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Manager of Company Announcements
ASX Limited
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SYDNEY NSW 2000

27 February 2009
BY E-LODGEMENT

Dear Sir / Madam

2008 Annual Financial Report

Attached is the Company's 2008 Annual Financial Report on United States Securities and Exchange Commission Form 10-K for the year ended 31 December 2008, together with the Consolidated Balance Sheets, Statement of Operations and Statement of Cash Flows and other relevant commentary ("Form 10-K").

HeartWare relies on relief available under ASIC Class Order 98/1418, and as such, lodges its audited Annual Financial Report for the year ended 31 December 2008 in the form of the Form 10-K which is prepared in accordance with United States Generally Accepted Accounting Principles (and which is denominated in US dollars).

Yours faithfully

David McIntyre
Chief Financial Officer &
Company Secretary

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, 2008

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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. Yes ☐ No ☑

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 ☐ Smaller reporting company ☑
(Do not check if a 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 outstanding common stock other than shares held by persons who may be deemed affiliates of the registrant, computed by reference to the closing sales price of the ordinary shares of HeartWare Limited (to which the registrant is the successor issuer) as of June 30, 2008, as reported on the Australian Securities Exchange, was approximately AU$66.4 million, or $63.9 million based on the then exchange rate.

As of January 31, 2009, the registrant had 8,866,702 shares of common stock, par value $.001, issued and outstanding.

Certain information in Part III of this Annual Report on Form 10-K is incorporated by reference to portions of the registrant's definitive proxy statement to be delivered to stockholders in connection with our 2009 Annual Meeting of Stockholders, or is to be included in Part III of an amendment to this Annual Report on Form 10-K, to be filed with the Securities and Exchange Commission.

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 Limited and HeartWare, Inc.
- "HeartWare International, Inc." and "Successor" refers to HeartWare International, Inc., a Delaware corporation incorporated on July 29, 2008.
- "HeartWare Limited" refers to HeartWare Limited, an Australian corporation.
- "HeartWare, Inc." and "Predecessor" refers to HeartWare, Inc., a Delaware corporation incorporated on April 3, 2003. HeartWare, Inc. was acquired by HeartWare Limited on January 24, 2005.

Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements that 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 performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation:

- our expectation regarding the completion of the proposed acquisition of us by Thoratec Corporation, a California corporation ("Thoratec");
- our expectations with respect to regulatory submissions and approvals;
- our expectations with respect to our clinical trials, including enrollment in our clinical trials;
- our expectations with respect to our intellectual property position;
- our ability to commercialize our existing products;
- our ability to develop and commercialize new products; and
- our estimates regarding our capital requirements.

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. 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.

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 redomiciliation of HeartWare Limited from Australia to Delaware. Prior to this date, HeartWare Limited was the parent company of the HeartWare Group, and, following the redomiciliation, HeartWare International, Inc. became the parent company. We further discuss our corporate history under "Business—Corporate History".

In connection with the redomiciliation, 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 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 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 "$" or "dollars" refer to United States dollars, the lawful currency of the United States of America. References to "AU$" refer to Australian dollars, the lawful currency of the Commonwealth of Australia.

Trademarks

HeartWare, the HeartWare® Ventricular Assist System, and MVAD™ are the trademarks of the Company, in the United States, 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 is a medical device company focused on developing small implantable pumps for the treatment of advanced heart failure.

Our first product, the HeartWare Ventricular Assist System (the "HeartWare System"), which includes a left ventricular assist device ("LVAD"), related 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, a full-output device capable of pumping up to 10 liters of blood per minute.

The HeartWare System has received Conformite Europeene ("CE") Marking in January 2009 which allows for commercial sales in Europe and is the subject of an ongoing US bridge-to-transplant clinical trial under an Investigational Device Exemption ("IDE") granted by the United States Food and Drug Administration ("FDA").

In 2008, we successfully completed enrollment in a combined European and Australian human clinical trial for the HeartWare System. This international trial began in March 2006 and initially called for the implantation of 20 patients. The trial was expanded to permit enrollment of 50 patients so as to provide increased depth of clinical data. Trial enrollment was completed in December 2008, and a subset of this data was used in support of our CE Marking application.

In April 2008, we received Conditional Investigational Device Exemption approval from the FDA, and began enrolling centers for a US bridge-to-transplant clinical study. On August 21, 2008 we announced that our first patient in the United States received the HeartWare System at Washington Hospital Center in Washington, DC. This marked the start of our U.S. trial under which 150 patients awaiting heart transplantation will be enrolled at up to 28 participating centers. Full approval of the IDE was received in September 2008.

Beyond the HeartWare System, we are also developing 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. The MVAD, which is currently at the development stage and undergoing animal studies focused on minimally invasive implantation techniques, is approximately one-third the size of the HVAD Pump. We believe that the MVAD will be implantable by surgical techniques that are even less invasive than those required to implant the HVAD Pump.

We are a development stage company with a limited operating history. To date, we have generated limited revenue from our product sales and have incurred net losses in each year since our inception. We also have generated limited income from interest. We expect our losses to continue at the current pace as we both increase our revenue and expand our clinical trial activities, seek regulatory approvals and initiate commercialization activities. We have financed our operations primarily through the issuance of equity. In January 2005, we issued shares through an initial public offering in Australia and a concurrent US private placement of shares which raised aggregate net proceeds of approximately $23.4 million. We also issued shares through private placements to both US and Australian investors, in May 2006, July 2007 and July 2008, which raised net proceeds of approximately $23.4 million, $30.9 million and $29.4 million, respectively.

We are headquartered in Framingham, Massachusetts and have an administrative office in Sydney, Australia and an operations and manufacturing facility in Miami Lakes, Florida.

Proposed Acquisition by Thoratec Corporation

Merger Agreement

On February 12, 2009, we entered into an Agreement and Plan of Merger (the "Merger Agreement") with Thoratec Corporation ("Thoratec"), Thomas Merger Sub I, Inc., a Delaware corporation and a direct wholly owned subsidiary of Thoratec ("Merger Subsidiary"), and Thomas Merger Sub II, Inc., a Delaware corporation and a direct wholly owned subsidiary of Thoratec ("Merger Subsidiary Two"). Pursuant to the terms of the Merger Agreement, Merger Subsidiary will merge with and into HeartWare, with HeartWare continuing as the surviving corporation (the "Merger") and, if the stock value of the consideration is at least 41% of the aggregate merger consideration at closing, immediately following the Merger, HeartWare, as the surviving corporation in the Merger, will merge with and into Merger Subsidiary Two, with Merger Subsidiary Two continuing as the surviving corporation and a wholly owned subsidiary of Thoratec (the "Second Merger" and together with the Merger, the "Mergers").

In the Merger, each share of common stock, including shares of common stock that prior to the closing were represented by CHESS Depositary Interests, of HeartWare will be converted into the right to receive a combination of (1) $14.30 in cash, without interest, and (2) 0.6054 shares of common stock of Thoratec. The aggregate value of the cash consideration payable in the Merger is approximately $141 million and, based on a price per share of Thoratec common stock of $26.25, the aggregate value of the stock consideration payable in the Merger is approximately $141 million.

In addition, if the volume weighted average of the per share closing prices of Thoratec common stock on The Nasdaq Stock Market, Inc. for the 20 consecutive trading days ending on and including the 5th trading day prior to, but not including, the closing date is less than 70% of $26.25, the Thoratec per share price used to determine the merger consideration, then HeartWare will have an option to terminate the Merger Agreement unless, subject to certain adjustments provided for in the Merger Agreement, Thoratec increases the number of shares of Thoratec common stock payable in the Merger such that the value of the stock portion of the merger consideration at closing is equal to 70% of the value of the stock consideration at signing. If that same volume weighted average price exceeds 130% of $26.25, then Thoratec may reduce the number of shares of Thoratec common stock payable in the Merger such that the value of the stock portion of the merger consideration at closing is equal to 130% of the value of the stock consideration at the signing of the Merger Agreement. If certain tax-related conditions are met and the Second Merger occurs, the Mergers, taken together, are intended to qualify as a tax-free reorganization for federal income tax purposes.

Thoratec and HeartWare have made customary representations and warranties in the Merger Agreement and agreed to certain customary covenants, including covenants regarding operation of the business of HeartWare and its subsidiaries prior to the closing and covenants prohibiting HeartWare from soliciting, or providing information or entering into discussions concerning, proposals relating to alternative business combination transactions, except in limited circumstances to permit the board of directors of HeartWare to comply with its fiduciary duties under applicable law.

Consummation of the Merger is subject to customary conditions, including adoption of the Merger Agreement by HeartWare's stockholders, the absence of legal impediments to consummation of the Merger and the expiration or termination of the required waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. Approval by Thoratec's shareholders is not required.

Thoratec and HeartWare may terminate the Merger Agreement under certain circumstances specified in the Merger Agreement. Upon the termination of the Merger Agreement in specified circumstances, HeartWare may be required to pay Thoratec a termination fee equal to $11.3 million, and in other specified circumstances, HeartWare may be obligated to pay Thoratec a termination fee equal to $5.0 million.

Support Agreements

In connection with the Merger Agreement, Apple Tree Partners I, L.P., a beneficial owner of approximately 30.2% of HeartWare common stock, and all of the directors and certain executive officers of HeartWare, entered into support agreements with Thoratec (each, a "Support Agreement") pursuant to which such stockholders have agreed to vote the shares of HeartWare common stock held by them to adopt the Merger Agreement and, subject to certain exceptions, not to dispose of their shares prior to the date of the HeartWare stockholder vote. The Support Agreements terminate upon termination of the Merger Agreement.

Loan Agreement

Concurrent with the execution and delivery of the Merger Agreement, Thoratec entered into a loan agreement with us and all of our subsidiaries, as guarantors (the "Loan Agreement"), in order to fund our ongoing operations until the closing of the Merger. The maximum aggregate amount that HeartWare may borrow under the Loan Agreement will not exceed $28.0 million. Thoratec has deposited $20.0 million into an escrow account pursuant to the Loan Agreement. Beginning on May 1, 2009, HeartWare may borrow up to an aggregate of $12.0 million and beginning on July 31, 2009 HeartWare may borrow up to an aggregate of $20.0 million. In the event that all of the conditions to closing the Merger other than the receipt of regulatory approvals have been satisfied and Thoratec exercises an option under the Merger Agreement to extend the outside date for the completion of the Merger until January 31, 2010, HeartWare may borrow up to an additional $8.0 million, which Thoratec must deposit into the escrow account at the time it exercises its extension option.

In the event that the Merger Agreement is terminated in accordance with its terms, Thoratec may convert the outstanding principal amount of the loans to HeartWare, including any accrued and unpaid interest, as well as any amounts remaining in the escrow account that have not been loaned to HeartWare, in whole or in part, into shares of HeartWare common stock based on a conversion rate equal to (i) $35.00 Australian dollars per share of HeartWare common stock or (ii) $21.5355 per share of HeartWare common stock in the event the Mergers are not consummated as a result of a termination by either HeartWare or Thoratec due to a competing acquisition proposal that the Board of Directors of HeartWare determines is a superior proposal in accordance with the terms of the Merger Agreement, in each case subject to adjustment as provided in the Loan Agreement.

The loans to HeartWare under the Loan Agreement accrue interest at the rate of 10% per annum and are due and payable, together with accrued and unpaid interest, on the earlier of (i) November 1, 2011, (ii) the Termination date and (iii) the date on which all of the loans accelerate and become due and payable in full in accordance with the Loan Agreement. The loans may accelerate upon a change of control of the borrower or events of default.

Investor's Rights Agreement

Concurrent with the execution of the Loan Agreement, we entered into an Investor Rights Agreement with Thoratec, pursuant to which we have agreed to provide certain registration rights with respect to any HeartWare common stock issued upon the conversion of the loans or any amounts held in the escrow account.

For a description of the risks associated with our proposed acquisition by Thoratec and a more complete description of the terms of the Merger Agreement and the transactions contemplated thereby, see "Item 1A — Risk Factors — Risks Relating to Our Proposed Acquisition by Thoatec", Form 8-K filed on February 13, 2009 and the definitive proxy statement to be filed with the SEC in connection with the Merger.

Market Opportunity

Heart Failure

Heart failure is one of the leading causes of death in the developed world. The American Heart Association estimates that heart failure affects over 5 million people in the United States alone. Heart failure is a cardiovascular disease with both an increasing incidence and death rate. Each year, approximately 600,000 new cases are diagnosed and 300,000 patients die from advanced heart failure in the United States.

The HeartWare System supports patients suffering from advanced stage heart failure. 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, it will tend to work harder in an effort to supply adequate blood flow into the aorta. The increased effort results in dilation, or enlargement, of the ventricle, rather than increased blood flow. This dilation then makes it harder for the heart to contract effectively which results in even lower blood flow and increased effort and further dilation of the ventricle. This progressive, degenerative process generally continues until the patient becomes debilitated and eventually dies from inadequate clearing of the lungs and inadequate flow of oxygenated blood throughout the body. The inadequate lung clearance or lung congestion is why the advanced stages of heart failure are called congestive heart failure, or CHF.

