and each term and provision of this Lease shall be valid and be enforceable to the fullest extent permitted by law. This Lease shall be construed in accordance with the laws of the State of Florida.

30. TIME OF ESSENCE: It is understood and agreed between the parties hereto that time is of the essence of all the terms and provisions of this Lease.

31. SUCCESSORS AND ASSIGNS: All terms and provisions of this Lease to be observed and performed by Tenant shall be applicable to and binding upon Tenant's respective heirs, personal representatives, successors and assigns, subject, however, to the restrictions as to assignment and subletting by Tenant as provided herein. All expressed covenants of this Lease shall be deemed to be covenants running with the land. All terms and provisions of this Lease to be observed and performed by Landlord shall be applicable to and binding upon Landlord's respective heirs, personal representatives, successors and assigns.

32. ATTORNEYS FEES: If either party defaults in the performance of any of the terms or provisions of this Lease and by reason thereof the other party employs the services of an attorney to enforce performance of the covenants, or to perform any service based upon defaults, then in any of said events the prevailing party shall be entitled to receive from the other party reasonable attorneys fees and all expenses and costs incurred by the prevailing party pertaining thereto (including costs and fees relating to any appeal) and in enforcement of any remedy.

33. PROHIBITION AGAINST RECORDING. Neither this Lease, nor any memorandum, affidavit or other writing with respect thereto, shall be recorded by Tenant or by anyone acting through, under or on behalf of Tenant except that Tenant shall be permitted to record a Memorandum of Lease in the form attached as Schedule B hereto.

34. MISCELLANEOUS: The terms Landlord and Tenant as herein contained shall include singular and/or plural, masculine, feminine and/or neuter, heirs, successors, personal representatives and/or assigns wherever the context so requires or admits. The "Landlord" shall be the owner of the Premises from time to time, and upon any sale of the Premises by the present owner, the new owner shall upon acceptance of a deed of conveyance become bound and liable as Landlord under all of the terms and provisions hereunder, (including any obligation to return the Security Deposit) and the former owner shall automatically be released from all obligations to the Tenant hereunder. The terms and provisions of this Lease are expressed in the total language of this Lease and the paragraph headings are solely for the convenience of the reader and are not intended to be all inclusive and shall not be deemed to limit or expand any of the provisions of this Lease. Any formally executed addendum or rider to or modification of this Lease shall be expressly deemed incorporated by reference herein unless a contrary intention is clearly stated therein. All exhibits and riders attached to this Lease are hereby incorporated in and made a part hereof. Nothing in this Lease shall be deemed to create a partnership or joint venture between Landlord and Tenant, the parties intending their relationship hereunder to be solely that of Landlord and Tenant. Fax signatures hereto shall be as valid and binding as an original; provided however, that without limiting the foregoing, upon the request of either party hereto, original signatures shall be provided. If requested by Tenant, Landlord shall use good faith commercially reasonable efforts to cooperate with Tenant (at no cost to Landlord) in Tenant's application for economic incentives relating to this Lease from any governmental or quasi-governmental authority.

35. BROKERAGE: Tenant and Landlord each represent and warrant to the other that neither has had any dealings or entered into any agreements with any person, entity, broker or finder other than Jones Lang LaSalle Brokerage, Inc., CBRE, The Katsikos Group and Easton & Associates (collectively the "**Disclosed Brokers**"), in connection with the negotiation of this Lease, and no brokers, persons, or entities other than the Disclosed Brokers are entitled to any commission or finder's fee in connection with the negotiation of this Lease. Tenant and Landlord each agree to indemnify, defend and hold the other harmless from and against any claims, damages, costs, expenses, attorneys' fees or liability for compensation or charges which may be claimed by any such unnamed broker, finder or other similar party by reason of any dealings, actions or agreements of the indemnifying party. Landlord shall pay all commissions due to the Disclosed Brokers pursuant to a separate agreement.

36. RADON GAS: RADON IS A NATURALLY OCCURRING RADIOACTIVE GAS THAT, WHEN IT HAS ACCUMULATED IN A BUILDING IN SUFFICIENT QUANTITIES, MAY PRESENT HEALTH RISKS TO PERSONS WHO ARE EXPOSED TO IT OVER TIME. LEVELS OF RADON THAT EXCEED FEDERAL AND STATE GUIDELINES HAVE BEEN FOUND IN BUILDINGS IN FLORIDA. ADDITIONAL INFORMATION REGARDING RADON TESTING MAY BE OBTAINED FROM YOU COUNTY PUBLIC HEALTH UNIT. [NOTE: THIS PARAGRAPH IS PROVIDED FOR INFORMATION PURPOSES PURSUANT TO SECTION 404.056(8), FLORIDA STATUTES (1988).]

37. TRIPLE NET LEASE: Landlord and Tenant acknowledge and agree that this Lease is a triple net lease. In this regard, Tenant shall be responsible and shall pay any and all costs, expenses, fees, assessments and charges of any nature or kind whatsoever relating to the Premises or Tenant's use and occupation of the Premises throughout the Term from and after the Commencement Date except as otherwise set forth in this Lease.

38. CONDITION PRECEDENT. Tenant acknowledges and agrees that Landlord is not yet the fee simple owner of the Premises and is under contract to purchase the Premises pursuant to the terms of that certain Contract For Purchase and Sale of Real Property dated November 2, 2010, as amended (the "**Purchase Contract**"). As a result, it shall be a condition precedent to Landlord's and Tenant's obligations hereunder that Landlord actually close upon title to the Premises under the Purchase Contract (the "**Closing**"). In the event that Landlord does not effect a Closing under the Purchase Contract, as the same may be amended or extended, for any reason whatsoever, then this Lease shall automatically terminate, whereupon both parties shall be released from all further obligations hereunder. Landlord shall immediately notify Tenant in writing whether the Closing has occurred or has not occurred. In the event that the Closing occurs and Landlord notifies Tenant in writing of such fact, the date of such notice from Landlord to Tenant shall be defined as the "Delivery Date" under this Lease. Notwithstanding anything to the contrary contained in this Section 38, in the event that the Closing has not occurred by January 31, 2011, this Lease shall automatically terminate, whereupon both parties shall be released from all further obligations hereunder.

39. LANDLORD'S LIABILITY: Tenant acknowledges that Landlord shall have the right to transfer all or any portion of its interest in the Project and to assign this Lease to the transferee. Tenant agrees that in the event of such a transfer Landlord shall automatically be released from all liability under this Lease related to all matters following the date of such transfer; and Tenant hereby agrees to look solely to Landlord's transferee for the performance of all prospective obligations of Landlord hereunder after the date of the transfer. Upon such a transfer, Landlord shall, at its option, return Tenant's Security Deposit to Tenant or transfer Tenant's Security Deposit to Landlord's transferee and, in either event, Landlord shall have no further liability to Tenant for the return of its Security Deposit. Subject to the rights of any lender holding a mortgage or deed of trust encumbering all or part of the Building, Tenant agrees to look solely to Landlord's equity interest in the Building (including rents, proceeds from the sale of any interest therein, insurance proceeds and condemnation proceeds) for the collection of any judgment requiring the payment of money by Landlord arising out of (a) Landlord's failure to perform its obligations under this Lease or (b) the negligence or willful misconduct of Landlord, its partners, employees and agents. No other property or assets of Landlord shall be subject to levy, execution or other enforcement procedure for the satisfaction of any judgment or writ obtained by Tenant against Landlord. No partner, employee or agent of Landlord shall be personally liable for the performance of Landlord's obligations hereunder or be named as a party in any lawsuit arising out of or related to, directly or indirectly, this Lease and the obligations of Landlord hereunder. The obligations under this Lease do not constitute personal obligations of the individual partners of Landlord, if any, and Tenant shall not seek recourse against the individual partners of Landlord or their assets.

40. ESTOPPEL CERTIFICATE.

A. Tenant shall from time to time upon not less than ten (10) business days prior written notice from Landlord execute, acknowledge and deliver to Landlord a statement in writing certifying the following: (a) that this Lease is unmodified and in full force and effect (or, if modified, stating the nature of such modification and certifying that this Lease, as so modified, is in full force and effect) (b) the date to which the Base Rent and other charges are paid in advance and the amounts so payable, (c) that there are not, to Tenant's knowledge, any uncured defaults or unfulfilled obligations on the part of Landlord, or specifying such defaults or unfulfilled obligations, if any are claimed, (d) that all tenant improvements to be constructed by Landlord, if any, have been completed in accordance with Landlord's obligations (e) that Tenant has taken possession of the Premises and (f) such other information as Landlord may reasonably request. Any such statement may be conclusively relied upon by any prospective purchaser or encumbrancer of the Building or the Project.

B. The failure of Tenant to deliver such statement within such time shall be conclusive upon Tenant that (a) this Lease is in full force and effect, without modification except as may be represented by Landlord, (b) there are no uncured defaults in Landlord's performance, (c) not more than one month's Base Rent has been paid in advance, (d) all tenant improvements to be constructed by Landlord, if any, have been completed in accordance with Landlord's obligations and (e) Tenant has taken possession of the Premises.

C. Landlord shall from time to time upon not less than ten (10) business days prior written notice from Tenant execute, acknowledge and deliver to Tenant an estoppel statement in the form attached as Exhibit C hereto. Any such statement may be conclusively relied upon by any prospective purchaser or lender of Tenant.