Our Target Markets—Class III and Class IV Patients

Our devices will be targeted primarily to advanced stage heart failure patients, or Class III and IV patients as defined by the New York Heart Association ("NYHA"). We estimate 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 be assisted by a circulatory assist device. We believe that there is a significant market opportunity for ventricular assist devices, or VADs, that are smaller, easier to use and more reliable than the devices that are currently available.

We estimate 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 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 would be candidates for a less invasive surgical approach such as the one we are developing with the MVAD. We believe that this 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

Heart transplantation is the only current curative therapy and ultimately provides the best recovery of cardiac function. Heart transplantation has become 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 up to ten years. 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.

Drug treatment and pacing devices that are designed to stimulate the heart do not halt the progression of CHF. Other approaches such as devices that allow physicians to reduce the size of the heart and cell based therapy are either in the early development stages or are otherwise not achieving outcomes that lead physicians to see them as viable solutions. Pharmacologic management of CHF focuses primarily on increasing the force of heart contractions. Drug regimens aim to improve the effectiveness of the heart's contractions and slow CHF progression but some investigations have suggested that the increase in survival is limited and that drug treatments merely delay the advance of CHF.

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 that has been shown to fully rehabilitate a patient from NYHA Class IV to Class I. 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."

A large population of end-stage heart failure patients can benefit from LVAD therapy, such as our HeartWare System. Within this population there are 3 different indications of use of LVADs: "bridge-to-transplant" 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 only 1,802 transplants conducted in the United States in 2008. We estimate that approximately 58% of patients spend 1 year or more on the transplant waiting list and approximately 37% of patients wait as long as 3 years or more. As of February 2009, 2,762 people are on the transplant waiting list in the United States. We estimate that approximately 30% of current transplant patients receive an LVAD as a bridge to transplant, meaning that the LVAD implantation is intended to stabilize the patient until a heart transplant becomes possible. 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 comfortable with the technology and confidence in the procedure grows in line with improving clinical data and device reliability.

Destination therapy — Circulatory assist devices can be used as a permanent or quasi-permanent therapy in those patients who are not candidates for heart transplantation due to, for example, their age or the presence of other diseases. The National Institutes of Health, or 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 is currently the only alternative but even with drug therapy the 12-month mortality rate is approximately 75%. We believe that device durability and reliability, together with ease of implantation, are important factors in determining whether destination therapy 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 shown recently 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. Confirmatory studies are underway in the United States by Thoratec Corporation, which has established the Harefield Recovery Protocol Study, or HARPS, with initial patient enrollment in the trial occurring in the first half of 2007. 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 clinical risks presented by pumps that are left in place for multiple years.

Our Solution and Products

Proprietary Pump Technology

The HeartWare System features the smallest 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, or rotor, which is the only moving part within the pump. The impeller is suspended within the pump housing through a combination of passive magnets and a hydrodynamic thrust bearing. The hydrodynamic thrust bearing operates by establishing a "cushion" of blood between the impeller and the pump housing. 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" mechanism.

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 friction or mechanical contact within the pump. We believe that this removal of contact should lead both to longer term reliability of the device and to a 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.

The HeartWare System

The first product in our portfolio, the HeartWare System, comprises 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 centrifugal pump designed to be implanted above the diaphragm in all patients. We believe the reduced surgical complexity involved in implanting the HeartWare System in the pericardial space generally leads to significantly shorter surgery time and a less invasive procedure relative to alternative devices, which are generally implanted in the abdomen.

Device reliability of the HeartWare System is 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 is approved for sale in Europe. In the United States, we must obtain Premarket Approval ("PMA") approval before the HeartWare System can be commercialized. In August 2008, we began our US bridge-to-transplant clinical trial after receiving approval of an Investigational Device Exemption by the FDA.

The HeartWare MVAD

The MVAD, currently under development, is a miniaturized device intended for chronic heart failure patients. The current design is a full-output axial flow pump with a fully suspended rotor and a 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 only minimally invasive surgery. The device will be implanted without the surgeon having to make an incision through the midline of the breastbone, or sternum, in order to gain access to the heart (a median sternotomy).

By way of comparison, one of the key breakthroughs that led to an expansion of the defibrillator market was the elimination of the sternotomy. We are hopeful that this will hold true for LVADs when the MVAD is introduced. We believe it is likely that many more patients will be willing to undergo a minimally invasive surgical procedure than are currently comfortable with the full sternotomy required for an LVAD implantation. We expect physician referrals to increase substantially for the same reason. We anticipate that the MVAD will increase the potential pool of eligible patients in the United States from the 100,000 per year who would be candidates for the HeartWare LVAD System to approximately 300,000.

The first MVAD preclinical studies began in August 2005. Animal studies are on-going 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;
- finalization of device (pump) prototypes and performance of confirmatory in-vivo (animal) studies;
- development 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 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. This system will be designed to provide inductive energy transfer, or recharging, across the skin, eliminating the need for a driveline and allowing implantation of the complete LVAD system, including the controller and batteries. TET technology is already used to recharge neurostimulators and other implantable electronic devices.

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. The implantable system is in the early stages of development. Before the implantable system will be available for clinical trials, the Company 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 and regulatory approvals.

We anticipate that our on-going development efforts in this area, aided by the continuing improvements in electronics and battery technologies, will result in the development of an implantable system that will be attractive to both physicians and patients alike.

We believe that the Company may also have a unique opportunity to provide a leading TET system due to the inherently lower power consumption and energy efficiency advantages in the HeartWare System as compared with other devices.

Our Business Strategy

Our goal is to be at the forefront of innovation in the LVAD sector by maintaining 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 provides us with a significant competitive advantage in the market. To capitalize on that advantage, our strategy is to begin commercial sales in Europe and to obtain regulatory approval for our initial product, the HeartWare System, for sale in the United States, while at the same time continuing to develop new products. Our plan includes:

Commercially launch the HeartWare System in Europe and Australia — With the recent receipt of CE Marking we continue to develop the necessary infrastructure to support commercial sales in Europe. We will adopt primarily a direct sales strategy and will focus initially on sites with which we already have existing relationships through our clinical trials. We expect to file for Therapeutic Goods Administration, or TGA, approval in Australia in the first half of 2009.

Obtain regulatory approval in the United States — In September 2008, we received a full Investigational Device Exemption from the FDA and commenced a 150 patient clinical trial in up to 28 centers. Completion of this trial will support an application for PMA and eventual commercial sales in the United States.

Continue our sales and marketing activities — We intend to launch programs and services to support the execution of the clinical trials in the United States and the commercial launch of our system in Europe and Australia in 2009, improve our product management processes, and build an infrastructure of sales and marketing personnel outside of the US, and build distribution channels and ordering systems to deliver our products to the market on a commercial scale.

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 TET. Our first MVAD animal studies began in August 2005, and in 2007 and 2008 we conducted animal studies focused on minimally invasive surgical techniques. We have a working prototype of our TET system, which we expect will improve patients' quality of life by eliminating the need for an external driveline. We expect development work for our TET system to continue throughout 2009. We are also continuing to develop enhancements to our existing HeartWare System peripheral equipment based upon early clinician and patient feedback as well as continuing to develop physiological control algorithms. The 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 — Our Advisory Board is comprised of leading professionals in the fields of cardiovascular surgery and cardiology. We have established relationships with several leading 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

There are tens of thousands of cardiologists around the world who manage patients with heart failure. Within the cardiology community, the three key categories that are applicable to HeartWare are general, heart failure and interventional cardiologists. The majority of cardiologists are "general" cardiologists. These physicians receive referrals from general practitioners and perform the initial diagnostic procedures which determine whether or not patients have heart disease and what type of heart disease they have. If the disease is coronary artery disease, the patients will be referred to either an interventional cardiologist, who can implant coronary stents or, if the disease is more advanced, to a cardiac surgeon who can perform a coronary artery bypass procedure. If the diagnosis is one of a structural anomaly of the heart such as heart failure, then the referral may go to the cardiac surgeon or to a heart failure cardiologist. The heart failure cardiologist may elect to refer the patient to a cardiac surgeon or an electrophysiologist for the implantation of a pacemaker device or to otherwise manage the patients' disease themselves. Cardiac surgeons implant circulatory assist devices and, as such, they represent our key target market for the HeartWare System.

We are currently establishing distribution capabilities, clinical support staff and training in Australia and Europe to support the commercial launch of the HeartWare System. We will expand our clinical support personnel with a view to supporting the hospital sites for our US clinical trial. Key to the development of our business is the creation of effective training and commercial support materials that educate the target clinicians and patients seeking information on VADs about the advantages of the HeartWare System. In addition, we will partner with leading physicians in the field (Key Opinion Leaders) to ensure clinical data about our system is being presented at scientific symposia, congresses, and trade shows, as well as ensure clinical results are published for mass distribution in peer reviewed cardiovascular journals.

We intend to work with a broad spectrum of health care industry participants to promote the clinical benefits of our device, including hospital administrators, cardiac surgery centers, cardiologists, surgeons, physicians, insurers and government and industry representatives. We will seek to establish strong relationships with key personnel within the hospital supply chain, including managers with authority for making equipment purchase decisions.

We also plan to recruit and train a direct sales force to market our product in Europe and Australia and engage distributors where appropriate. We expect that our Australian operations center will serve as a base of operations to enter the Asian market for the HeartWare System.

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 16 issued US patents and 11 issued Australian patents, 3 issued patents in each of Germany, the United Kingdom and France, as well as patents issued in the Netherlands, Japan, Spain, Italy, Korea, Canada, Italy and Israel. We also have 37 pending US patent applications and a number of international patent applications filed under the Patent Cooperation Treaty, as well as in Japan, Europe, Australia, China, India, Korea and Israel.

Our US 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. Pending patent applications covering technologies for MVAD pump technology, if granted, will expire in 2024 and 2025.

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 are aware of other companies developing ventricular assist devices, including centrifugal and axial flow ventricular assist devices and of patents and published patent applications held by these companies in those fields. To this end, we have reviewed all ventricular assist device patents owned by third parties of which we are aware and believe that our current products do not infringe any valid claims of the third party patents that we have analyzed. There are a large number of patents directed to ventricular assist device therapies, however, and there may be other patents or pending patent applications of which we are currently unaware that may impair our ability to operate. We are currently not aware of any third parties infringing our issued claims.

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 legal proceedings that relate to patents or proprietary rights.

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

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

Each of our heart pumps will be regulated by the FDA as a medical device under the US Food, Drug, and Cosmetic Act. FDA regulations govern:

- product design and development;
- product testing;
- product manufacturing;
- product safety;
- product labeling;
- product storage;
- record keeping;
- pre-market 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).

Each product that we currently plan to distribute commercially in the United States will require a PMA from the FDA. Because our pumps are implanted devices, they are deemed to pose a significant risk. To market our products in the United States, the FDA must approve the device following a Company submission for PMA. The FDA can also impose restrictions on the sale, distribution or use of devices at the time of their clearance or approval, or subsequent to marketing.

Premarket Approval

Each of our devices will be regulated as a Class III medical device. Obtaining a PMA from the FDA is required before marketing of a Class III medical device in the United States can proceed. The process of obtaining a PMA is costly, lengthy and uncertain. A PMA 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 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 labeling.

If the FDA determines that a PMA is complete, the FDA accepts the application and begins an in-depth review of the submitted information. The FDA, by statute and regulation, has 180 days to review an accepted pre-market approval 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. A review panel may be convened as part of any FDA review of our HeartWare System. In addition, the FDA will conduct a pre-approval inspection of our and our suppliers' facilities to evaluate compliance with the quality system regulation. They may also conduct a Bioresearch Monitoring ("BIMO") inspection of the clinical trial including the clinical data sites. Under the Medical Device User Fee and Modernization Act of 2002, the fee to submit a PMA can be up to $185,000 per PMA, but certain companies, like HeartWare, may qualify for a small business exemption. PMA supplements are required for modifications to the manufacturing process, labeling, use and design of a device that is approved through the pre-market approval process. PMA supplements often require submission of the same type of information as a PMA except that the supplement is limited to information needed to support any changes from the device covered by the original PMA.

Clinical Trials

A clinical trial is required to support a PMA. We have begun our US clinical trial under an Investigational Device Exemption that will allow us to enroll 150 patients in up to 28 sites. 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.

Pervasive and Continuing FDA Regulation

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 and adverse event reporting 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 5 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 expect to submit for TGA approval early in 2009.