D. The failure of Landlord to deliver such statement within such time shall be conclusive upon Landlord that (a) this Lease is in full force and effect, without modification except as may be represented by Tenant, (b) there are no uncured defaults in Tenant's performance, (c) all tenant improvements to be constructed by Tenant have been completed in accordance with Tenant's obligations and (e) Tenant has taken possession of the Premises.

41. TENANT IMPROVEMENTS. Except as expressly set forth in the Work Letter attached as Exhibit B hereto and made a part hereof, it is specifically understood and agreed that Landlord has no obligation and has made no promises to alter, remodel, improve, renovate, repair or decorate the Premises, the Project, or any part thereof, or to provide any allowance for such purposes, and that no representations respecting the condition of the Premises or the Project have been made by Landlord to Tenant except as otherwise expressly set forth in this Lease.

42. ENTIRE AGREEMENT: This Lease contains the entire agreement between the parties hereto and all previous negotiations leading thereto, and the Lease may be modified only by an agreement in writing signed and sealed by Landlord and Tenant. No surrender of the Premises shall be valid unless accepted by Landlord in writing (other than surrender of the Premises on the Expiration Date). Tenant acknowledges and agrees that Tenant has not relied upon any statement, representation, prior written or prior or contemporaneous oral promises, agreements or warranties except such as are expressed herein.

43. ACCESS. Tenant shall be allowed access to and use of the Premises 24 hours per day, 7 days per week.

44. TENANT'S REMEDIES FOR LANDLORD DEFAULT. Other than with respect to Landlord's obligations to comply with those certain specified time frames under Section 2 of this Lease and under the Work Letter attached hereto as Exhibit B, Landlord shall not be in default under this Lease unless Landlord fails to perform obligations required of Landlord within thirty (30) days after written notice by Tenant to Landlord and to the holder of any mortgage or deed of trust encumbering the Premises or the Project whose name and address shall have theretofore been furnished to Tenant in writing, specifying wherein Landlord has failed to perform such obligation; provided, however, that if the nature of Landlord's obligation is such that more than thirty (30) days are required for its cure, then Landlord shall not be in default if Landlord commences performance within such thirty (30) day period and thereafter diligently pursues the same to completion.

Notwithstanding the foregoing, if Landlord's obligation relates to a repair or maintenance obligation under this Lease, and the nature of the repair or maintenance is such that failure to make such repair or maintenance immediately would be life threatening or where there is imminent danger to Tenant's property or there is a possibility that a failure to take immediate action could cause a material disruption in Tenant's normal and customary business activities ("**Emergency Repair**") then Tenant shall notify Landlord by telephone of the need to make such Emergency Repair and if Tenant is unable to contact Landlord or Landlord is not able to take immediate action, then Tenant shall have the right to make such repairs or maintenance. If the repair or maintenance made by Tenant is of the type that Landlord is not permitted to pass through the cost of the same to the Tenant in accordance with the terms of Section 12A. of this Lease, Landlord shall, within fifteen (15) days following receipt of Tenant's request for reimbursement (accompanied by bills or receipts evidencing such costs), reimburse Tenant for its cost to make such repair or maintenance, and Tenant shall have the right to deduct such amounts from its rental obligations hereunder if Landlord fails to so reimburse Tenant within said time period.

Furthermore, if Landlord fails to make repairs or maintenance that Landlord is obligated to make in accordance with the terms of this Lease after the expiration of the applicable notice and cure period and subject to Force Majeure **(**but any delay due to a Force Majeure Event shall be taken into account for only up to forty five (45) days)**,** and Tenant, using a commercially reasonable standard for conduct, determines that the failure to make such repairs or maintenance substantially interferes with its ability to conduct business from the Premises, then Tenant shall receive an equitable abatement of Rent on a per diem basis based upon the portion or all of the Premises that is unusable by Tenant for the number of days in the period commencing with the day that Landlord's notice and cure periods have expired until such time as the repairs or maintenance are made and Tenant can conduct its business in the entire Premises**.** Tenant shall have the right to make such repairs or maintenance if Landlord is not taking action or proceeding with due diligence to complete same. If the repair or maintenance made by Tenant is of the type that Landlord is not permitted to pass through the cost of the same to Tenant in accordance with the terms of Section 12A. of this Lease, Landlord shall, within fifteen (15) days following receipt of Tenant's request for reimbursement (accompanied by bills or receipts evidencing such costs), reimburse Tenant for its cost to make such repair or maintenance. In the event that Tenant obtains a final non-appealable judgment against Landlord because Landlord has failed to reimburse Tenant for its costs to make repairs or maintenance in accordance with this Section 44, Tenant shall be permitted to deduct the amount of said judgment from the Rent coming due under this Lease.

In no event shall Tenant have the right to terminate this Lease as a result of Landlord's default, and Tenant's remedies shall be limited to damages and/or an injunction or as otherwise provided in this Section. Tenant hereby waives its right to recover consequential damages (including, but not limited to, lost profits) or punitive damages arising out of a Landlord default. This Lease and the obligations of Tenant hereunder shall not be affected or impaired because Landlord is unable to fulfill any of its obligations hereunder or is delayed in doing so, if such inability or delay is caused by reason of a Force Majeure Event, and the time for Landlord's performance shall be extended for the period of any such delay. Any claim, demand, right or defense by Tenant that arises out of this Lease or the negotiations which preceded this Lease (other than a claim arising out of Landlord's introduction of any Hazardous Materials on or about the Premises or out of the Disclosed Environmental Matter) shall be barred unless Tenant commences an action thereon, or interposes a defense by reason thereof, within one (1) year after the date that Tenant becomes aware (or reasonably should have become aware) of the inaction, omission, event or action that gave rise to such claim, demand, right or defense. Any claim, demand, right or defense by Landlord that arises out of this Lease or the negotiations which preceded this Lease, other than a claim related to a Tenant's Release, shall be barred unless Landlord commences an action thereon, or interposes a defense by reason thereof, within one (1) year after the date that Landlord becomes aware (or reasonably should have become aware) of the inaction, omission, event or action that gave rise to such claim, demand, right or defense.

45. PARKING. Parking areas shall be provided at no additional cost to Tenant. During the Term of the Lease, Tenant shall be entitled to 252 non-reserved parking spaces (the "**Parking Spaces**") in the parking area identified on Exhibit A-2 (the "**Parking Area**")

46. COMMON AREAS. At all times during the Term, and subject to Landlord's right to pass through such costs and expenses as an Operating Expense in accordance with Section 4.B. of this Lease, Landlord will maintain the Project, including the Common Areas and all mechanical and lighting equipment and drainage facilities thereon, in first class order, condition and repair and in compliance with all Applicable Laws and will keep the Common Areas clean and free from rubbish, and cause the Common Areas to be well lit during at least such hours as Tenant is operating its business. Landlord will maintain and repaint any directional signs, markers and parking space lines as often as necessary. Landlord shall use reasonable efforts minimize disruption to Tenant's operations in the Premises during the performance of maintenance to the Common Areas. Landlord will not cause or permit any material change in size, location or configuration of the curb cuts (points of access), driveways or service drives shown on Exhibit A-1 nor construct any obstructions which will have an adverse affect on access to the Premises or the Common Areas unless required to do so by Applicable Laws.

47. LANDLORD'S REPRESENTATIONS AND WARRANTIES.

(a) Landlord is the sole fee simple owner of the Land, the Building and the Project and none of the matters of record prohibits the operation of Tenant's Permitted Use of the Premises.

(b) Notwithstanding anything to the contrary set forth in this Lease, in undertaking its maintenance and repair and service obligations and rights of entry and alteration and other rights hereunder by Landlord and/or others, Landlord shall make reasonable efforts not to unreasonably interfere with the conduct of Tenant's business, access to the Premises or any parking rights of Tenant hereunder, and in the undertaking and exercise of such obligations and rights, Tenant's parking and access to and use of the Premises shall not be materially decreased or diminished or unreasonably interfered with.

(c) Landlord represents, warrants and covenants that it is now in a solvent condition and that no bankruptcy or insolvency proceedings are pending or contemplated by or against Landlord. Each of the persons executing this Lease on behalf of Landlord represents and warrants that Landlord is duly organized and existing, is qualified to do business in the state in which the Premises is located, has full right and authority to enter into this Lease, that the persons signing on behalf of Landlord are authorized to do so and that the terms, conditions and covenants in this Lease are enforceable against Landlord.

(d) As of the date of this Lease, Landlord is not a party to any agreement or litigation which could adversely affect the ability of Landlord to perform its obligations under this Lease or which would constitute a default on the part of Landlord under this Lease.

48. TENANT'S REPRESENTATIONS AND WARRANTIES

Tenant represents, warrants and covenants that it is now in a solvent condition and that no bankruptcy or insolvency proceedings are pending or contemplated by or against Tenant. Each of the persons executing this Lease on behalf of Tenant represents and warrants that Tenant is duly organized and existing, is qualified to do business in the state in which the Premises is located, has full right and authority to enter into this Lease, that the persons signing on behalf of Tenant are authorized to do so and that the terms, conditions and covenants in this Lease are enforceable against Tenant.