Other Regulations

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

Third Party Reimbursement

In the United States, hospitals and doctors generally rely on third-party payers, such as Medicare, private health insurance plans and health maintenance organizations to reimburse 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 2001, the Center for Medicare and Medicaid Services, or CMS, filed a notice that implantable ventricular assist devices would be reimbursed under Diagnosis Related Group ("DRG") 103, which is the highest DRG and covers heart transplantation. Using the new published payment rates, the base Medicare payment to CMS-certified centers increased to $136,000. 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 DRG 103 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 US policies for circulatory assist devices, including Blue Cross and Blue Shield but such coverage may not be available if insurance providers refuse to cover "experimental devices". We believe that many private insurers will cover our devices if they are also covered by Medicare.

European 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, the physician will continue to drive the decision as to which LVAD to purchase.

Competition

Competition in the LVAD industry is expected to increase as better devices become available. In the long run, we believe that only smaller, less invasive, reliable and durable devices will remain as viable alternatives for the treatment of congestive heart failure.

Our principal competitors include Thoratec Corporation, World Heart Corporation, Jarvik Heart, MicroMed Technology, Inc, Ventracor Limited, Berlin Heart AG, Abiomed, Inc. and Terumo Heart, Inc., and a range of other smaller, specialized medical device companies with devices at varying stages of development. We are not aware of whether any of these competitors is currently developing a new full-output pump that is equivalent in size or smaller than the HVAD Pump and which might be implanted by similar techniques. Further, there may be companies unknown to us that are developing competitive pumps of lesser or similar output levels or other competitive products, and we can offer no assurance that the above competitors or these other parties will not be successful in their efforts.

We believe that the key features of our technology that provide us with an advantage over our competitors' products include:

- small device size which allows for routine implantation in the space immediately surrounding the heart in all patients, known as the pericardial space, in all patients unlike other full-output LVADs that are currently available;
- a hybrid passive magnetic and hydrodynamic impeller suspension system which eliminates the need for mechanical bearings, providing a "wearless mechanism"; and
- a design that includes a wide-bladed impeller which facilitates clear blood flow paths through the pump and an integrated inflow cannula which optimizes blood flow characteristics.

Although we believe our technology provides us with a competitive advantage over our competitor's products, we note that:

- our products are in the early stages of development, we have limited implantation experience, and our success is dependent on our clinical trials proving the safety and efficacy of our products;
- a number of our competitors have significantly greater financial and human resources than we do and have established reputations, as well as worldwide distribution channels and sales and marketing capabilities that are larger and more established than ours; and
- our market is an emerging market and is reliant upon acceptance of LVAD technology.

Research and Development

From the date of our inception through December 31, 2008, we have incurred approximately $55.7 million on research and development of our technologies. Research and development costs include activities related to the research, development, design, testing, and manufacturing of prototypes of our products. It also includes clinical activities and regulatory costs. Research and development costs also include cost associated with certain HeartWare employees engaged in research and development activities, as well as external consultants and contractors that we may engage from time to time; along with a portion of the overhead costs we incur to operate our manufacturing facility. We expect our research and development expenses to increase significantly as we continue the development of our HeartWare System, initiate commercialization activities, research the application of, and develop our miniaturized heart pump technology, conduct additional clinical trials and hire additional employees.

Manufacturing

Our manufacturing activities to date**,** and for the foreseeable future, will continue to consist primarily of process development, component assembly, quality control testing and research and development activities. We manufacture products for commercial sale in Europe and for clinical trials in the United States.

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.

A number of critical components of our HeartWare System, including the center post, pump housing and impeller, are provided by outside suppliers and then assembled and tested by us in-house. We do not presently have supply agreements with all of our suppliers and we have not secured second source suppliers for some of our critical suppliers.

Employees

As of December 31, 2008, we had 111 employees, of whom approximately 86 employees are engaged in operations activities including research and development, quality assurance and manufacturing activities, 13 are engaged in marketing and clinical activities and 12 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 legal proceedings.

Corporate History

HeartWare International, Inc. was incorporated in the State of Delaware on July 29, 2008 as a wholly-owned subsidiary of HeartWare Limited, a corporation incorporated in Australia on November 26, 2004. On November 13, 2008, HeartWare Limited completed its redomiciliation from Australia to Delaware pursuant to certain schemes of arrangement approved by an Australian court. In connection with this redomiciliation, each holder of HeartWare Limited ordinary shares was issued one share of HeartWare International, Inc. common stock in exchange for every 35 ordinary shares of HeartWare Limited. As a result, HeartWare Limited became a wholly-owned subsidiary of HeartWare International, Inc., and HeartWare International, Inc. became the parent company of the HeartWare Group.

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., or Kriton, 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., and 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 was 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 88 million shares and a convertible note in the principal amount of $1.1 million. The convertible note was redeemed during the third quarter of 2008.

As described under the heading of "Proposed Acquisition by Thoratec" of this Item 1, on February 12, 2009, we entered into the Merger Agreement, pursuant to which Merger Subsidiary will merge with and into HeartWare, with HeartWare continuing as the surviving corporation (the "Merger") and, if the stock value of the consideration is at least 41% of the aggregate merger consideration at closing, immediately following the Merger, HeartWare, as the surviving corporation in the Merger, will merge with and into Merger Subsidiary Two, with Merger Subsidiary Two continuing as the surviving corporation and a wholly owned subsidiary of Thoratec. For a description of the risks associated with our proposed acquisition by Thoratec, see "Item 1A — Risk Factors — Risks Relating to Our Proposed Acquisition by Thoratec."

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 Relating to Our Proposed Acquisition by Thoratec

We and Thoratec may not meet the closing conditions which could result in failure of the acquisition of us by Thoratec.

Thoratec's acquisition of us is conditioned upon various closing conditions set forth in the Merger Agreement, which include, among other things, adoption of the Merger Agreement by HeartWare's stockholders, the absence of legal impediments to consummation of the Merger and the expiration or termination of the required waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. We and Thoratec cannot predict whether and when these conditions will be satisfied. If for any reason the conditions are not satisfied, Thoratec will not be obligated to complete its acquisition of us.

If the proposed acquisition by Thoratec is delayed or is not completed, we may not have sufficient liquidity to continue to operate.

At December 31, 2008, we had approximately $20.8 million in cash and cash equivalents. In connection with the Merger Agreement, Thoratec also provided us with a convertible loan facility of up to $28 million to help fund our operations until the anticipated closing of the acquisition, however in certain circumstances, advances outstanding under this loan facility could accelerate and become due and payable in full in accordance with the Loan Agreement. We estimate these funds are sufficient to support our operations for at least the next twelve months. While we operate under the Merger Agreement with Thoratec, we are not permitted to seek additional financing through the sale of equity or debt securities without Thoratec's consent. If the proposed acquisition by Thoratec is delayed, we may not have sufficient funds to complete the transaction without drawing down the loan facility. If the Merger is ultimately not completed, we will require additional financing to continue to operate. There can be no assurance that such additional financing will be available at that time on commercially acceptable terms if at all.

If the proposed acquisition by Thoratec is not completed, we will have incurred substantial costs that may adversely affect our financial results and operations and the market price of our common stock, whether traded in the form of common stock or CDIs.

If the proposed acquisition by Thoratec is not completed, the price of our common stock, whether traded in the form of common stock or CDIs, may decline to the extent that the current market price of our common stock reflects a market assumption that the proposed acquisition by Thoratec will be completed. In addition, we have incurred and will incur substantial transaction costs and expenses in connection with the proposed acquisition by Thoratec. These costs are primarily associated with the fees of attorneys, accountants and our financial advisors. In addition, we have diverted significant management resources in an effort to complete the proposed acquisition by Thoratec and are subject to certain restrictions contained in the Merger Agreement on the conduct of our business. If the proposed acquisition by Thoratec is not completed, we will have incurred significant costs, including the diversion of management resources, for which we will have received little or no benefit. Also, if the proposed acquisition by Thoratec is not completed under certain circumstances specified in the Merger Agreement, we may be required to pay to Thoratec termination fees of either $5 million or $11.3 million.

In addition, if the proposed acquisition by Thoratec is not completed, we may experience negative reactions from the financial markets and our customers, stockholders, surgeons, suppliers and employees. Each of these factors may also adversely affect the trading price of our common stock and our financial results and operations.

The proposed acquisition by Thoratec is subject to the receipt of consents and approvals from government entities that may impose conditions that could have an adverse effect on us and could cause abandonment of the acquisition.

Completion of the Merger is conditioned upon, among other things, the expiration or termination of the required waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. The reviewing authorities may not permit the Merger at all or may impose restrictions or conditions on the Merger that may seriously harm the surviving company if the Merger is completed. Any delay in the completion of the Merger could diminish the anticipated benefits of the Merger or result in additional transaction costs, loss of revenue or other effects associated with uncertainty about the transaction.

Provisions of the Merger Agreement may deter alternative business combinations and could negatively impact the stock price of HeartWare if the Merger Agreement is terminated in certain circumstances.

The Merger Agreement prohibits us from soliciting, initiating, facilitating or encouraging certain alternative acquisition of us by any third party, subject to exceptions set forth in the Merger Agreement. The Merger Agreement also provides for the payment by us of a termination fee of $11.3 million if the Merger Agreement is terminated in certain circumstances in connection with a competing third-party acquisition proposal. These provisions limit our ability to pursue offers from third parties that could result in greater value to our stockholders. The obligation to pay the termination fee may also discourage a third party from pursuing an alternative acquisition proposal. If the proposed acquisition by Thoratec is terminated and we determine to seek another business combination, we cannot assure you that we will be able to negotiate a transaction with another company on terms comparable to the terms of the Merger, or that we will avoid incurrence of any fees associated with the termination of the Merger Agreement. In the event the Merger Agreement is terminated, our stock price may decline.

Risks Relating to Our Business

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

We are a development stage company with a limited operating history. We have incurred net losses since our inception, including net losses of $23.8 million and $21.9 million for the fiscal years ended December 31, 2008 and 2007, respectively. As of December 31, 2008, our deficit accumulated during the development stage was $77.0 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. We continue to incur 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 clinical trials,
- continuing further product research and development,
- seeking regulatory approvals,
- expanding our sales and marketing capabilities,
- increasing our manufacturing operations, and
- complying with the requirements related to being a public company.

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 or otherwise generate revenues sufficient to achieve profitability. If we do achieve profitability, we may not be able to sustain it.

Our products may never achieve market acceptance.

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 side effects;
- potential advantages over alternative treatments or competitive products;
- the strength of marketing and distribution support; 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 product revenue and we may not become profitable or be able to sustain profitability.

We have limited sales, marketing and distribution experience.

To develop and increase sales, distribution and marketing capabilities, we would have to invest significant amounts of financial and management resources. In developing these sales, marketing and distribution functions ourselves, we could 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 facilities in Miami Lakes, Florida. If there were a disruption to our existing manufacturing facility, for example, due to a hurricane, 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 were unable to produce sufficient quantities of our HeartWare System for sale outside the US 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.

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 technical challenges to increasing manufacturing capacity and efficiency, and developing commercial-scale manufacturing facilities would 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 the requirements for the launch of the product or to meet future demand, if at all.

If we are unable to manufacture a sufficient or consistent supply of the HeartWare System, 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, all of our capital raising activities has been undertaken in Australian dollars while most of our expenditures are incurred in US dollars. Our international sales will be denominated in local currencies, not US dollars and fluctuations in foreign currency exchange rates could impact reported revenue and earnings. We try to mitigate our exposure to currency exchange risks by holding some funds in US dollars.

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 will be limited to commercial sales outside of the US and from our clinical trial within the United States. Our cash and cash equivalents on hand and expected cash flows from operations, including expected sales, will not be sufficient to fund our operations for the next twelve months. In connection with its proposed acquisition of us, Thoratec has provided us with a convertible loan facility of up to $28 million to fund ongoing operations until the closing of the transaction, which is expected to occur in the second half of 2009. If the acquisition is not completed, we will need to seek additional funding. 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., or Kriton, 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 to receive a payment if there is a deemed liquidation event of HeartWare, Inc. may restrict our ability to structure our Company and its operations and could inhibit our ability to obtain financings.

Our products have not yet been approved for commercial sale within the United States, and our success will depend heavily on the success of our clinical trial program for our lead device, the HeartWare System. If we are unable to complete, or experience significant delays of, our US trial, 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 harmed.

In 2008, we completed enrollment for our international clinical trial by implanting our 50th patient with our lead device, the HeartWare System. On January 30, 2009, we received approval for CE Marking and expect to sell the HeartWare System outside of the US in 2009. However, future revenue will be limited if we do not receive regulatory approval to commercially sell our products in the United States.

In November 2007, we made a submission to the FDA for an IDE to commence a bridge-to-transplant clinical trial in the United States for our HeartWare System. In 2008, we received full IDE approval and commenced the trial in September 2008. The purpose of the proposed study is to evaluate the safety and effectiveness of the HeartWare System in patients eligible for cardiac transplantation with refractory, advanced heart failure. The proposed primary endpoint is survival for heart transplantation, survival to explant for myocardial recovery, or survival to 180 days on device support, whichever occurs first. As of January 31, 2009, we have completed implants in 7 patients with cumulative support duration of more than 300 days.

Completion of our clinical trial program could be delayed or adverse events during the trial could cause us to 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 or by us. Any failure or significant delay in completing clinical trials for our product candidates will harm our financial results and the commercial prospects for our product candidates.

The completion of our clinical trial program 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 equivalent products that have received approval for sale;
- failure of patients to complete the clinical trial;
- patients preferring to use approved devices rather than experimental devices such as our HeartWare System;
- unforeseen safety issues;
- lack of 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; and
- varying interpretation of data by regulatory agencies.

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.

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 will have a material adverse effect on our business, financial condition or results of operations.

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 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 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 US 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 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. In October 2008, we received a Certificate of Registration certifying that the Company's Quality Management System complies with the requirements of ISO 13485:2003. If we fail to continue to comply with ISO regulations the FDA or European Union organizations may withdraw clearance to market, require a product recall or take other enforcement action.

Product issues could result in substantial costs and write-downs.

Our products are subject to various regulatory guidelines and are perishable. Identified quality problems or failure to sell product before it expires could result in scrapping or expensive rework of product. Quality issues could result in the recall and replacement of entire lots of products, substantial costs and write-offs and harm to our business reputation and financial results.

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

Even if we obtain regulatory approvals 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. 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.

Our products may never achieve market acceptance even if we obtain regulatory approvals.

Even after we obtain regulatory approvals 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 side effects;
- potential advantages over alternative treatments or competitive products;
- the strength of marketing and distribution support; and
- sufficient third party coverage or reimbursement.

If our HeartWare System, or any other product that we may develop, is approved but does not achieve an adequate level of acceptance by physicians, patients, health care payers and the medical community, we may not generate product revenue and we may not become profitable or be able to sustain profitability.

If we fail to obtain an adequate level of reimbursement for our products by third party payers, there may be no commercially viable markets for our product candidates or the markets may be much smaller than expected.

The availability and levels of reimbursement by governmental and other third party payers affect the market for our product candidates. The efficacy, safety, performance and cost-effectiveness of our product candidates and of any competing products will determine the availability and level of reimbursement. Reimbursement and health care payment systems vary significantly by country, and include both government sponsored health care and private insurance. 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. We may not obtain reimbursement or pricing approvals in a timely manner or at all. Our failure to receive reimbursement or pricing approvals would negatively impact market acceptance of our products in the markets in which those approvals are sought.

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. In addition, third party payers continually attempt to contain or reduce the costs of health care by challenging the prices charged for health care products and services. 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 adversely affected.

If hospitals do not conduct destination therapy procedures using the HeartWare System, market opportunities for our product will be diminished.

If hospitals do not conduct destination therapy procedures using our products, 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 hospital's 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.

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 applicable regulatory standards to manufacture a sufficient supply of our products. In addition, the FDA must approve facilities that manufacture our products for US 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 of, 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.

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 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. We are in the process of negotiating supply agreements with our key suppliers but have not formalized any supply arrangements, with the exception of the productions service agreement described below.

We have second-source suppliers for many, but not all, of our components. If, however, any critical components are not delivered on time or at all or are delivered outside of specifications, for any reason, contractual or otherwise, our business may be seriously harmed financially. Additionally, significant changes to our components may require product redesign and new regulatory clearances, either of which could significantly delay or prevent production or involve substantial cost.

We are in the process of negotiating a production services agreement with Minnetronix, Inc., located in Minnesota, as the supplier of the patient monitor and controllers. A prior agreement expired on August 17, 2008. Though we continue to receive production services from Minnetronix, we cannot guarantee that we will be able to successfully negotiate a new agreement. Even if we do reach a new agreement, and although we submit 12-month forecasts to Minnetronix, we cannot assure you that they will be able to have the capacity to accommodate our demand in a timely manner.

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 process, 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 entering into and renewing agreements with one or more external parties to manufacture components of our technology. If we 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 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. As of December 31, 2008, we have 16 issued US patents and 11 issued Australian patents, 3 issued patents in each of Germany, the United Kingdom and France, as well as patents issued in the Netherlands, Japan, Spain, Italy, Korea, Canada, Italy, and Israel. We also have 37 pending US patent applications and a number of international patent applications filed under the Patent Cooperation Treaty, as well as in Japan, Europe, Australia, China, India, Korea and Israel. Our pending and future patent applications may not issue as patents or, if issued, may not issue in a form that will provide us any competitive advantage. Even if issued, existing or future patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of terms of patent protection we may have for our products. 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 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.

Intellectual property litigation could be costly and disruptive to us.

From time to time, third parties may assert patent, copyright, trademark and other intellectual property rights to technologies used in our business. Any claims, with or without merit, could be time-consuming, result in costly litigation, divert the efforts of our technical and management personnel and require us to pay substantial damages. If we are unsuccessful in defending ourselves against these types of claims, we may be required to do one or more of the following:

- stop our ongoing or planned clinical trials or delay or abandon commercialization of the product that is the subject of the suit;
- attempt to obtain a license to sell or use the relevant technology or substitute technology, which license may not be available on reasonable terms or at all; or
- redesign those products that use the relevant technology.

In the event a claim against us was successful and we could not obtain a license to the relevant technology on acceptable terms or license a substitute technology or redesign our products to avoid infringement, our business would be significantly harmed.

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. We generally seek to protect this information by confidentiality 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 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 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 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. In addition, we will need to manage relationships with various 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.

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 and Ventracor Limited, as well as several private companies, such as Jarvik Heart, Inc and Terumo Heart, Inc. Some of these competitors have significantly greater financial and human resources than we do and have established reputations or products, as well as distribution channels and sales and marketing capabilities that are larger and more established than ours. 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.

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:

- 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.

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. 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 other than for Mr. LaRose, our Chief Scientific Officer. 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 carries an inherent risk of product liability claims. Such liability claims may be expensive to defend and may result in large judgments against us. 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 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. Such claims against us, regardless of their merit, could result in significant awards against us that could materially harm our business, financial condition and results of operations.

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 an 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 this Annual Report on Form 10-K. The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures, and internal control over financial reporting as of December 31, 2008. Based on that evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures, and internal control over financial reporting are effective as of December 31, 2008.

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. 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.

Risk Factors 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 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. For example, the closing price of our CDIs (and previously ordinary shares of HeartWare Limited) traded on the ASX has ranged from AU$0.35 to AU$0.65 in the 12 months ended December 31, 2008. In addition, our shares of common stock began trading on the NASDAQ on February 24, 2009. Prior to that time, there had been no public market for our common stock in the United States. If an active trading market for our common stock does not develop in the United States, the market price and liquidity of our common stock may be adversely affected. 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 concerning us or our competitors;
- regulatory developments, enforcement actions bearing on advertising, marketing or sales, and disclosure regarding completed, ongoing or future clinical trials;
- quarterly variations in operating results, 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;
- fluctuations in the economy, world political events or general market conditions; and
- failure to complete the acquisition of us by Thoratec.

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.

Your interests may differ or conflict with those of the Company's largest shareholder.

As of December 31, 2008, Apple Tree Partners I, L.P., or Apple Tree, owned approximately 30% of our outstanding shares. As a result, Apple Tree has and will continue to have significant influence over the outcome of any matter, including a change of control, requiring approval of holders of shares. The interests of Apple Tree may differ from or conflict with the interests of other shareholders regarding a potential change of control of us or other matters requiring a vote of shareholders. Apple Tree's significant influence over us and our subsidiaries may delay or prevent a change in control even if desired by the other holders of shares, which could adversely affect the trading price of the shares.

If there are substantial sales of common stock, our share price could decline.

If our existing shareholders sell a large number of shares or the public market, should one develop, perceives that existing shareholders might sell a large number of shares, the prices at which our shares may trade could decline significantly. Sales of substantial amounts of shares by shareholders in the public market, or even the potential for such sales, are likely to adversely affect the market price of the shares.

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 shareholders 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 DGCL, 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 Nasdaq. 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.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

Our corporate headquarters are located in Framingham, Massachusetts. We have an administrative office in Sydney, Australia and an operations and manufacturing facility in Miami Lakes, Florida.

Our office in Framingham, Massachusetts consists of 7,040 square feet of office space. The lease expires on January 31, 2013.

The Sydney, Australia office space is approximately 400 square feet. The lease expires in June 2009 and we do not have a right to renew this lease. However, we expect to be able to renew the lease on favorable terms if so desired.

We also leased an operations and manufacturing facility in Miami Lakes, Florida. The facility is 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 commenced on April 28, 2008 and the term of the lease is for an initial period of three years with 2 five year extensions.

Our manufacturing activities to date consist primarily of process development, component assembly, quality control testing and research and development activities. Currently, approximately two-thirds of our space in Miami Lakes is being used for these production activities.

We believe that our main facility located in Miami Lakes, Florida and our other office spaces are suitable and adequate for our needs now and for the foreseeable future notwithstanding that we may consider alternative operations facilities as noted above. We believe that the current or any replacement facilities of ours and our specialized suppliers will be sufficient to meet our needs now and for the foreseeable future. We intend to continue utilizing our suppliers and assembling our products for the foreseeable future in the same manner in which we have been operating.

Item 3. LEGAL PROCEEDINGS

None.

Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Reference is made to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 22, 2008.

Part II

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

Our shares of common stock trade in the form of CHESS Depository 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" as of November 13, 2008. Prior to that date, our ordinary shares of HeartWare 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 price of the CDIs of HeartWare International, Inc. (and previously ordinary shares of HeartWare Limited) as traded on the ASX, in Australian and as converted to US dollars.

Period	High (AU$)	Low (AU$)	High (US$)	Low (US$)
Fiscal Year 2008:				
First Quarter	0.55	0.35	0.51	0.32
Second Quarter	0.65	0.36	0.63	0.34
Third Quarter	0.64	0.40	0.51	0.32
Fourth Quarter	0.62	0.40	0.50	0.28
Fiscal Year 2007:				
First Quarter	0.87	0.64	0.70	0.52
Second Quarter	0.92	0.60	0.78	0.51
Third Quarter	0.65	0.55	0.57	0.49
Fourth Quarter	0.80	0.53	0.71	0.47

As of January 31, 2009, the Company had 8,866,702 shares of common stock issued and outstanding and there were 1,302 holders of record of our common stock.

Commencing February 24, 2009, our shares of common stock trade on the Nasdaq Global Market under the symbol of "HTWR".

We have not declared or paid any dividends on our shares and do not anticipate doing so for the foreseeable future.

Equity Compensation Plans

The following table sets forth information regarding the Company's Equity Compensation Plans as of December 31, 2008:

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	629,936	$ 16.89	345,401
HeartWare International, Inc. Restricted Stock Unit Plan	142,846	$ 0.00	6,154
HeartWare International, Inc. 2008 Stock Incentive Plan	—	N/A	469,140
Equity compensation plans not approved by security holders:			
Non-Plan options	68,438	$ 18.02	N/A

Item 6. SELECTED FINANCIAL DATA

The following selected consolidated statement of operations data for the years ended December 31, 2008, 2007 and 2006 and for the period from November 26, 2004 (inception) to December 31, 2008 and the balance sheet data as of December 31, 2008 and 2007 have been derived from our consolidated audited financial statements included elsewhere in this Annual Report on Form 10-K. The following selected consolidated statement of operations data for the year ended December 31, 2004 and balance sheet data as of December 31, 2005 and 2004 have been derived from our consolidated audited 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 redomiciliation mentioned above, 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 redomiciliation transaction, whether such information pertains to a date or period of time subsequent or prior to the redomiciliation transaction.

On January 24, 2005, HeartWare Limited (the "Successor") acquired all of the voting stock of HeartWare, Inc., a Delaware corporation (the "Predecessor"). Our consolidated financial statements reflect the results of the Predecessor for all periods after January 24, 2005. The selected financial data for the Predecessor are derived from the audited financial statements which are not included in this Annual Report on Form 10-K.

	Successor					Predecessor	
		Years Ended December 31,			Cumulative Period from November 26, 2004 (Inception) Through December 31,	Year Ended December 31,	Cumulative Period from April 8, 2003 (Inception) Through December 31,
(In thousands, except per share data)	2008	2007	2006	2005	2008	2004	2004
Statement of Operations Data:							
Revenues	$ 332	$ —	$ —	$ —	$ 332	$ —	$ —
Cost of revenues	78	—	—	—	78	—	—
General and administrative expenses	10,981	7,303	6,024	4,312	28,620	138	304
Research and development expenses	18,644	14,636	11,650	10,732	55,662	4,795	6,066
Depreciation	—	—	—	—	—	88	123
In process research and development expensed when acquired	—	—	—	—	—	—	3,984
Other income (expense), net	5,607	—	248	1,211	7,066	(982)	(1,230)
Provision for income taxes	—	—	—	—	—	—	—
Net loss	(23,764)	(21,939)	(17,427)	(13,833)	(76,963)	(6,003)	(11,707)
Basic and diluted loss per share	(3.00)	(3.60)	(3.49)	(3.67)			

	As of December 31,				As of December 31,
	2008	2007	2006	2005	2004
Balance Sheet Data:					
Cash and cash equivalents	$ 20,804	$ 28,276	$ 16,698	$ 10,037	$ 139
Total assets	30,338	32,355	20,243	11,970	372
Total liabilities	3,583	3,083	2,779	2,245	12,027
Total shareholders' equity	26,756	29,272	17,464	9,725	11,654

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

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 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.