49. LEASE OF PERSONAL PROPERTY. During the Term of this Lease, Tenant shall be entitled to use the fixtures, trade fixtures, equipment, machinery, furnishings, appliances, and items of personal property owned by Landlord and located in the Premises as the same will be identified in a list to created by Landlord and Tenant (the "**FF&E**") at no additional cost or expense. Landlord makes no representation or warranty about the quality and/or condition of the FF&E and Tenant shall be solely responsible for maintaining, repairing and replacing the FF&E during the Term of this Lease. Tenant agrees to surrender to Landlord, at the end of the Term of this Lease and/or upon any cancellation or early termination of this Lease, the FF&E in as good condition as the FF&E was in at the beginning of the Term of this Lease, ordinary wear, tear and casualty excepted and otherwise in accordance with the terms of Section 25 of this Lease. The parties acknowledge and agree that the Tenant's Property is excepted from the provisions of this Section, and that Tenant shall have the right to remove the Tenant's Property from the Premises at the end of the Term and/or upon the cancellation or early termination of this Lease.

50. NON-RECOURSE. Notwithstanding anything to the contrary in this Lease, in the event of any controversy or claim arising out of or relating to this Lease, the breach hereof, or the transactions contemplated hereby, Landlord acknowledges and agrees that it shall look solely to the assets of Tenant and shall have no recourse against any other party, including, without limitation, any partner, officer, principal, director, employee, agent or affiliate of Tenant or its affiliates or any shareholder, partner, officer, principal, director, employee, agent or affiliate of any of the foregoing.

51. SIGNAGE. Tenant shall have the right to install signs on all sides of the exterior walls of the Premises and on all exterior doors, including dock doors, to the Premises and on any monument sign that may be constructed by Landlord at the Premises or the Project, in compliance with Applicable Laws and with Landlord's prior written approval with respect to location, design, installation method and aesthetics (which approval may be withheld by Landlord in its reasonable discretion). Prior to Tenant's commencing installation of any signs, Tenant shall deliver to Landlord proof reasonably satisfactory to the Landlord from the applicable zoning authority that the signage complies with all Applicable Laws. Tenant also acknowledges that Landlord may permit other tenants of the Project to install signs and logos elsewhere within the Project. Tenant's right to install signage is personal to Tenant and may not be assigned by Tenant. Upon the expiration or earlier termination of this Lease, Tenant shall, with the supervision of Landlord's approved contractor, promptly remove any signage installed by Tenant and repair all damage to the Building caused thereby.

52. OPTIONS TO RENEW.

A. Provided no default exists and Tenant or a Permitted Transferee (as hereinafter defined) is occupying the entire Premises at the time of such election, Tenant or a Permitted Transferee may renew this Lease for an additional period of five (5) years (the "**First Extension Term**") on the same terms provided in this Lease (except as set forth below), by delivering written notice (the "**Renewal Notice**") of the exercise thereof to Landlord at least twelve (12) months prior to the Expiration Date of this Lease. Upon Tenant's or a Permitted Transferee's timely notice of the exercise of the option to renew for the First Extension Term, the Lease shall be extended on the same terms provided in this Lease, except as follows:

(a) The Base Rent payable during such First Extension Term shall be the Fair Market Rental Rate (as hereinafter defined), for buildings comparable to the Project in Miami-Dade County, Florida, at the commencement of such First Extension Term, for space of equivalent quality, size, utility and location, with the length of the First Extension Term, concessions, allowances, brokers' fees and the credit standing of Tenant or the Permitted Transferee to be taken into account; and

(b) Landlord shall lease to Tenant or the Permitted Transferee the Premises in their then current condition, and Landlord shall not provide to Tenant or the Permitted Transferee any allowances (e.g., moving allowance, construction allowance, tenant improvements allowance and the like) or other tenant inducements.

For purposes of this Section 52, the Fair Market Rental Rate (the "**FMRR**") shall mean the rent, as of the date in question, which a landlord, willing but not obligated to lease, would accept for the Premises, and which a tenant, willing but not obligated to rent, would pay therefor in an arms-length transaction. Landlord shall deliver written notice (the "**Landlord Notice**") to Tenant or the Permitted Transferee, within thirty (30) days after Landlord's receipt of a timely Renewal Notice, which sets forth the FMRR as determined by Landlord to be payable during the applicable Extension Term after consideration of the factors set forth above. Tenant or the Permitted Transferee shall have the right, within thirty (30) days following the date of the Landlord Notice, to deliver written notice that it accepts Landlord's determination of the FMRR, or that it disagrees with Landlord's determination of the FMRR. Thereafter, if the parties are unable to agree as to the FMRR by the date that is sixty (60) days following the Renewal Notice, either party may give written notice that it is designating an appraiser (the "**First Appraiser**") to determine the FMRR. Within fifteen (15) days after the service of such notice, the other party shall give written notice to the party giving the first notice, which notice shall designate the second appraiser (the "**Second Appraiser**"). If the Second Appraiser is not so designated by the time above specified, then the party designating the First Appraiser may request appointment of the Second Appraiser by the president of the Miami Chapter of the American Institute of Real Estate Appraisers (the "**Appraisal President**"). The First and Second Appraisers so designated or appointed shall meet within ten (10) days after the Second Appraiser is appointed; and if within thirty (30) days after the Second Appraiser is appointed, the First and Second Appraisers do not agree upon the FMRR, they shall then (i) each report to Landlord and Tenant or the Permitted Transferee their respective determinations of the FMRR, and (ii) appoint a Third Appraiser (the "**Third Appraiser**"). If the First Appraiser and Second Appraiser are unable to agree upon the Third Appraiser within ten (10) days, the parties shall request that such appointment be made by the Appraisal President. In the event of the failure, refusal or inability of any appraiser to act, a new appraiser shall be appointed in his stead, which appointment shall be made in the same manner as herein before provided for the appointment of such appraiser so failing, refusing or being unable to act. Within thirty (30) days after his appointment, the Third Appraiser shall select either the determination of the First Appraiser or the determination of the Second Appraiser as the FMRR, and such determination shall be final and binding upon the parties. Each party shall pay the fees and expenses of the appraiser appointed by such party, and the fees and expenses of the Third Appraiser, and all other expenses, if any, shall be borne by the party whose determination of FMRR was not selected by the Third Appraiser. Any appraiser designated to serve as above provided shall be disinterested, shall be a member of the American Institute of Real Estate Appraisers, and shall be familiar with commercial property values in Miami-Dade County.

For purposes of this Section 52, the term "Permitted Transferee" shall mean any Affiliate to whom the Lease has been assigned pursuant to the terms of Section 15 of the Lease.

Tenant's or the Permitted Transferee's right to extend the term of this Lease for the First Extension Term shall terminate if (i) this Lease or Tenant's or the Permitted Transferee's right to possession of the Premises is terminated, (ii) Tenant or the Permitted Transferee, at any time during the Lease Term, assigns any of its interest in this Lease or sublets any portion of the Premises (other than to an Affiliate by Tenant in accordance with the terms of Section 15 of the Lease), or (iii) Tenant or the Permitted Transferee fails to timely exercise its option under this Section 52A. for the First Extension Term, time being of the essence with respect to Tenant's or the Permitted Transferee's exercise thereof.

B. Provided no default exists and Tenant or a Permitted Transferee is occupying the entire Premises at the time of such election, Tenant or a Permitted Transferee may renew this Lease for a second additional period of five (5) years (the "**Second Extension Term**") on the same terms provided in this Lease (except as set forth below), by delivering written notice (the "**Second Renewal Notice**") of the exercise thereof to Landlord at least twelve (12) months prior to the expiration of the First Extension Term. Upon Tenant's or a Permitted Transferee's timely notice of the exercise of the option to renew for the Second Extension Term, the Lease shall be extended on the same terms provided in this Lease, except as follows:

(a) The Base Rent payable during such Second Extension Term shall be the FMRR for buildings comparable to the Project in Miami-Dade County, Florida, at the commencement of such Second Extension Term, for space of equivalent quality, size, utility and location, with the length of the Second Extension Term, concessions, allowances, brokers' fees and the credit standing of Tenant or the Permitted Transferee to be taken into account; and

(b) Landlord shall lease to Tenant or the Permitted Transferee, the Premises in their then current condition, and Landlord shall not provide to Tenant or the Permitted Transferee any allowances (e.g., moving allowance, construction allowance, tenant improvements allowance and the like) or other tenant inducements.

Tenant's or a Permitted Transferee's right to extend the term of this Lease for the Second Extension Term shall terminate if (i) this Lease or Tenant's or the Permitted Transferee's right to possession of the Premises is terminated, (ii) Tenant or the Permitted Transferee, at any time during the First Extension Term, assigns any of its interest in this Lease or sublets any portion of the Premises (other than to an Affiliate by Tenant in accordance with the terms of Section 15 of the Lease), or (iii) Tenant or the Permitted Transferee fails to timely exercise its option under this Section 52.B for the Second Extension Term, time being of the essence with respect to Tenant's or the Permitted Transferee's exercise thereof.

53. ROOF-TOP USAGE RIGHTS. At Tenant's sole cost and expense, Tenant shall have the right ("**Rooftop Rights**") to install, maintain and repair no more than two (2) antennas, satellite dishes or similar communications equipment (but not cell phone towers) (the "**Antenna**") on the roof of one of the Buildings and such cabling, conduit and other ancillary equipment as are reasonably necessary to operate the Antenna (the "**Ancillary Equipment**"), all as such Antenna and Ancillary Equipment shall be approved in writing by Landlord, in Landlord's sole and absolute discretion, provided that such Antenna and Ancillary Equipment shall be for the sole use of the Tenant in the conduct of its business and further that such Antenna and Ancillary Equipment shall be reasonably consistent with the needs of Tenant's business operations at the Premises. The Antenna and the Ancillary Equipment are hereinafter sometimes collectively referred to as the "**Equipment**" and are under and subject to the following conditions:

(a) Tenant shall comply with all applicable laws and requirements and shall obtain, and deliver to Landlord written evidence of, any approval(s) required under any recorded covenants or restrictions applicable to the Building.

(b) Tenant shall obtain Landlord's prior approval of the location of the Equipment on the roof of the Building and of the specifications for the Equipment. Tenant acknowledges that Landlord's approval of the location of the Equipment will take aesthetics into account. Tenant agrees to pay all costs to erect a parapet wall or other visual screen that Landlord, in its sole discretion, may require, so that the Equipment is not visible from the ground. Tenant agrees to follow Landlord's roofing contractor's recommendations and requirements in connection with the installation of the Equipment on the roof of the Building. Tenant shall pay all reasonable costs incurred by Landlord in connection with the Equipment including without limitation all commercially reasonable architectural, engineering, contractors', consultants and legal fees.

(c) Tenant shall: (i) deliver to Landlord the plans, specifications and necessary permits, together with certificates evidencing that Tenant's contractors and subcontractors have adequate insurance coverage naming Landlord and Landlord's agent as additional insureds, at least ten (10) days prior to the commencement of the installation of the Equipment; (ii) confirm to Landlord that such installation of the Equipment shall not impair the structural strength of the Building or any other improvements or reduce the value of the Project or affect any utility lines, communication lines, equipment or facilities in the Building serving any tenant other than Tenant; (iii) comply with Section 12 of the Lease; (iv) confirm to Landlord that the occupants of the Building and of any adjoining property shall not be disturbed by the installation and operation of the Equipment; and (v) remove or relocate the Equipment from the roof of the Building at Tenant's sole cost and expense so that Landlord may effectuate any repairs, maintenance or replacement of the roof that Landlord's property manager deems necessary in its sole discretion.

(d) Landlord and Tenant shall each use good faith efforts to schedule a time and date for the installation of the Equipment that is mutually satisfactory and convenient. At least three (3) business days prior to installation, Tenant shall notify Landlord of the date and time of the installation. Landlord or Landlord's agent shall have the right to be present during the installation.

(e) Tenant shall maintain the Equipment in a safe, good and orderly condition. The installation, maintenance, repair and removal of the Equipment shall be performed at Tenant's sole expense in a manner which will not impair the integrity of, damage or adversely affect the warranty applicable to, the roof or any other portion of the Building.

(f) No later than the expiration or sooner termination of the Term, at Tenant's sole expense, Tenant shall remove the Equipment and repair any resulting damage.

(g) Tenant's indemnification of Landlord pursuant to Section 16C of this Lease also applies to the Equipment and Tenant's use of any portion of the Building therefor. Without limiting the foregoing, Tenant shall solely be responsible for any damages or injury caused by or in any way relating to the Equipment, including, but not limited to, damage or injury caused by reason of the Equipment collapsing or being blown from the roof or any other portion of the Building.

(h) Tenant acknowledges that at the time this Lease is executed, Landlord may have leased space on the roof of the Building and may hereafter lease additional space on the roof of the Building to other tenants for uses including, without limitation, the installation, maintenance and operation of equipment and facilities, and that such tenants may from time to time replace, add to and/or upgrade such equipment and facilities. The Equipment shall be installed, utilized and maintained in a manner so as not to cause interference with any other tenants of the Building or the Project, including, without limitation, other tenants on the roof of the Building existing on or prior to the Commencement Date ("**Pre-Existing Tenants**"), or their equipment or facilities, including, without limitation, any equipment or facilities of such Pre-Existing Tenants, nor cause damage to the equipment or facilities of such other Pre-Existing Tenants. In the event the Equipment does interfere with any other Pre-Existing Tenants or user of the Building or the Project, or their equipment or facilities, including, without limitation, any equipment or facilities of such tenant or user of the Building or the Project, as same may be replaced, added to or upgraded (to the extent permitted by applicable law), Tenant shall have three (3) business days after receipt of written notice of such interference in which to take all steps necessary to correct and eliminate such interference at its sole cost and expense, except in the event of an emergency in which event Tenant shall have only twenty-four (24) hours following receipt of notice, including, without limitation, telephonic notice of such interference, to eliminate such interference. Should such interference not be eliminated, in Landlord's sole discretion, within such three (3) business day (or twenty-four (24) hour, as applicable) period (the "**Interference Grace Period**"), then Tenant shall cease operations of the Equipment, except for intermittent testing periods. If Tenant cannot eliminate such interference within thirty (30) days following the Interference Grace Period, Landlord shall have the right to terminate the Rooftop Rights, without an abatement or reduction in Rent effective on the date Landlord gives Tenant written notice of its election to terminate the Rooftop Rights. Nothing contained herein shall be construed as limiting Landlord from pursuing any cause of action against Tenant on account of such breach.

(i) Tenant acknowledges that Landlord has not and does not hereby make any representations or warranties whatsoever to Tenant regarding the potential interference with the Equipment emanating from the equipment or facilities of Landlord or any other tenants or owners of the Building or other buildings, whether owned by Landlord or not, in the vicinity of the Building and that Landlord shall have no responsibility whatsoever to Tenant with respect to any present or future, actual or potential interference from any such other equipment or facilities located on the Building or any other such building in the vicinity of the Building.

(j) Tenant's Equipment shall provide microwave/radio/cellular telecommunication service ("**Telecommunication Service**") for Tenant's use only. Without limiting the foregoing, Tenant shall have no right to use the Equipment as a conduit for providing Telecommunication Service to others, including, without limitation, tenants or users of the Building, the Project, or anywhere else, except with the prior written consent of the Landlord, which consent shall be in the sole discretion of the Landlord.

(k) Landlord shall have the right at any time to require Tenant to move all or any part of the Equipment to any other space in the roof of the Building (but Tenant shall not be responsible for any costs to erect a parapet wall or other visual screen that Landlord may require for the new location). If Landlord elects to have Tenant relocate all or any part of the Equipment, Landlord shall give Tenant written notice at least ten (10) days prior to the move date.

54. FORCE MAJEURE EVENT AND TENANT'S OBLIGATIONS. This Lease and the obligations of Landlord hereunder shall not be affected or impaired because

Tenant is unable to fulfill any of its obligations hereunder or is delayed in doing so, if such inability or delay is caused by reason of a Force Majeure Event, and the time for Tenant's performance shall be extended for the period of any such delay provided, however, that a Force Majeure Event shall be inapplicable to any payments of money due from Tenant or Landlord under this Lease.

55. CHANGES TO PROJECT . Landlord shall have the right, in Landlord's sole discretion, from time to time, to make changes to the size, shape, location, legal description, number and extent of the improvements comprising the Project, to sell portions of the Project or to expand the Project by adding additional real property or buildings to the Project (hereinafter collectively referred to as "Changes"). Such Changes may include, but are not limited to, the Common Areas, security systems, parking control systems, driveways, entrances, parking spaces, parking areas and landscaped areas. In the event Landlord makes any such Changes, including without limitation, adding to the Project any additional building containing rentable area, Landlord may elect to include certain expenses and/or real property taxes with respect to any such additional building as Operating Expenses and/or Real Property Taxes (as the case may be), in which case Tenant's Pro Rata Share of Operating Expenses with respect to such expenses and/or real property taxes shall be modified to reflect the rentable area of such additional building. In connection with the Changes, Landlord may, among other things, erect scaffolding or other necessary structures at the Project, limit or eliminate access to portions of the Project, including portions of the Common Areas, or perform work in the Building or within the Project which work may create noise, dust or leave debris within the Project. Tenant hereby agrees that such Changes and Landlord's actions in connection with such Changes shall in no way constitute a constructive eviction of Tenant or entitle Tenant to any abatement of rent. Provided that the Changes do not prohibit access to or the Permitted Use of the Premises or reduce the amount of the Parking Spaces or relocate the Parking Area, Landlord shall have no responsibility or for any reason be liable to Tenant for any direct or indirect injury to or interference with Tenant's business arising from the Changes, nor shall Tenant be entitled to any compensation or damages from Landlord for any inconvenience or annoyance occasioned by such Changes or Landlord's actions in connection with such Changes.