Overview

HeartWare is a medical device company focused on developing the world's smallest implantable pumps 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.

The HeartWare System received CE Marking, which allows us to sell the device in Europe, in January 2009 and is the subject of clinical trials under an FDA Investigational Device Exemption ("IDE") clinical trial in the United States for a bridge-to-transplant application.

In 2008, we successfully completed enrollment of a combined European and Australian human clinical trial for the HeartWare System. This international trial began in March 2006 and called for the implantation of 20 patients. The trial had been expanded to permit enrollment of 50 patients so as to provide increased depth of clinical data. Enrollment in this trial was the basis for application for and subsequent receipt of approval to CE Marking the HeartWare System.

In April 2008, we received Conditional IDE approval from the FDA and began enrolling centers for a US bridge-to-transplant clinical study. In August 2008, our first patient in the United States received the HeartWare System at Washington Hospital Center in Washington, DC. This marked the start of our US bridge-to-transplant clinical trial, under which 150 patients awaiting heart transplantation will be enrolled at up to 28 participating centers. Full IDE approval was received in September 2008.

Beyond the HeartWare System, we are also evaluating our next generation device, the Miniaturized Ventricular Assist Device, or 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. The MVAD, which is currently at the prototype stage and undergoing animal studies focused on minimally invasive implantation techniques, is approximately one-third the size of the HVAD Pump. We believe that the MVAD will be implantable by surgical techniques that are even less invasive than those required to implant the HVAD Pump.

We are a development stage company with a limited operating history. To date, we have generated limited revenue from our product sales and we have incurred net losses in each year since our inception. We also have generated limited income from interest. We expect our losses to continue and to increase as we expand our clinical trial activities, seek regulatory approvals and initiate commercialization activities.

We have financed our operations primarily through the issuance of common shares. In January 2005, we issued shares through an initial public offering in Australia and a concurrent US private placement of shares which raised aggregate net proceeds of approximately $23.4 million. We also issued shares through private placements to both US and Australian investors, in May 2006, July 2007 and July 2008, which raised net proceeds of approximately $23.4 million, $30.9 million and $29.4 million, respectively.

As described under the heading of "Proposed Acquisition by Thoratec" of Item 1 of this Annual Report on Form 10-K, on February 12, 2009, we entered into the Merger Agreement, pursuant to which Merger Subsidiary will merge with and into HeartWare, with HeartWare continuing as the surviving corporation (the "Merger") and, if the stock value of the consideration is at least 41% of the aggregate merger consideration at closing, immediately following the Merger, HeartWare, as the surviving corporation in the Merger, will merge with and into Merger Subsidiary Two, with Merger Subsidiary Two continuing as the surviving corporation and a wholly owned subsidiary of Thoratec. For a description of the risks associated with our proposed acquisition by Thoratec, see "Item 1A — Risk Factors — Risks Relating to Our Proposed Acquisition by Thoratec".

We are headquartered in Framingham, Massachusetts. We have an administrative office in Sydney, Australia and an operations and manufacturing facility in Miami Lakes, Florida.

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. 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, translation of foreign currency, accounting for research and development costs, accounting for share-based payments and income taxes. 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 for product sales in accordance with SEC Staff Accounting Bulletin No. 104 ("SAB 104"), *Revenue Recognition*. We ship product on a consignment basis to our customers. Revenue from product sales is only recognized when substantially all the risks and rewards of ownership have transferred to our customers (which generally occurs on the date the product is implanted), the selling price is fixed and collection is reasonably assured. Revenue recognized to date is from sales of devices in connection with our US clinical trial.

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 product line and subsequently began selling our product through our US clinical trial. Therefore, effective September 1, 2008, we adopted a policy for capitalizing inventory and recognizing cost of sales.

Prior to September 1, 2008, all costs associated with manufacturing the HeartWare System and related surgical and peripheral products were expensed as R&D costs. Until we sell the inventory for which costs were previously expensed, the carrying value of our inventories and our cost of sales will reflect only incremental costs incurred subsequent to the commencement of capitalization of inventory on September 1, 2008. As such, as we sell that portion of our existing inventory there will be a period of time where we will recognize manufacturing revenue with little or no corresponding cost. Therefore we anticipate our gross margin on sales of our product will fluctuate for the foreseeable future and will not be comparable from quarter to quarter.

Inventories are stated at the lower of cost or market. Cost is determined on a standard cost method which approximates the FIFO method. 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 can be can be held for sale or used in non-revenue clinical trials. Products consumed in non-revenue clinical trials are expensed as part of research and development costs when consumed.

Research and Development

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

Share-Based Payments

We elected to early adopt SFAS 123(R), "Share-Based Payment", effective January 1, 2005. We use a Black-Scholes option value method. Under the fair value recognition provisions of SFAS 123(R), we recognize share-based compensation net of an estimated forfeiture rate and therefore only recognize compensation cost for those shares expected to vest over the service period of the award.

Calculating share-based compensation expense requires the input of highly subjective judgment and assumptions, including estimates of expected life of the option, share price volatility and a forfeiture rate.

We estimate the volatility of our shares on the date of grant based on the historical volatility of our publicly-traded shares. We estimate the forfeiture rate based on our historical experience of past 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 at the time of grant for Australian government bonds with similar lives. When appropriate, we estimate the expected term calculation based upon the simplified method provided under SEC Staff Accounting Bulletin (SAB) No. 110. Under SAB No. 110, the expected term is developed by averaging the contractual term of the stock option grants (up to 10 years) with the associated vesting term (typically 4 years).

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.

Income Taxes

We account for income taxes in accordance with Statement of Financial Accounting Standard No. 109, or SFAS 109, *Accounting for Income Taxes*, as clarified by FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* ("FIN No. 48"). 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 SFAS No. 109.

FIN No. 48 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

The Company translates all assets and liabilities of non-US entities at the year-end exchange rate and translates expenses at the average exchange rates in effect during the year. 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 shareholders' equity, titled "Accumulated Other Comprehensive Income (Loss)." Items in Accumulated Other Comprehensive Income (Loss) are not tax affected as the Company has incurred a net loss in each period since inception.

The exchange rates between the US and Australian dollars have fluctuated significantly since inception and this exchange rate was 0.6928 AU dollars for each US dollar at December 31, 2008, resulting in a significant change in the cumulative translation adjustment for the year then ended.

In addition, HeartWare Limited, which operates in a functional currency of AU dollars, holds US dollar cash accounts. Exchange rate fluctuations affect the value of these accounts and may result in foreign currency gains and losses. Such gains and losses are included in the consolidated statements of operations. Any such gains and losses are initially recognized in AU$ and then converted to US$ at an average exchange rate.

If the exchange rate declines, the value in Australian dollars of our US dollar denominated cash holdings held by our Australian subsidiary increases, resulting in foreign exchange translation gains in that period. During 2008, we saw a significant decline in the exchange rate between AU and US dollars. Foreign exchange gains and losses will continue to fluctuate as the exchange rate varies.

Fiscal Years 2008 and 2007

Revenue

We are a development stage company and have generated revenue of $331,799 in the year ended December 31, 2008 from product sales through our US clinical trial. We had no revenue from product sales in the years prior to 2008. We have completed enrollment of our combined European and Australian clinical trial for the HeartWare System and received CE Marking approval in January 2009. We expect to generate commercial revenue from this product outside of the United States, commencing in early 2009. However, even if we receive the necessary regulatory approvals in the United States, future product sales are dependent on market acceptance among physicians, patients, health care payers or the medical community as well as our capacity to supply customers by manufacturing sufficient quantities of our products.

Cost of Goods Sold

Cost of goods sold totaled $77,632 during the year ended December 31, 2008. There was no cost of goods sold recognized during the year ended December 31, 2007. Our first product revenues were generated in the quarter ended September 30, 2008. As we had inventory on hand that had previously been expensed as R&D costs (see Critical Accounting Policies and Estimates – Inventory Capitalization), we believe that our gross margins will be distorted for comparative purposes into 2010 depending on market demand for our products and utilization of components in the production process. In addition, as we use a standard costing method for determining costs of inventory and have limited experience setting standards and manufacturing our products actual results may differ from standards which could result in inconsistent gross margins from quarter to quarter.

Selling, General and Administrative

Selling, general and administrative expenses include office expenses associated with general corporate administration. 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 2008, we experienced significant growth as we completed enrollment in our international clinical trial, and initiated enrollment in our first human clinical trial in the United States, continued to manage dual reporting structures 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.

In 2008, selling, general and administrative expenses were approximately $11.0 million, or 37%, of operating expenses, as compared to $7.3 million, or 33% of operating expenses in 2007. The increase was primarily a result of an increase in headcount and related employee costs, increased office costs and professional fees associated with our redomiciliation to the US, travel and marketing activities in preparation for commercial activities.

Research and Development

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

Even as we approach commercialization of the HeartWare System product line, we expect that research and development expenses will continue to represent a significant portion of our operating expenses for the foreseeable future related to new product development. In addition, we expect increased clinical costs that will be expensed to research and development relating to the HeartWare System for US clinical trials.

As discussed above, we experienced significant growth in 2008. We achieved significant research and development milestones, completing enrollment of our international human clinical trial, beginning enrollment for our U.S. clinical trial and the furtherance of animal studies for less invasive implantable techniques for our next generation heart pump, the MVAD. In 2008, research and development expenses were $18.6 million, or 63%, of operating expenses as compared to $14.6 million, or 67% of operating expenses, in 2007. The increase of approximately $4.0 million was primarily driven by increased headcount and related employee costs as well as increased clinical trial costs, professional fees and other research and development expenses related to existing research projects and expenses associated with regulatory activities associated with obtaining IDE, CE Marking and ISO certification.

Other Income

Other income consists primarily of interest income and foreign exchange income or loss.

Interest income is primarily derived from cash and short-term deposits accounts, denominated in both Australian and United States dollars, held in Australia. Interest income was approximately $1.2 million in 2008 as compared to $951,000 in 2007. The increase was primarily due to increased average cash balances in 2008 as a result of the completion of a private placement of shares in July 2008.

Foreign exchange income was approximately $4.6 million in 2008 as compared to a loss of approximately $851,000 in 2007. The difference was due to fluctuations in the value of our Australian and US dollar-based cash holdings as a result of movements in the exchange rate between the Australian dollar and the US dollar.

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, 2008, 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 progress toward the commercialization of our products.

Fiscal Years 2007 and 2006

Revenue

HeartWare is a development stage company that did not generate revenue in either of the years ended December 31, 2007 and 2006. During the fiscal years 2007 and 2006, the Company conducted a combined European and Australian clinical trial with our first product, the HeartWare System.

Cost of Goods Sold

There were no costs of goods sold recognized during the years ended December 31, 2007 and 2006, as we had no revenue from sale of products in those years.

Selling, General and Administrative

During 2007, we experienced significant growth as we continued enrollment in our first human clinical trial, became a US SEC reporting company subject to periodic filings in the United States in addition to our continued Australian reporting and compliance requirements, raised additional capital and continued to expand 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.

In 2007, selling, general and administrative expenses were approximately $7.3 million, or 33%, of operating expenses, as compared to $6.0 million, or 34% of operating expenses in 2006. Of the increase of approximately $1.3 million, approximately $1.0 million was a result of an increase in non-cash, share-based compensation expense. Other increases in legal and office expenses were partially offset by decreases in employee relocation and salaries and wages. Salaries and wages in 2006 included termination expense paid to the former Chief Executive Officer.

Research and Development

As discussed above, we experienced significant growth in 2007 and achieved significant research and development milestones, including expanding our international human clinical trial and the commencement of animal studies for less invasive implantable techniques for our next generation heart pump, the MVAD. In 2007, research and development expenses were $14.6 million, or 67%, of operating expenses as compared to $11.6 million, or 66% of operating expenses, in 2006. The increase of approximately $3.0 million was primarily driven by increased salaries and wages and related employee costs of approximately $2.0 million as well increased travel, clinical expenses, office expenses and share based compensation expense.

Other Income

Interest income is primarily derived from cash and short-term deposits accounts, denominated in both Australian and United States dollars, held in Australia. Interest income was approximately $951,000 in 2007 as compared to $844,500 in 2006. The increase was primarily due to increased average cash balances in 2007 as a result of the completion of a private placement of shares and a shareholder purchase plan in July 2007, under which we raised net proceeds of approximately $30.9 million.