56. RIGHT OF FIRST OFFER TO LEASE ADDITIONAL SPACE. Landlord and Tenant hereby acknowledge and agree that, subject to the rights of other current and future tenants or occupants in the Project, Tenant shall have a right to lease Right of First Offer Space (the "**ROFO**") as set forth more specifically below:

a. As used in this Lease, "**ROFO Space**" shall mean space in any of the buildings identified as 7D, 7F, 7G, 7H, 7L, 7M, 7N and 7W on the site plan attached hereto as Exhibit A-1, as, when and if the same becomes available for lease by the Landlord.

b. Landlord agrees that prior to entering into a new lease with any prospective tenant or other occupant it shall provide Tenant with written notice (the "**Offer Notice**") offering the ROFO Space to Tenant, which Offer Notice shall include all of the terms and conditions under which Landlord is willing to lease the ROFO Space to Tenant (including without limitation the location and approximate square footage of the ROFO Space, the Base Rent payable for such ROFO Space and any additional parking that will be made available with such ROFO Space). Tenant shall evidence its receipt of the Offer Notice by confirming receipt thereof in writing to Landlord promptly after Tenant's receipt of the Offer Notice. The terms to be included in the Offer Notice shall be determined by Landlord in its commercially reasonable discretion. Tenant shall have ten (10) business days from receipt of the Offer Notice to elect, in writing, to lease the ROFO Space, failing which Tenant shall have no further right to lease such ROFO Space and Landlord may enter into a lease with a third party for such space or portion thereof on such terms as shall be determined by Landlord.

c. Notwithstanding anything to the contrary contained herein, if after using good faith commercially reasonable efforts, Landlord and Tenant have not entered into an amendment to add the ROFO Space to the Lease within thirty (30) days of the date that Tenant has elected, pursuant to subsection (b) above, to lease the ROFO Space, then (i) the Tenant's right of first offer shall be null and void and Tenant shall have no further right to lease the ROFO Space, (ii) Tenant shall execute and deliver to Landlord such document as is reasonably acceptable to Landlord indicating that the right of first offer is null and void and that Tenant has no further right to lease the ROFO Space.

d. Tenant shall not be entitled to exercise the ROFO at any time when Tenant is in default under the Lease and such default has continued beyond any applicable notice and grace period.

e. Tenant's ROFO for the ROFO Space in question shall automatically expire at the time that Landlord sells or ceases to own the applicable ROFO space.

f. Landlord further agrees that if Landlord has made an Offer Notice to Tenant, and Landlord subsequently determines that it would be willing to offer to the market a Base Rent in an amount that is lower than the Base Rent for the ROFO Space that was the subject of such Offer Notice by 15% or more, Landlord will re offer the ROFO Space to Tenant in accordance with the terms of section 56b. above.

57. RIGHT OF FIRST OFFER TO PURCHASE THE PREMISES. Landlord and Tenant hereby acknowledge and agree that provided that: (i) no Event of Default by Tenant exists under this Lease, (ii) Tenant has not assigned this Lease or sublet all or part of the Premises (except as permitted under the terms of the Lease), or (iii) Tenant is not holding over in the Premises, Tenant shall have a one time right to purchase the Premises from the Landlord as set forth more specifically below:

a. Landlord agrees that prior to offering the Premises for sale to any prospective purchaser, Landlord shall provide Tenant with written notice (the "**Sale Offer Notice**") offering the Premises to Purchaser, which Sale Offer Notice shall include all of the terms and conditions under which Landlord is willing to sell the Premises to Tenant. Tenant shall evidence its receipt of the Sale Offer Notice by confirming receipt thereof in writing to Landlord promptly after Tenant's receipt of the Sale Offer Notice. The terms to be included in the Sale Offer Notice shall be determined by Landlord in its commercially reasonable discretion and shall include a release or a partial release of the Premises from any mortgage encumbering the Premises. Tenant shall have ten (10) business days from receipt of the Sale Offer Notice to elect, in writing, to purchase the Premises in accordance with the terms of the Sale Offer Notice, failing which Tenant shall have no further right to purchase the Premises and Landlord may sell the Premises or any portion thereof to a third party on such terms as shall be determined by Landlord.

b. Notwithstanding anything to the contrary contained herein, if after using good faith commercially reasonable efforts, Landlord and Tenant have not entered into a purchase and sale agreement for the Premises within thirty (30) days of the date that Tenant has elected, pursuant to subsection (a) above, to purchase the Premises in accordance with the terms of the Sale Offer Notice, then (i) the Tenant's right of first offer to purchase the Premises shall be null and void and Tenant shall have no further right to purchase the Premises, (ii) Tenant shall execute and deliver to Landlord such document as is reasonably acceptable to Landlord indicating that the right of first offer is null and void and that Tenant has no further right to purchase the Premises.

c. Tenant's right of first offer to purchase the Premises as set forth in this Section 56 (the "Offer Right") is personal to Tenant and may not be assigned by Tenant in connection with an assignment of this Lease or otherwise. The Offer Right may not be exercised by anyone other than Tenant. Any attempted assignment of the Offer Right shall be of no effect and the Offer Right shall become forever null and void as of the date of the purported assignment.

Tenant expressly acknowledges and agrees that the Offer Right shall not apply in the event of any of the following:

(i) The sale of the Premises to an affiliate of Landlord or to a government entity;

(ii) The sale of the Premises in connection with a sale of all or substantially all of Landlord's assets or shares (or interests);

(iii) The entering into of any management agreement or any similar agreement which transfers control of the Project by Landlord;

(iv) The entering into by Landlord of any ground lease, mortgage, or trust deed upon all or any portion of the Project, any advances made thereunder and all renewals, modifications, consolidations, replacements, extensions, and re-financings thereof;

(v) The entering into a contract by Landlord for the sale of more than one property wherein the Project is one of such properties; or

(vi) Any transfer of the Project for no material consideration for estate planning or other similar purposes.

The Offer Right shall be subject and subordinate to any mortgage now, or hereafter placed, upon the Project or any portion of the Project, and to any renewals, modifications, consolidations, replacements, extensions, and re-financings thereof. Tenant agrees to use good faith and commercially reasonable efforts to execute and acknowledge any such SNDA as Landlord reasonably requests (provided same is in form and substance reasonably acceptable to Tenant) within ten (10) business days after Landlord's delivery of the same to Tenant. Tenant's failure to execute the SNDA within ten (10) business days after written demand shall constitute an Event of Default by Tenant hereunder.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties hereto have signed, sealed and delivered this Lease in several counterparts each of which shall be deemed an original, but all constituting a single agreement, at Miami-Dade County, Florida, as of the day and year first above written.

Witnesses:

LANDLORD:

MCP EWE, LLC, a Delaware limited liability company

[Signature not legible]

/s/ Ed Easton

[Signature not legible]
(As to Landlord)

TENANT:

HEARTWARE, INC., a Delaware corporation

By: /s/ Douglas E. Godshall
Name: Douglas E. Godshall
Title: President/CEO

[Signature not legible]

[Signature not legible]
(As to Tenant)

EXHIBIT A

LAND
(see attached pages)

EXHIBIT A-1

SITE PLAN OF THE PROJECT

(see attached page)

EXHIBIT A-2

PARKING AREA

EXHIBIT B

WORK LETTER

(a) Tender of Possession. Landlord shall deliver the Premises to Tenant in their existing "as is" condition pursuant to the terms set forth in Section 2 of the Lease.

(b) Tenant Improvements. Tenant shall have the right to make certain tenant improvements to the Premises (as generally described on Exhibit B-1 hereto), including the right to construct a fence (the "**Fence**") around the perimeter of the Premises (the "**Tenant Improvements**"). Tenant shall cause Tenant's architect, Operations Concepts, Inc. (the "**Tenant's Architect**"), to prepare a space plan (which shall include the design and location of the Fence) with respect to the Premises (the "**Space Plan**"). Tenant shall submit the Space Plan to Landlord for its written approval, which approval shall not be unreasonably withheld, conditioned or delayed. Landlord shall either approve or deny the Space Plan within ten (10) business days of Tenant's submittal. The failure of Landlord to respond within such ten (10) business day period shall be deemed non-approval, however, the failure of Landlord to respond within ten (10) business days after a second request by Tenant after the expiration of the first ten (10) business day period shall be deemed approval. Within ten (10) business days of receipt of any proposed changes from the Landlord, Tenant will prepare revisions as appropriate and submit the revised Space Plan to Landlord, which will be deemed approved and final ten (10) days after delivery to Landlord unless Landlord provides Tenant additional written objections thereto within such 10-day period. The parties shall continue this process in good faith until the Space Plan is finally approved. Upon approval of the Space Plan, Tenant shall cause Operations Concepts Inc. (the "**Tenant's Engineer**") to prepare detailed plans and specifications for the Tenant Improvements in accordance with the approved Space Plan which shall be in sufficient detail to enable Tenant to obtain a building permit for the construction of the Tenant Improvements (the "**Plans**"). Tenant shall submit the Plans to the Landlord for its review and written approval, which approval shall not be unreasonably withheld, conditioned or delayed. Landlord shall either approve or deny the Plans within ten (10) business days of Tenant's submittal, provided however, that in the event that Landlord is required, in Landlord's commercially reasonable discretion, to retain professionals to review the Plans, Landlord shall have an additional ten (10) business day period to retain such professionals for the review of the Plans, so long as Landlord is diligently proceeding with such review and provided that Landlord has notified Tenant, within ten (10) business days after Tenant's submittal, of the reason that Landlord requires the professional review. The failure of Landlord to respond within such ten (10) business day period (as the same may be extended for an additional ten (10) business days in accordance with the preceding sentence) shall be deemed non-approval. Within ten (10) business days of Tenant's receipt of any proposed changes by Landlord, which shall be reasonable in nature and stated in sufficient detail so as to allow the necessary modifications by Tenant, Tenant will prepare revisions as appropriate and submit the revised Plans to Landlord, and Landlord shall either approve or deny the Plans within five (5) business days of Tenant's submittal. Any proposed changes by Landlord shall be reasonable in nature and stated in sufficient detail so as to allow the necessary modifications by Tenant. Upon Tenant's receipt of the Plans as modified by Landlord, Tenant shall have ten (10) business days within which to return the Plans to Landlord, as modified and the parties shall continue this process in good faith until the Plans are finally approved.