Foreign exchange loss was approximately $851,000 in 2007 as compared to $584,000 in 2006. The difference was due to fluctuations in the value of our Australian and US dollar-based cash holdings as a result of movements in the exchange rate between the Australian dollar and the US dollar.

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, 2007, 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 progress toward the commercialization of our products.

Liquidity and Capital Resources

At December 31, 2008, our cash and cash equivalents were $20.8 million as compared to $28.3 million at December 31, 2007. The decrease is primarily a result of cash used in operating activities, partially offset by net cash receipts of $29.4 million resulting from the private placement of shares in July 2008.

Cash used in operating activities for the year ended December 31, 2008 was approximately $24.1 million as compared to $19.0 million for the year ended December 31, 2007. For the year ended December 31, 2008, this amount included a net loss of $23.8 million and non-cash adjustments to net income of approximately $2.0 million which primarily consisted of approximately $705,000 of depreciation and amortization and $1.2 million of share-based compensation. Included in cash used in operating activities in 2008 is approximately $3.5 million for the purchase of inventories. As noted above, we began capitalizing inventory in September 2008. We expect inventory purchases to significantly increase throughout 2009 in support of our US clinical trial and commercial sales in Europe.

For the year ended December 31, 2007, cash used in operating activities included a net loss of $21.9 million and non-cash adjustments to net income of approximately $2.9 million which primarily consisted of approximately $539,000 of depreciation and amortization and $2.3 million of share-based compensation.

Investing activities used cash of approximately $2.3 million and $1.0 million for the years ended December 31, 2008 and 2007, respectively. These amounts in 2008 and 2007 were primarily to acquire property, plant and equipment and capitalized patent costs. The increase in costs is a result of continued growth as described above.

Cash provided by financing activities for years ended December 31, 2008 and 2007 was $28.0 million and $30.9 million, respectively as a result of capital raises during both periods and partially offset by the repayment of a convertible note during the third quarter of 2008. We describe our issuances of shares in Note 10 — Shareholders' Equity to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K. We used the proceeds from the private placements of our shares in 2008 and 2007 to fund the on-going cost of operations, including continued research and development, marketing costs, manufacturing and operational costs and other regulatory and compliance costs as well general working capital. We intend to use the remainder of the proceeds for similar operating activities.

In July 2008, in conjunction with a private placement, we issued an aggregate of 1,778,130 shares at a price per share of $16.80 (AU$17.50) for aggregate gross proceeds of $30.2 million. Offering costs associated with the issuance were approximately $841,000.

We will require additional funds to support our long-term operations, build a sales and marketing infrastructure to support commercial distribution of our products and continue research and development. We began generating revenue in August 2008 with the commencement of our US clinical trial. Continued revenue is contingent upon market acceptance of our products among physicians, patients, health care payers or the medical community as well as our capacity to successfully and efficiently manufacture our products. We expect to continue to incur significant spending due to increased selling and marketing costs, on-going regulatory and compliance requirements, increased clinical trial costs associated with our US clinical trial and additional operating expenses related to continued corporate growth.

On February 12, 2009, concurrent with the execution and delivery of the Merger Agreement, we entered into a Loan Agreement in order to fund our ongoing operations until the closing of the Merger. Thoratec has deposited $20.0 million into an escrow account pursuant to the Loan Agreement. Beginning on May 1, 2009, HeartWare may borrow up to an aggregate of $12.0 million and beginning on July 31, 2009 HeartWare may borrow up to an aggregate of $20.0 million. In the event that all of the conditions to closing the Merger other than the receipt of regulatory approvals have been satisfied and Thoratec exercises an option under the Merger Agreement to extend the outside date for the completion of the Merger until January 31, 2010, HeartWare may borrow up to an additional $8.0 million, which Thoratec must deposit into the escrow account at the time it exercises its extension option. The maximum aggregate amount that HeartWare may borrow under the Loan Agreement will not exceed $28.0 million.

The loans to HeartWare under the Loan Agreement accrue interest at the rate of 10% per annum and are due and payable, together with accrued and unpaid interest, on the earlier of (i) November 1, 2011, (ii) the Termination date and (iii) the date on which all of the loans accelerate and become due and payable in full in accordance with the Loan Agreement. The loans may accelerate upon a change in control of the borrower or events of default.

We believe that cash and cash equivalents on hand, expected cash flows from operations and the access to capital pursuant to the above described loan agreement will be sufficient to fund our operations for at least the next twelve months.

Contractual Obligations

At December 31, 2008, our debt and contractual financial obligations and commitments by due dates were as follows:

	Payments due by period (in thousands of dollars)			
	Total	Less than 1 year	1-3 years	3-5 years
Operating lease obligations	$ 2,331	$ 839	$ 1,320	$ 172
Purchase obligations	2,591	2,591	—	—
Milestone payments under settlement agreement	750	750	—	—
Total	$ 5,672	$ 4,180	$ 1,320	$ 172

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 that is 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.

Foreign Currency Rate Fluctuations

We conduct business in foreign countries. For US reporting purposes, the Company translates all assets and liabilities of its non-US entities at the year-end exchange rate and translates revenue and expenses at the average exchange rates in effect during the year. The net effect of these translation adjustments is shown in the accompanying consolidated financial statements as a component of shareholders' equity.

Our Australian subsidiary holds US and Australian dollar denominated cash accounts. Fluctuations in the exchange rate of the US dollar against the AU dollar can result in foreign currency exchange gains and losses that impact our financial results and our overall cash position. These foreign currency transaction gains and losses are included in other, net in the consolidated statements of operations. The gains and losses are recorded in AU dollars, the functional currency the Australian entity, and translated to US dollars, at an average exchange rate, for US reporting purposes. Continued fluctuation of the exchange rate could result in financial results that are not comparable from quarter to quarter.

We do not presently utilize foreign currency forward contracts and instead hold cash reserves in the currency 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 Shareholders
HeartWare International, Inc.

We have audited the accompanying consolidated balance sheets of HeartWare International, Inc. (a Development Stage Company) as of December 31, 2008 and 2007, and the related consolidated statements of operations, comprehensive loss, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2008, and the cumulative period from November 26, 2004 (date of inception) through December 31, 2008. 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. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, 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. (a Development Stage Company) as of December 31, 2008 and 2007, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, and the cumulative period from November 26, 2004 (date of inception) through December 31, 2008, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Notes 3 and 8 to the consolidated financial statements, the Company adopted Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment", on a prospective basis on January 1, 2005. In addition, as discussed in Notes 3 and 9 to the consolidated financial statements, the Company adopted Financial Accounting Standards Board Interpretation No. 48, "Accounting for Uncertainty in Income Taxes", on a prospective basis on January 1, 2007.

/s/ Grant Thornton LLP

Fort Lauderdale, Florida
February 25, 2009

HEARTWARE INTERNATIONAL, INC.
(A Development Stage Company)
CONSOLIDATED BALANCE SHEETS

	December 31, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,803,656	$ 28,276,388
Accounts receivable	244,198	—
Inventories, net	3,508,065	—
Prepaid expenses and other current assets	1,061,737	782,922
Total current assets	25,617,656	29,059,310
Property, plant and equipment, net	3,608,626	2,977,645
Other intangible assets, net	823,495	318,211
Restricted cash held by lessor	288,429	—
Total Assets	$ 30,338,206	$ 32,355,166
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 699,064	$ 509,487
Accrued expenses and other current liabilities	2,883,587	1,246,846
Convertible notes, current	—	1,326,963
Total current liabilities	3,582,651	3,083,296
Commitments and contingencies		
Shareholders' equity:		
Preferred stock — $.001 par value; 5,000,000 shares authorized; no shares issued and outstanding at December 31, 2008 and 2007, respectively	—	—
Common stock — $.001 par value; 25,000,000 shares authorized; 8,866,702 and 7,088,572 shares issued and outstanding at December 31, 2008 and 2007, respectively	8,867	7,089
Additional paid-in capital	112,400,642	81,852,174
Deficit accumulated during the development stage	(76,962,787)	(53,199,166)
Accumulated other comprehensive income (loss):		
Cumulative translation adjustments	(8,691,167)	611,773
Total Shareholders' Equity	26,755,555	29,271,870
Total Liabilities and Shareholders' Equity	$ 30,338,206	$ 32,355,166

The accompanying notes are an integral part of these financial statements

HEARTWARE INTERNATIONAL, INC.
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,			Cumulative Period from November 26, 2004 (Inception) Through December 31,
	2008	2007	2006	2008
Revenues	$ 331,799	$ —	$ —	$ 331,799
Cost of revenues	77,632	—	—	77,632
Gross profit	254,167	—	—	254,167
Operating expenses:				
Selling, general and administrative expenses	10,981,131	7,303,145	6,024,374	28,620,289
Research and development expenses	18,643,557	14,636,198	11,649,822	55,662,341
Total operating expenses	29,624,688	21,939,343	17,674,196	84,282,630
Loss from operations	(29,370,521)	(21,939,343)	(17,674,196)	(84,028,463)
Foreign exchange gain (loss)	4,550,193	(851,032)	(583,805)	3,609,179
Interest income, net	1,245,140	950,675	844,522	3,757,458
Other, net	(188,433)	(99,299)	(13,229)	(300,961)
Loss before income taxes	(23,763,621)	(21,938,999)	(17,426,708)	(76,962,787)
Provision for income taxes	—	—	—	—
Net loss	$(23,763,621)	$(21,938,999)	$(17,426,708)	$ (76,962,787)
Loss per common share — basic and diluted	$ (3.00)	$ (3.60)	$ (3.49)	
Weighted average shares outstanding — basic and diluted	7,929,054	6,086,542	4,991,149	

The accompanying notes are an integral part of these financial statements

HEARTWARE INTERNATIONAL, INC.
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Years Ended December 31,			Cumulative Period from November 26, 2004 (Inception) Through December 31,
	2008	2007	2006	2008
Net loss	$(23,763,621)	$(21,938,999)	$(17,426,708)	$ (76,962,787)
Foreign currency translation	(9,302,940)	542,148	732,661	(8,691,167)
Comprehensive loss	$(33,066,561)	$(21,396,851)	$(16,694,047)	$ (85,653,954)

The accompanying notes are an integral part of these financial statements

HEARTWARE INTERNATIONAL, INC.
(A Development Stage Company)
CONSOLIDATED STATEMENT OF SHAREHOLDERS' EQUITY

	Common Shares, $.001 Par Value Per Share		Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Income (Loss)	Total
	Shares Issued	Amount				
Balance at November 26, 2004, (inception)	—	$ —	$ —	$ —	$ —	$ —
Issuance of founding ordinary shares	57	—	794	—	—	794
Balance December 31, 2004	57	—	794	—	—	794
Issuance of ordinary shares pursuant to the acquisition of HeartWare, Inc.	2,514,286	2,514	(1,226,798)	—	—	(1,224,284)
Issuance of ordinary shares pursuant to initial public offering, net of offering costs	1,852,539	1,853	23,435,744	—	—	23,437,597
Issuance of ordinary shares pursuant to share option exercise	11,297	11	59,565	—	—	59,576
Issuance of ordinary shares pursuant to cashless warrant exercise	81,714	82	(82)	—	—	—
Share-based compensation	—	—	1,947,537	—	—	1,947,537
Net loss	—	—	—	(13,833,459)	—	(13,833,459)
Accumulated other comprehensive income (loss):						
Foreign currency translation adjustment	—	—	—	—	(663,036)	(663,036)
Balance December 31, 2005	4,459,893	4,460	24,216,760	(13,833,459)	(663,036)	9,724,725
Issuance of shares pursuant to capital raise, net of offering costs	847,992	848	23,377,521	—	—	23,378,369
Issuance of shares pursuant to shareholder purchase plan	2,155	2	61,252	—	—	61,254
Issuance of shares pursuant to share option exercise	11,743	12	103,124	—	—	103,136
Share-based compensation	—	—	890,319	—	—	890,319
Net loss	—	—	—	(17,426,708)	—	(17,426,708)
Accumulated other comprehensive income (loss):						
Foreign currency translation adjustment	—	—	—	—	732,661	732,661
Balance December 31, 2006	5,321,783	5,322	48,648,976	(31,260,167)	69,625	17,463,756
Issuance of shares pursuant to shareholder purchase plan	57,226	57	1,062,901	—	—	1,062,958
Issuance of shares pursuant to share option exercise	3,656	4	21,698	—	—	21,702
Issuance of shares pursuant to capital raise, net of offering costs	1,705,907	1,706	29,853,944	—	—	29,855,650
Share-based compensation	—		2,264,655	—	—	2,264,655
Net loss	—	—	—	(21,938,999)	—	(21,938,999)
Accumulated other comprehensive income (loss):						
Foreign currency translation adjustment	—	—	—	—	542,148	542,148
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)
Accumulated other comprehensive income (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