Landlord and Tenant acknowledge and agree that each will use good faith commercially reasonable efforts to cooperate with one another to expedite the process of approving the Space Plan and the Plans in accordance with the preceding section. Notwithstanding the same, Tenant acknowledges that Landlord will not be deemed to be acting unreasonably hereunder in the event that Landlord disapproves of any Space Plan or Plans submittal because the Space Plan or Plans as submitted contain improvements that do not comply with Applicable Laws or covenants affecting the Project, or if Landlord believes, in Landlord's commercially reasonable opinion, that the requested improvements will have a material adverse affect on the Premises, the Building or the Project. Tenant further acknowledges and agrees that with respect to any improvements that will be made to the exterior of the Premises (including the Fence), Landlord will be entitled to consider the location, design, installation method and aesthetics of any such exterior improvements when considering its approval of such improvements. If applicable, Landlord shall reasonably cooperate with Tenant (at no cost to Landlord) to obtain approval for the construction of the Fence from any architectural control committee applicable to the Project.

Once Landlord approves the Plans, Landlord shall not be permitted to require changes to the Plans as approved, unless such changes are required by Applicable Law or by a governmental authority. Upon approval of the Plans, the Tenant shall construct the Tenant Improvements, at Tenant's sole expense (subject to the application of the Tenant Improvement Allowance described below), subject to the following conditions:

(i) Tenant shall engage a general contractor which has been expressly approved by Landlord, which approval shall not be unreasonably withheld, conditioned or delayed, for the construction of the Tenant Improvements and the Fence. At least ten (10) days prior to the commencement of construction of the Tenant Improvements or the Fence, Tenant shall deliver to Landlord a certificate of insurance for each of Tenant's contractors evidencing adequate insurance coverage naming Landlord and Landlord's agents as additional insureds.

(ii) In addition to the rights of Landlord and its agents to inspect the Premises as set forth in Section 22 of the Lease, Landlord and its agent shall have the right to conduct walk through inspections of the Premises during and following completion of the Tenant Improvements.

(iii) Tenant shall cause the Tenant Improvements and the Fence to be constructed in a good and workmanlike manner in accordance with the approved Plans and in full compliance with all applicable laws and regulations of all governmental authorities having jurisdiction. Tenant shall submit to Landlord for its review and written approval, all proposed change orders with respect to the Plans which (a) affect the structure of the Building or any other improvements; (b) affect any Building systems, including, without limitation, any utility lines, communications lines, equipment or facility in the Building serving any tenant other than Tenant; (c) exceed $25,000.00 individually; and/or (d) exceed $50,000.00 in the aggregate, and Tenant will not implement any such proposed change orders unless and until approved by Landlord in writing. Landlord shall either approve or deny any such changes (which approval or denial shall not be unreasonably withheld, conditioned or delayed) within ten (10) business days of Tenant's request, provided however, that in the event that Landlord is required, in Landlord's commercially reasonable discretion, to retain professionals to review the proposed change orders, Landlord shall have an additional ten (10) business day period to retain such professionals for the review of the change orders, so long as Landlord is diligently proceeding with such review and provided that Landlord has notified Tenant, within ten (10) business days after Tenant's submittal, of the reason that Landlord requires the professional review. The failure of Landlord to respond within such ten (10) business day period (as the same may be extended for an additional ten (10) business days in accordance with the preceding sentence) shall be deemed non-approval, however, the failure of Landlord to respond within ten (10) business days after a second request by Tenant after the expiration of the first ten (10) business day period (as the same may be extended for an additional ten (10) business days in accordance with the preceding sentence) shall be deemed approval. Tenant shall submit to Landlord copies of all other change orders with respect to the Plans not requiring Landlord approval as provided in this Sub-section (iv), prior to implementing any such proposed change orders. Upon completion of construction of the Tenant Improvements Tenant shall provide to Landlord on CAD disk "as built" plans and specifications with respect to the Tenant Improvements.

(iv) Tenant shall deliver to Landlord copies of all certificates of occupancy, permits and licenses required to be issued by any governmental authorities in connection with the construction of the Tenant Improvements and the Fence.

(v) Subject to the satisfaction of the conditions set forth above, Landlord shall pay to Tenant's general contractor and professionals, in monthly progress payments, on or before the 30th day of the month following receipt of the Payment Request (as hereinafter defined), the Tenant Improvement Allowance (as hereinafter defined), based on the Progress Payment Affidavits prepared on AIA Form G701 submitted to Landlord along with accompanying original releases of lien from the general contractor and its subcontractors and suppliers, all of which have been approved by Tenant, Tenant's Architect and Landlord for payment on or before the 25th day of each month (the "**Payment Request**"). Landlord shall have ten (10) business days from receipt of the Payment Request to review and approve or recommend adjustments to same (which approval or recommendations shall not be unreasonably withheld, conditioned or delayed). The failure of Landlord to respond within the ten (10) business day period shall be deemed approval. Tenant shall provide any other documentation that Landlord may reasonably require to substantiate the Payment Request.

The "Tenant Improvement Allowance" shall mean $1,750,000.00. Landlord shall make the Tenant Improvement Allowance available to Tenant on the Commencement Date of the Lease.

Landlord and/or its agents, architects, engineers, and other construction management professionals, shall be paid a construction management/ review fee in the amount of $50,000.00 by Tenant for all of their oversight and review services in connection with this Lease, which fee shall be paid monthly out of the Tenant Improvement Allowance. Tenant shall be solely responsible for overseeing the completion of the Tenant Improvements and the Fence. The Tenant Improvement Allowance may be used to cover all hard and soft costs incurred in connection with the construction of the Tenant Improvements including, without limitation, all fees and costs in connection with the preparation of the Final Plans (including, without limitation, all revisions thereto), all fees and costs in connection with the obtaining of required permits and approvals therefor, all fees and costs in connection with the construction and installation of the Tenant Improvements, and all construction supervision fees.

(vi) To the extent the cost to complete the Tenant Improvements exceeds the Tenant Improvement Allowance, Tenant shall be responsible for payment of all such excess costs and expenses. No portion of the Tenant Improvement Allowance shall be utilized to purchase furniture or equipment for the Premises or for Tenant's moving expenses. In the event there remains any unused portion of the Tenant Improvement Allowance at the conclusion of the Tenant Improvements, then Landlord shall retain the same.

(vii) Tenant shall be permitted to have access to the Premises to enable Tenant to be able to construct the Tenant Improvements and the Fence. Tenant shall be responsible for the cost of all utilities, air conditioning, elevator, and security services once the Premises are tendered to Tenant.

(viii) Tenant's contractor shall comply with Landlord's reasonable rules and regulations, applied in a nondiscriminatory fashion, applicable to contractors performing work within the Building.

(ix) Landlord and Tenant shall each designate a Representative to make binding decisions on their respective behalf's in connection with this Work Letter. Landlord's Representative shall mean Albert Couto. Tenant's Representative shall mean Andres Toledo. Landlord and Tenant shall each have the right to appoint a successor or substitute Representative by delivering five (5) days prior written notice to the other party. Landlord and Tenant agree that any request, direction or communication regarding the Tenant Improvements shall only be valid if delivered in writing to Tenant's Representative or Landlord's Representative as the case may be.

(c) "Landlord Delay" shall mean the number of days of delay in construction and completion of the Tenant Improvements by Tenant which is caused by Landlord, including, without limitation, Landlord's failure to respond to Tenant within the time frames set forth in this Work Letter or interference with Tenant's completion of the Tenant Improvements.

(d) Tenant shall not be required to provide a payment and performance bond for the cost of the Tenant Improvements or the Fence.

(e) Tenant shall have the right to use a staging area to be designated by Landlord in reasonable proximity to the Premises during construction of the Tenant Improvements and the Fence.

EXHIBIT B-1

DESCRIPTION OF TENANT IMPROVEMENTS

The construction of laboratory, research and medical device manufacturing facilities together with ISO Class 8 clean room capabilities.

SCHEDULE A

GUARANTY OF LEASE

THIS GUARANTY OF LEASE (the "Guaranty") is made as of this _____ _____ day of _____, 2010, by HEARTWARE INTERNATIONAL, INC. (the "Guarantor"), having an address at 205 Newbury Street, Suite 101, Framingham, MA 01701, in favor of MCP EWE LLC, a Delaware limited liability company (the "Lessor"), and is executed pursuant to that certain Lease dated of even date herewith (the "Lease") between Lessor and HEARTWARE, INC. (the "Lessee") with respect to those certain Premises consisting of three (3) industrial warehouse/office facility buildings containing a total of approximately 130,952 square feet and known as Buildings "7A", "7B" and "7C" as more particularly described in the Lease (the "Premises").

In order to induce Lessor to execute the Lease, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Guarantor has guaranteed and hereby does guaranty the payment and performance of all liabilities, obligations, and duties (including, without limitation, payment of rent) imposed upon Lessee under the terms of the Lease, as if Guarantor has executed the Lease as Lessee thereunder, irrespective of the expiration of the Lease, or the insufficiency, invalidity, or unenforceability of any security interest which might have been, or be hereafter, given to Lessor to secure Lessee's obligations contained in the Lease. This Guaranty is a guaranty of full payment and performance and not merely collection.

Subject to the Guarantor Cure Period (as hereinafter defined), Guarantor hereby acknowledges, and waives notice of, acceptance of this Guaranty and all other notices in connection herewith or in connection with the liabilities, obligations, and duties guaranteed hereby, including, but not limited to, notices of default by or to Lessee under the Lease, and waives demand for payment, protest, diligence, presentment, and notice of protest on the part of Lessor in the enforcement of any liability, obligation, or duty guaranteed hereby. Guarantor further waives, to the fullest extent permitted by law, all defenses given to sureties and guarantors by statute, at law, or in equity.

Notwithstanding the foregoing or anything to the contrary contained in this Guaranty, prior to Lessor exercising any rights as against Guarantor, Lessor shall provide Guarantor with the same notice and opportunity to cure defaults by Lessee as are required to be provided to Lessee pursuant to the Lease, plus an additional period of ten (10) business days (the "Guarantor Cure Period"). Lessor shall provide to Guarantor a simultaneous copy of all notices of default sent to Lessee as a condition of the commencement of such additional ten (10) business days of the Guarantor Cure Period.

Guarantor further agrees that Lessor shall not be first required to enforce against Lessee or any other person any liability, obligation, or duty guaranteed hereby before seeking enforcement thereto against Guarantor (but which enforcement against Guarantor is subject to the Guarantor Cure Period). Suit may be brought and maintained against Guarantor by Lessor to enforce any liability, obligation, or duty guaranteed hereby without joinder of Lessee or any other person. The liability of Guarantor shall not be affected by any indulgence, compromise, settlement, or variation of terms which may be extended to Lessee by Lessor or agreed upon by Lessor and Lessee (except as hereinafter set forth), and shall not be impaired, modified, changed, released, or limited in any manner whatsoever by any impairment, modification, change, release, or limitation of the liability of Lessee or its estate in bankruptcy, or of any remedy for the enforcement thereof, resulting from the operation of any present or future provision of the National Bankruptcy Code, or any similar law or statute of the United States or any State thereof. Lessor and Lessee, without notice to, or consent by, Guarantor, may at any time or times enter into such extensions, amendments, assignments, subleases, or other covenants respecting the Lease as they may deem appropriate, including, but not limited to, an increase in the rent due under the Lease or any other obligation thereunder; and Guarantor shall not be released thereby, but shall continue to be fully liable for the payment and performance of all liabilities, obligations, and duties of Lessee under the Lease as so extended, amended, assigned, subleased, or otherwise modified. Furthermore, Guarantor's obligations and covenants under this Guaranty shall in no way be affected or impaired by reason of the happening from time to time of any of the following, whether or not Guarantor has been notified thereof or consented thereto: (a) any invalidity, illegality or unenforceability of the Lease, or any termination of the Lease for any reason whatsoever (including a Bankruptcy); (b) any defenses or rights of set-off or counterclaim of Lessee or Guarantor; (c) Lessor's waiver of the performance or observance by Lessee, Guarantor or any other party of any covenant or condition contained in the Lease or this Guaranty; (d) the doing or the omission of any act referred to in the Lease or this Guaranty (including the giving of any consent referred to in the Lease or this Guaranty); (e) Lessor's failure or delay to exercise any right or remedy available to Lessor or any action on the part of Lessor granting indulgence or extension in any form whatsoever; (f) the release of Lessee or Guarantor from the performance or observance of any covenant or condition contained in the Lease or this Guaranty by operation of law; or (g) any other matters whatsoever, whether or not similar to those specifically mentioned herein, other than the full performance of all obligations of Lessee under the Lease.

This Guaranty is absolute, irrevocable, unconditional, and continuing in any event, and shall not terminate until the payment of all sums and the performance of all obligations evidenced by the Lease.

No such payment by Guarantor pursuant to any provision of this Guaranty shall entitle Guarantor, by subrogation, indemnification or otherwise, to the rights of Lessor, to any payment by Lessee, or to any recovery from any property of Lessee, until after payment in full under this Guaranty. Guarantor waives any right Guarantor may now or hereafter have against Lessee (and/or any other guarantor of Lessee's obligations under the Lease) with respect to this Guaranty (including, without limitation, any right of subrogation, reimbursement, exoneration, contribution, indemnification or similar right, and any right to participate in any claim, right or remedy of Lessor against Lessee or any security which Lessor now or hereafter has with respect to the Lease), whether such right arises under an express or implied contract, by operation of law, or otherwise, until after payment in full under this Guaranty. Guarantor shall be deemed not to be a "creditor" (as defined in the National Bankruptcy Code) of Lessee by reason of the existence of this Guaranty in the event that Lessee becomes a debtor in any proceeding under the National Bankruptcy Code. Should Lessor repay to Lessee or Guarantor, or be obligated by applicable law to repay to Lessee or Guarantor, any amounts previously paid, then this Guaranty shall be reinstated in the amount Lessor repays or is so obligated to repay.

If all or any part of the Lease is rejected, disaffirmed or otherwise avoided pursuant to applicable law affecting creditors' rights, then Guarantor shall, and does hereby (without the necessity of any further agreement or act), assume all obligations and liabilities of Lessee under the Lease to the same extent as if Guarantor were originally named Lessee under the Lease and there had been no such rejection, disaffirmance or avoidance. Guarantor shall upon Lessor's request promptly confirm in writing such assumption.

It is understood that other agreements similar to this Guaranty may, at Lessor's sole opinion and discretion, be executed by other persons with respect to the Lease. This Guaranty shall be joint and several and cumulative of any such agreements and the liabilities and obligations of Guarantor hereunder shall in no event be affected or diminished by reason of such other agreements. Moreover, if Lessor obtains the signature of more than one guarantor in this Guaranty, or obtains additional guaranty agreements, or both, Guarantor agrees that Lessor, in Lessor's sole discretion, may (i) bring suit against all guarantors of the Lease jointly and severally or against any one or more of them, (ii) compound or settle with any one or more of the guarantors for such considerations as Lessor may deem proper, and (iii) release any one or more of the guarantors from liability. Guarantor further agrees that no such action shall impair the rights of Lessor to enforce the Lease against any remaining guarantor or guarantors, including Guarantor (except to the extent of a separate recovery by Lessor from any such remaining guarantor or guarantors).

Guarantor agrees that if Lessor shall employ an attorney to present, enforce, or defend any or all of Lessor's rights or remedies hereunder or under the Lease, Guarantor shall pay any reasonable attorneys' fees incurred by Lessor in such connection, whether such fees are incurred before or at trial or on appeal. Notwithstanding the foregoing, in the event of any litigation between Lessor and Guarantor arising out of the Lease or this Guaranty, the prevailing party shall be entitled to recover its costs and expenses incurred in such litigation, including reasonable attorneys' fees, at all levels, including appeals.

In the event the Lessor, or any successor owner of the Building, sells, conveys, or otherwise transfers the Premises or the Lease, this Guaranty shall not be abrogated thereby, and shall continue in full force and effect. Guarantor hereby agrees to execute any such document or certificate as may be reasonably requested by Lessor or any successor owner of the Building to confirm the foregoing and the continuing validity of this Guaranty.

Any notice which Lessor may elect to send shall be binding upon Guarantor if mailed to Guarantor's address set forth above or to the last address known to Lessor, by United States certified or registered mail, return receipt requested, or by Federal Express or other overnight courier, and shall be deemed conclusively delivered when same are either hand delivered, or three (3) business days after deposited in the U.S. mail, postage prepaid, certified, return receipt requested, or delivered by a nationally recognized courier for overnight delivery with such delivery charge being prepaid. A courtesy copy of all notices shall also be delivered to Akerman Senterfitt, One S.E. Third Avenue, Suite 2500, Miami, Florida 33131, Attention Carol S. Faber, Esq. (Ph# 305-374-5600) however Lessor's failure to deliver any such courtesy copy shall not invalidate or otherwise impair the effectiveness of any notice given to Guarantor. Guarantor may, by notice to Lessor, designate a different address or addresses for notices.

This Guaranty shall be governed by, and construed in accordance with, the laws of the State of Florida. If any provision of this Guaranty should be held to be invalid or unenforceable, the validity and enforceability of the remaining provisions of this Guaranty shall not be affected thereby. Guarantor hereby consents to the exercise of personal jurisdiction over Guarantor by any federal or local court in the jurisdiction in which the Premises is located. Guarantor appoints Mr. Jeff Held, having an address at 205 Newbury Street, Suite 101, Framingham, MA 01701 (Ph# 508-739-0841), as Guarantor's agent for receipt of service of process on Guarantor's behalf in connection with any suit, writ, attachment, execution or discovery or supplementary proceedings in connection with the enforcement of this Guaranty. Service shall be effected by any means permitted by the court in which any action is filed. Service shall be deemed effective upon receipt. Guarantor shall designate a change of address or agent by written notice given by certified mail, return receipt requested, at least ten (10) days before such change is to become effective.