The accompanying notes are an integral part of these financial statements

HEARTWARE INTERNATIONAL, INC.
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,			Cumulative Period from November 26, 2004 (Inception) Through December 31,
	2008	2007	2006	2008
CASH FLOWS FROM OPERATING ACTIVITIES				
Net loss	$(23,763,621)	$(21,938,999)	$(17,426,708)	$ (76,962,787)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	663,894	518,367	371,497	1,800,987
Amortization	41,187	20,679	16,528	88,855
Share-based compensation expense	1,151,619	2,264,655	890,319	6,254,130
Loss on disposal of assets	189,380	100,739	13,229	303,348
Accrued interest on convertible note	(81,633)	26,254	22,126	(14,025)
Change in operating assets and liabilities:				
Accounts receivable	(244,198)	—	—	(244,198)
Inventories, net	(3,508,065)	—	—	(3,508,065)
Prepaid expenses and other current assets	(229,815)	(129,688)	(229,689)	(635,431)
Note receivable, current	—	—	—	794
Accounts payable	59,906	196,681	(666,383)	(260,555)
Accrued expenses and other current liabilities	1,660,070	(78,567)	1,071,959	2,914,317
Net cash used in operating activities	(24,061,276)	(19,019,879)	(15,937,122)	(70,262,630)
CASH FLOWS FROM INVESTING ACTIVITIES				
Additions to property, plant and equipment	(1,490,248)	(880,446)	(1,732,372)	(5,515,589)
Additions to patents	(546,471)	(121,693)	(34,945)	(912,351)
Restricted cash held by lessor	(288,429)	—	—	(288,429)
Net cash provided by acquisition	—	—	—	126,380
Proceeds from dispositions of assets	—	8,435	23,701	32,136
Net cash used in investing activities	(2,325,148)	(993,704)	(1,743,616)	(6,557,853)
CASH FLOWS FROM FINANCING ACTIVITIES				
Repayment of convertible note	(1,360,929)	—	—	(1,360,928)
Proceeds from issuance of share capital	30,239,247	32,839,448	25,083,953	113,282,449
Payment of offering costs	(840,620)	(1,899,138)	(1,541,194)	(5,903,581)
Net cash provided by financing activities	28,037,698	30,940,310	23,542,759	106,017,940
Effect of exchange rate changes on cash	(9,124,006)	651,892	798,807	(8,393,801)
CHANGE IN CASH AND CASH EQUIVALENTS	(7,472,732)	11,578,619	6,660,828	20,803,656
CASH AND CASH EQUIVALENTS — BEGINNING OF PERIOD	28,276,388	16,697,769	10,036,941	—
CASH AND CASH EQUIVALENTS — END OF PERIOD	$ 20,803,656	$ 28,276,388	$ 16,697,769	$ 20,803,656
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:				
Interest paid	$ 88,870	$ —	$ —	$ 88,870

The accompanying notes are an integral part of these financial statements

Note 1 Description of Business

HeartWare International, Inc., referred to in these notes collectively with its subsidiaries HeartWare Limited and HeartWare, Inc. as "we," "our," "HeartWare" or the "Company", is a medical device company focused on developing and commercializing a family of blood pumps that are surgically implanted to help augment blood circulation in patients suffering from chronic and end-stage heart failure, which is one of the leading causes of death in the developed world.

The Company believes that its first product line, the HeartWare Ventricular Assist System (the "HeartWare System"), which includes a full output ventricular assist device (the "HVAD Pump") and related surgical tools and accessories, is the smallest full-output left ventricle assist device that is currently in clinical trials or in the marketplace. It is the only centrifugal pump designed to be implanted above the diaphragm in all patients.

Beyond the HeartWare System, the Company is also evaluating its 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. The MVAD, which is currently at the prototype stage and undergoing animal studies focused on minimally invasive implantation techniques, is approximately one-third the size of the HeartWare System. The Company believes that the MVAD will be implantable by surgical techniques that are even less invasive than those required to implant the HeartWare System. The Company expects to initiate human clinical trials for the MVAD in 2011.

In addition the Company continues to develop its product pipeline with projects that include an implantable electronics device, or transcutaneous energy transfer system ("TETS") and further miniaturization of the pump towards the development of a pump that is intended to be positioned within the body's vasculature network and implanted by minimally invasive catheter-based techniques.

The Company completed enrollment of a combined European and Australian human clinical trial for the HeartWare System. This international trial began in March 2006 and called for the implantation of 20 patients. The trial had been expanded to permit enrollment of 50 patients so as to provide increased depth of clinical data. Enrollment of this trial is now complete. In January 2009, the Company received Conformite Europeene ("CE") Marking which allows us to market and sell our device in Europe.

In May 2008, the Company received an Investigational Device Exemption from the FDA, and began enrolling centers for a US bridge-to-transplant clinical study. On August 21, 2008, the Company announced that its first patient in the United States received the HeartWare System at Washington Hospital Center in Washington, DC. This marked the start of the Company's US bridge-to-transplant clinical trial, under which 150 patients awaiting heart transplantation will be enrolled at up to 28 participating centers.

The Company is headquartered in Framingham, Massachusetts and has an administrative office in Sydney, Australia and an operations and manufacturing facility in Miami Lakes, Florida.

Development Stage

The Company is a development stage company with a limited operating history. To date, it has generated limited revenue from the Company's product sales in the United States, and it has incurred net losses in each year since the Company's inception. The Company also generates limited income from interest. The Company expects its losses to continue and to increase as the Company expands its clinical trial activities, seeks regulatory approvals and initiates commercialization activities.

As such, the Company's financial statements have been prepared in accordance with the accounting and reporting principles prescribed by Statement of Financial Accounting Standards ("SFAS") No. 7, "Accounting and Reporting by Development Stage Enterprises," issued by the Financial Accounting Standards Board ("FASB").

Prior to marketing its products in the United States, the Company's products must undergo rigorous pre-clinical and clinical testing and an extensive regulatory approval process implemented by the FDA and other regulatory authorities. There can be no assurance that the Company will not encounter problems in clinical trials that will cause the Company, the FDA or other regulatory authorities to delay or suspend clinical trials. The Company's success will depend in part on its ability to successfully complete clinical trials, obtain and maintain necessary regulatory approvals, obtain patents and product license rights, maintain trade secrets and operate without infringing on the proprietary rights of others, both in the United States and other countries. There can be no assurance that patents issued to the Company will not be challenged, invalidated or circumvented, or that the rights granted there under will provide proprietary protection or competitive advantages to the Company. The Company completed a private placement in July 2008, however, the Company will require further capital in order to meet its long-term objectives. The Company will need to seek substantial additional financing through public and/or private financing, and financing may not be available when the Company needs it or may not be available on acceptable terms.

Basis of Presentation

Effective November 13, 2008, the Company 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 Australian Securities Exchange ("ASX") in the form of CHESS Depositary Interests ("CDIs"). Each CDI represents 1/35th of a share of common stock.

Note 2 Liquidity

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. However, the Company has sustained substantial losses from operations since its inception, and such losses have continued through December 31, 2008. At December 31, 2008, the Company had a deficit accumulated during the development stage of approximately $77 million. On February 12, 2009, the Company entered into an Agreement and Plan of Merger with Thoratec and concurrently entered into a Loan Agreement to fund the Company's operations through consummation of the Merger. The loan amount is not to exceed $28.0 million (see Note 15 – Subsequent Events for further information). In 2009, cash on hand and the loan proceeds will primarily be applied for the purposes of meeting expected costs associated with establishing a European sales infrastructure, expanding the Company's human clinical trials, product development, regulatory and other compliance costs as well as for general working capital. The Company believes its cash on hand and cash available under the Loan Agreement is sufficient to support its planned operations throughout 2009 and into 2010.

Note 3 Significant Accounting Policies

Principles of Consolidation

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

Accounting Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States ("US 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 period. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents are recorded in the consolidated balance sheets at cost, which approximates fair value. The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. The Company maintains the majority of its cash and cash equivalents in Australia, denominated in both Australian and United States dollars. As of December 31, 2008 and 2007, the Company had approximately $17.9 million and $27.5 million, respectively, maintained in banks in Australia, as translated into US dollars at the spot rate at the end of the respective year.

Inventories

Components of Inventories at December 31 are as follows:

	December 31,	
	2008	2007
Inventories, net		
Raw material	$ 813,276	$ —
Work-in-process	1,690,852	—
Finished goods	1,003,937	—
	$ 3,508,065	$ —

Inventories are stated at the lower of cost or market. Cost is determined on a standard cost method which approximates the FIFO method. Work-in-process and finished goods includes direct and indirect labor and manufacturing overhead. Provision is made to reduce excess and obsolete inventories to net realizable value.

Prior to September 1, 2008, the Company included all costs associated with manufacturing as part of R&D expense. Effective September 1, 2008, the Company began to capitalize in inventory the costs of manufacturing the HeartWare System. Until the Company consumes the inventory for which a portion of the costs were previously expensed, the carrying value of the Company's inventories and its cost of sales will reflect only incremental costs incurred subsequent to capitalization of inventory on September 1, 2008. The Company could be required to expense capitalized costs of the HeartWare System in the event of a denial or delay of approval by US regulatory bodies, a delay in commercialization, or other potential factors.

Property, Plant and Equipment

The Company records property, plant and equipment and leasehold improvements at historical cost. Expenditures for maintenance and repairs are charged to expense; additions and improvements are capitalized. The Company generally provides 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.

Other Intangible Assets

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

		2008		2007	
Amortizable Intangible Assets	Life (Years)	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Patents	15	$ 912,351	$ (88,856)	$ 365,880	$ (47,669)

Amortization expense for the years ended December 31, 2008, 2007 and 2006 was $41,187, $20,679 and $16,528, respectively.

Estimated amortization expense for each of the 5 succeeding fiscal years based upon the Company's intangible asset portfolio at December 31, 2008 is $60,823.

Share-Based Payments

We elected to early adopt SFAS 123(R), "Share-Based Payment", effective January 1, 2005. We use a Black-Scholes option pricing method. Under the fair value recognition provisions of SFAS 123(R), we recognize share-based compensation net of an estimated forfeiture rate and therefore only recognize compensation cost for those shares expected to vest over the service period of the award.

Calculating share-based compensation expense requires the input of highly subjective judgment and assumptions, including estimates of expected life of the option, share price volatility and a forfeiture rate.

We estimate the volatility of our shares on the date of grant based on the historical volatility of our publicly-traded shares. When appropriate, we estimate the expected term calculation based upon the simplified method provided under SEC Staff Accounting Bulletin (SAB) No. 110. Under SAB No. 110, the expected term is developed 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 risk-free interest rate based on rates in effect for Australian Government bonds, with similar lives, at the time of grant. We estimate the forfeiture rate based on our historical experience of past 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.

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 are required to use different assumptions, our share-based compensation expense could be materially different in the future.

Impairment of Long-Lived Assets

The Company reviews its 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, 2008, no indicators of impairment existed.

Income Taxes

The Company accounts for income taxes in accordance with SFAS No. 109, "*Accounting for Income Taxes*" ("SFAS No. 109"), as clarified by FASB Interpretation No. 48, "*Accounting for Uncertainty in Income Taxes* ("FIN No. 48"). 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, the Company considers tax regulations of the jurisdictions in which it operates, estimates of future taxable income and available tax planning strategies. If tax regulations, operating results or the ability to implement tax-planning strategies varies, adjustments to the carrying value of the deferred tax assets and liabilities may be required. Valuation allowances are based on the "more likely than not" criteria of SFAS No. 109.

FIN No. 48 requires that the Company 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

The Company translates all assets and liabilities of non-US entities at the year-end exchange rate and translates expenses at the average exchange rates in effect during the year. Equity transactions are translated at rates in effect at the times of the transactions. The net effect of these translation adjustments is shown in the accompanying consolidated financial statements as a component of shareholders' equity, titled "Accumulated Other Comprehensive Income (Loss)." Items in Accumulated Other Comprehensive Income (Loss) are not tax affected as the Company has incurred a net loss in each period since inception.

In addition, the Australian subsidiary, HeartWare Limited, which operates in a functional currency of AU dollars, holds US dollar cash accounts. Exchange rate fluctuations affect the value of these accounts and may result in foreign currency gains and losses. Such gains and losses are included in the consolidated statements of operations. Any such gains and losses are initially recognized as they occur in AU$ and then converted to US$ at an average exchange rate.

The exchange rate between the US and Australian dollar has fluctuated substantially during the year ended December 31, 2008. This fluctuation has resulted in significant changes in the cumulative translation adjustments and foreign exchange gains during the year ended December 31, 2008.

Research and Development

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

Vendor Concentration

For the year ended December 31, 2008, we purchased approximately 58% 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, 2008, the amounts due to these vendors total approximately $115,000.

Marketing and Advertising Costs

Marketing, advertising and promotional costs are expensed when incurred.

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 is computed by dividing net loss for the period by the weighted average number of common shares outstanding during the period, plus the dilutive effect of common share equivalents, such as options. Due to the net loss for all periods presented, all common share equivalents were excluded because their inclusion would have been anti-dilutive.