Guarantor represents and warrants that Lessor's execution of the Lease is a material and direct economic benefit to Guarantor and constitutes good, valuable and sufficient consideration for Guarantor's execution of this Guaranty, notwithstanding any future rejection or other termination of all or any part of the Lease. Guarantor represents and warrants that all financial statements and information regarding Guarantor that have been or will be delivered to Lessor are true, correct and complete as of the date they were or will be delivered to Lessor. Each individual signing this Guaranty warrants and represents that he or she is duly authorized to execute and deliver this Guaranty, and that, if Guarantor is a corporation, Guarantor is a duly organized corporation in good standing under the laws of the state of its incorporation, and has the power and authority to enter into this Guaranty, and that all corporate action requisite to authorize Guarantor to enter into this Guaranty has been duly taken.

This Guaranty shall be binding upon Guarantor and Guarantor's successors, heirs, executors, administrators, and assigns, and shall inure to the benefit of Lessor and Lessor's successors, heirs, executors, administrators, and assigns.

No principal, partner, member, officer, director, trustee or affiliate of Guarantor who is a natural person shall have any personal liability under any provision of this Guaranty.

GUARANTOR AND BY ACCEPTANCE HEREOF, LESSOR, EACH HEREBY WAIVES TRIAL BY JURY IN ANY ACTION, PROCEEDING, OR COUNTERCLAIM ON ANY MATTERS ARISING OUT OF OR IN ANY WAY CONNECTED WITH THE LEASE OR THIS GUARANTY.

EXECUTED as of the day and year first above written, to be effective as of the date of the Lease.

WITNESSES:

/s/

/s/

GUARANTOR:

HEARTWARE INTERNATIONAL, INC.

By: /

Name:
Title:

Address: 205 Newbury St., Framingham, MA

COMMONWEALTH OF MASSACHUETTS)
)ss:
COUNTY OF MIDDLESEX)

The foregoing instrument was acknowledged before me this _____ day of _____, 2010, by _____, as _____ of HEARTWARE INTERNATIONAL, INC., a Delaware corporation, on behalf of said corporation. He is personally known to me or produced a Mass. Drivers license as identification.

/s/

Print Name:

Notary Public
/s/

My commission expires:

EXHIBIT C

FORM OF LANDLORD ESTOPPEL CERTIFICATE

The undersigned ("**Landlord**") hereby certifies that:

1. Landlord is the lessor of that certain space (the "**Premises**") in the _____ project located in Miami-Dade County, Florida, pursuant to the terms of that certain Standard Lease dated _____, _____ (the "**Lease**"), entered into between Landlord and Heartware, Inc., as lessee ("**Tenant**").

2. The Lease, a true, correct, and complete copy of which is attached as **Exhibit A** hereto, constitutes the entire agreement between Landlord and Tenant and there have been no amendments, written or oral, to the Lease except as follows (if left blank, there shall be deemed to be none):_____.

3. The Lease is presently in full force and effect and, to the best of Landlord's knowledge and without any independent investigation of the Premises by Landlord, neither Landlord nor Tenant is in default under the Lease.

4. All improvements or repairs required under the terms of the Lease to be made by Tenant through the date hereof have been satisfactorily completed. All allowances and other payments due to Tenant under the terms of the Lease have been paid in full, except the following (if left blank, there shall be deemed to be none):_____.

5. Tenant has accepted the Premises which is comprised of _____ rentable square feet of space and is in occupancy of the Premises.

6. The Commencement Date of the Lease was _____, _____, and the Lease will expire on _____, subject to Tenant's options to renew the Lease for two (2) successive periods of five (5) years each as set forth in Section 52 of the Lease.

7. Tenant has paid the Rent due under the Lease through _____. No rent has been prepaid by Tenant under the Lease except as set forth in this Section 7.

8. The amount of the Security Deposit held by Landlord under the terms of the Lease is $_____ (if left blank, there shall be deemed to be none).

9. Landlord has not assigned all or any part of its interest in the Lease.

10. Landlord acknowledges and agrees that this Landlord Estoppel Certificate may be relied upon by Tenant, any successor to Tenant and any lender providing financing to Tenant.

LANDLORD

_____

By: _____

Its: _____

Date: _____

EXHIBIT A

Attach copy of Lease and all amendments

SCHEDULE B

[FORM OF MEMORANDUM OF LEASE]

Prepared by and upon recordation

return to:

Carol S. Faber

Akerman Senterfitt

One Southeast Third Avenue, 25th Floor

Miami, Florida 33131

MEMORANDUM OF LEASE

This is a Memorandum of Lease by and between MCP EWE LLC, a Delaware limited liability company ("Landlord") and HEARTWARE, INC., a Delaware corporation ("Tenant"):

1. *Date of Lease: December 9, 2010.*

2. *Description of Premises: See Exhibit "A" attached hereto*

3. *Expiration Date: February 28, 2022.*

4. *Renewal Option: 2 (two) five (5) year renewal options.*

5. *This Memorandum of Lease does not alter, amend, modify or change the Lease or the exhibits which are a part thereof in any respect. It is executed by the parties to be recorded in the Public Records of Miami-Dade County, Florida for the purpose of giving notice of the existence of the Lease, and it is the intent of the parties that it will be so recorded and will give notice of and confirm the Lease and exhibits and all of their terms to the same extent as if fully set forth herein. In the event of any conflict or inconsistency between the provisions of this Memorandum of Lease and the Lease and exhibits and schedules attached thereto, the provisions of the Lease and exhibits and schedules attached thereto shall control. Reference is made to the Lease for further details as set forth therein and in the exhibits and schedules attached thereto.*

6. *All capitalized but undefined terms used in this Memorandum of Lease have the meanings ascribed to them in the Lease.*

7. *This Memorandum may be executed in counterparts, each of which shall be deemed an original, but all of which, together shall constitute one and the same instrument.*

[Remainder of page left blank intentionally]

IN WITNESS WHEREOF, Tenant has caused this Memorandum of Lease to be duly executed and sealed as of the date and year first referenced above.

TENANT:

WITNESSES

HEARTWARE, INC., a Delaware corporation

_____ *By:* _____

Signature *Name:*

_____ *Title:* _____

Print Name

_____

Signature

_____

Print Name

STATE OF _____)

) ss:

COUNTY OF _____)

The foregoing instrument was acknowledged before me this _____ *day of December, 2010, by* _____, *as* _____ *of HEARTWARE, INC., a Delaware corporation, on behalf of the corporation. He is:*

☐ *personally known to me; or*

☐ *produced a driver's license issued by the* _____ *Department of Highway Safety and Motor Vehicles as identification; or*

☐ *produced the following identification:* _____

_____

NOTARY PUBLIC, STATE OF

_____

_____

(Print, Type or Stamp Commissioned Name of Notary Public)

IN WITNESS WHEREOF, Landlord has caused this Memorandum of Lease to be duly executed and sealed as of the date and year first referenced above.

LANDLORD:

WITNESSES

MCP EWE LLC, a Delaware limited liability company

_____ *By:* _____

Signature *Name:*

_____ *Title:*

Print Name

_____

Signature

_____

Print Name

STATE OF _____)

) ss:

COUNTY OF _____)

The foregoing instrument was acknowledged before me this _____ *day of December, 2010, by* _____, *as* _____ *of MCP EWE LLC, a Delaware limited liability company, on behalf of the company. He is:*

☐ *personally known to me; or*

☐ *produced a driver's license issued by the* _____ *Department of Highway Safety and Motor Vehicles as identification; or*

☐ *produced the following identification:* _____

_____

NOTARY PUBLIC, STATE OF

_____

_____

(Print, Type or Stamp Commissioned Name of Notary Public)

Exhibit 21.1

LIST OF SUBSIDIARIES

NAME OF SUBSIDIARY	STATE OR OTHER JURISDICTI INCORPORATION OR ORGANIZ
HeartWare Pty. Limited (formerly HeartWare Limited) (1)	Australia
HeartWare, Inc. (2)	Delaware
HeartWare GmbH (3)	Germany
HeartWare (UK) Limited (4)	United Kingdom

(1) 100% owned by HeartWare International, Inc.
(2) 100% owned by HeartWare Pty. Limited
(3) 100% owned by HeartWare, Inc.
(4) 100% owned by HeartWare, Inc.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We have issued our reports dated February 24, 2011, 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, 2010. We hereby consent to the incorporation by reference of said reports in the Registration Statements of HeartWare International, Inc. on Form S-8 (File No. 33-155359, effective November 13, 2008) and Forms S-3 (File No. 333-161417, effective December 3, 2009, File No. 333-164004, effective January 20, 2010, and File No. 333-171054, effective December 9, 2010).

/s/ Grant Thornton LLP

Fort Lauderdale, Florida

February 24, 2011

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER 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 24, 2011

/s/ Douglas Godshall
Douglas Godshall
Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO RULE 13A-14(a) OR RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934

I, David McIntyre, 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 24, 2011

/s/ David McIntyre
David McIntyre
Chief Financial Officer

(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER 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, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned 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 24, 2011

/s/ Douglas Godshall
Douglas Godshall
Chief Executive Officer

(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER 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, 2010 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 24, 2011

/s/ David McIntyre
David McIntyre
Chief Financial Officer

(Principal Financial Officer)