New Accounting Standards

In September 2006, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 157, *Fair Value Measurements*. SFAS No. 157 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. In February 2008, FASB issued FASB Staff Position FAS 157-2, "Effective Date of FASB Statement No. 157" which delayed the effective date of SFAS No. 157 for all non-financial assets and liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis. SFAS No. 157 was effective for the Company on January 1, 2008. The adoption of SFAS No. 157 related to the Company's financial assets and liabilities did not have a material impact on their fair value measurement or require expanded disclosures.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of FASB Statement No. 115*. SFAS No. 159 allows entities to voluntarily choose to measure many financial assets and financial liabilities at fair value through earnings. Upon initial adoption, SFAS No. 159 provides entities with a one-time chance to elect the fair value option for existing eligible items. The effect of the first measurement to fair value is reported as a cumulative-effect adjustment to the opening balance of retained earnings in the year SFAS No. 159 is adopted. SFAS No. 159 is effective as of the beginning of fiscal years starting after November 15, 2007. Currently, we have not elected to account for any of our eligible items using the fair value option under SFAS No. 159. As a result, the Company's adoption of SFAS No. 159, effective January 1, 2008, did not have a material impact on the Company's consolidated financial position, results of operations or cash flows.

In June 2007, the FASB ratified a consensus opinion reached by the Emerging Issues Task Force ("EITF") on EITF Issue 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities. The guidance in EITF Issue 07-3 requires the Company to defer and capitalize non-refundable advance payments made for goods or services to be used in research and development activities until the goods have been delivered or the related services have been performed. If the goods are no longer expected to be delivered nor the services expected to be performed, the Company would be required to expense the related capitalized advance payments. The consensus in EITF Issue 07-3 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2007 and is to be applied prospectively to new contracts entered into on or after December 15, 2007. The Company adopted EITF Issue 07-3 effective January 1, 2008. The impact of applying this consensus did not have a material impact on the Company's consolidated financial position and results of operations.

In December 2007, the FASB issued SFAS No. 141(R), Business Combinations and SFAS No. 160, Non-controlling Interests in Consolidated Financial Statements. SFAS No. 141(R) and SFAS No. 160 introduce significant changes in the accounting for and reporting of business acquisitions and non-controlling interests in a subsidiary. SFAS No. 141(R) continues the movement toward the greater use of fair values in financial reporting and increased transparency through expanded disclosures. SFAS No. 141(R) changes how business acquisitions are accounted for and will impact financial statements at the acquisition date and in subsequent periods. In addition, SFAS No. 141(R) will impact the annual goodwill impairment test associated with acquisitions that close both before and after its effective date. SFAS No. 141(R) applies prospectively to fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. An entity may not apply SFAS No. 141(R) before that date. The adoption of these statements is not expected to have a material effect on the financial statements of the Company.

In March 2008, the FASB issued SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities. SFAS No.161 changes the disclosure requirements for derivative instruments and hedging activities. Entities are required to provide enhanced disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under FASB Statement 133 and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance and cash flows. SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. This statement is not expected to have an impact on the Company's consolidated financial statements.

In May 2008, the FASB issued SFAS No. 162, The Hierarchy of Generally Accepted Accounting Principles, which identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements in conformity with generally accepted accounting principles in the United States. This Statement is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles. The Company does not expect that the adoption of this pronouncement will have a significant impact on its financial condition, results of operations and cash flows.

Note 4 Other Balance Sheet Information

Components of selected captions in the consolidated balance sheets at December 31 are as follows:

	Estimated Useful Lives	December 31, 2008	December 31, 2007
Property, Plant and Equipment			
Machinery and equipment	5 to 7 years	$ 4,428,452	$ 3,327,331
Leasehold improvements	3 to 7 years	212,891	95,951
Office equipment, furniture and fixtures	5 to 7 years	271,275	279,536
Purchased software	5 to 7 years	406,983	388,749
		5,319,601	4,091,567
Less: accumulated depreciation		(1,710,975)	(1,113,922)
		$ 3,608,626	$ 2,977,645

Depreciation expense was $663,894, $518,367 and $371,497 for the years ended December 31, 2008, 2007 and 2006, respectively.

	December 31, 2008	December 31, 2007
Accrued expenses and other current liabilities		
Accrued payroll and other employee costs	$ 1,721,506	$ 837,881
Accrued material purchases	417,344	—
Accrued research and development materials	494,997	181,172
Accrued professional fees	149,146	209,819
Other accrued expenses	100,594	17,974
	$ 2,883,587	$ 1,246,846

Note 5 Exchange of Equity Interests Among Entities Under Common Control

On January 24, 2005, HeartWare Limited acquired all of the outstanding voting stock of HeartWare, Inc., a company based in Miramar, Florida developing heart pump technology that now forms the Company's core technology platform. HeartWare Limited issued 88 million shares and a convertible note in the principal amount of $1.1 million less a write-off of amounts due to a shareholder of approximately $140,000. The convertible note has been subsequently redeemed during the third quarter of 2008.

As the acquisition, for accounting purposes, is an exchange of equity interests among entities under common control, the transaction was accounted for at the historical cost of the assets and liabilities acquired from HeartWare, Inc. The accompanying consolidated statements of operations for the years ended December 31, 2008, 2007 and 2006 reflect the results of operations of HeartWare, Inc. from the date of acquisition, January 24, 2005.

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 6 Borrowings and Credit Facilities

Convertible Note – Related Party

The Company repaid $1,360,928 plus accrued interest of $88,870 to Apple Tree Partners I, L.P. during the year ended December 31, 2008 related to a convertible note, denominated in Australian dollars, in the principal amount of AU$1,420,000. Prior to conversion the note accrued interest at 2.0% per annum. The conversion price was AU$1.00 per ordinary share. The principal and accrued interest on the convertible note was repayable on demand as of January 31, 2007, and was therefore included as a current liability as of December 31, 2007.

Interest expense related to this note, which is included in interest income, net in the accompanying consolidated statements of operations, was $17,555, $26,254 and $22,126 for the years ended December 31, 2008, 2007 and 2006 respectively.

Note 7 Leases

The Company leases manufacturing and office facilities under operating leases, some of which contain renewal options. Rent expense was $833,571 in 2008, $738,559 in 2007 and $484,226 in 2006. The Company recognizes rent expense on a straight-line basis over the term of the lease. Future minimum rental commitments at December 31, 2008 under non-cancelable operating lease agreements are as follows:

	Operating Leases
Year Ending December 31,	
2009	$ 839,369
2010	859,798
2011	459,804
2012	165,293
2013	6,893
Total minimum lease payments	$ 2,331,157

Note 8 Equity Incentive Plans

The Company has issued share-based payment awards to employees, non-executive directors and outside consultants through various approved plans and outside of any formal plan. The Company issues new shares upon exercise of stock awards.

As noted above, on November 13, 2008, the Company completed an Australia court approved redomiciliation, whereby the ultimate parent company of the HeartWare Group became a US Company, HeartWare International, Inc. As part of redomiciliation all share-based plans of HeartWare Limited were cancelled and new plans were formed under HeartWare International, Inc. All awards outstanding at the time of the redomiciliation were cancelled and reissued by HeartWare International, Inc. The awards were issued on the same terms and conditions with the only exception being the number of shares and exercise prices were adjusted to reflect a reverse split in the ratio of 35 to 1 and any fractional shares were rounded down. The reverse split had no impact on the valuation of the grants and therefore did not result in any additional compensation. The exercise price of all grants is denominated in AU dollars; the amounts below have been translated to US dollars.

A detailed discussion of share-based payment awards granted and outstanding is below. For all periods presented the current and former plans have been combined. Original issuance dates have been used but the number of shares issued and exercise prices have been adjusted to give retroactive effect to the redomiciliation and reverse split for all periods presented.

HeartWare International, Inc. Employee Share Option Plan ("ESOP") (formerly HeartWare Limited Employee Share Option Plan)

On August 5, 2008, the Company adopted the HeartWare International, Inc. Employee Share Option Plan. All plan issuances were made in accordance with previous grants under the HeartWare Limited Employee Share Option Plan.

The ESOP allows the Company to grant options for common stock in the Company to employees and directors. The ESOP provides for the issuance of up to 11% of the then outstanding shares of common stock. At December 31, 2008, there were 345,401 shares reserved for future issuance under the ESOP.

Each option issued under the ESOP allows the holder to subscribe for and be issued one share of common stock of the Company. Options may generally be exercised after they have vested and prior to the specified expiry date if applicable exercise conditions are met, if any. The expiry date can be for periods of up to ten years from the date of grant of the option.

The options vest in accordance with the plan on an individual award basis. Though some options have had immediate vesting, the majority of options are granted with vesting on a pro-rata basis over periods ranging from two to four years. Prior to November 2007, all options were granted with time-based vesting.

In November 2007, the Company granted approximately 83,000 options, approximately 79,000 of which are still outstanding, with performance based vesting criteria. The performance based options will vest in four equal tranches contingent upon the achievement of pre-determined corporate milestones related primarily to the development of the Company's products and the achievement of certain prescribed clinical and regulatory objectives. The Company currently estimates that the options will vest over a period of 16 to 54 months commencing on the grant date. Any options not vested after five years from the date of grant automatically expire.

At December 31, 2008, the Company has determined that vesting of only the first tranche of options (19,633) of the grants, issued with performance criteria, meet the definition of "probable" under SFAS No. 5, Accounting for Contingencies. As such, share-based compensation expense has only been recorded for the first tranche of options. At each period, we will review the likelihood that any of the remaining three tranches will vest, and if the vesting is deemed probable, we will 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.

Information in US$, as converted from AU$ at the then year-end spot rate, related to the ESOP, including all tranches of the performance options, at December 31 is as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2005	402,812	16.10		$ 1,272,313
Granted	289,010	31.30		
Exercised	(11,743)	9.39		
Forfeited	(118,721)	27.20		
Expired	(34,117)	16.48		
Outstanding at December 31, 2006	527,241	23.01		$ —
Granted	121,412	26.06		
Exercised	(3,656)	6.17		
Forfeited	(4,829)	33.36		
Expired	(610)	32.46		
Outstanding at December 31, 2007	639,558	22.78		$ —
Granted	103,838	13.86		
Exercised	—	0.00		
Forfeited	(69,762)	23.86		
Expired	(43,698)	22.96		
Outstanding at December 31, 2008	629,936	$ 18.62	6.39	$ —
Exercisable at December 31, 2008	295,808	$ 16.89	4.39	$ —

The aggregate intrinsic value in the table above represents the quoted market value less the weighted average exercise price at year end times the number of options outstanding. As the weighted average exercise price was above the quoted market price on December 31, 2008, 2007 and 2006, there is no aggregate intrinsic value on these dates.

There were no options exercised for the year ended December 31, 2008. The intrinsic value for options exercised during the year ended December 31, 2007 was approximately $60,500. Cash received from share option exercises for the years ended December 31, 2007 and 2006 was approximately $22,000 and $103,000, respectively.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing valuation model using the assumptions in the table below. Compensation is recognized on an accelerated accrual method over the estimated vest period.

The weighted average grant date fair value per share of options granted during the years ended December 31, 2008, 2007 and 2006 was $9.37, $13.66 and $16.03, respectively.

At December 31, 2008, the Company had approximately $1.76 million of unrecognized compensation cost related to non-vested share option awards, including performance based awards not yet deemed probable of vesting. The expense is expected to be recognized over a weighted average period of 1.38 years.

Weighted Average Black-Scholes Option Pricing Assumptions

	2008	2007	2006
Dividend yield	0%	0%	0%
Estimated annual volatility	58.78%	52.66%	54.82%
Risk-free interest rate	5.88%	5.96%	5.67%
Estimated forfeiture rate	12.50%	12.50%	12.12%
Estimated holding period (years)	6.25	7.47	10

HeartWare International, Inc. Restricted Stock Unit Plan (formerly HeartWare Limited Performance Rights Plan)

On August 5, 2008, the Company adopted the HeartWare International, Inc. Restricted Stock Unit Plan ("RSUP"). The plan replaces the HeartWare Limited Performance Rights Plan. All plan issuances were made in accordance with previous grants under the HeartWare Limited Performance Right Plan. The RSUP permits the Company to grant restricted stock units ("RSU's") to employees to acquire common shares of the Company at an exercise price of $0.00. The RSUP allows for the issuance of RSU's to acquire up to approximately 149,000 shares of the Company's common stock. Each RSU issued under the RSUP allows the holder to subscribe for and be issued one share of common stock of the Company. The RSU's that ultimately vest expire 10 years from the date of grant. At December 31, 2008, there were 6,154 shares reserved for future issuance under the RSUP.

The RSU's granted with original Performance Rights Plan issuance dates from November 2007 to May 2008 vest in four equal tranches contingent upon the achievement of pre-determined corporate milestones. The RSU's granted in November 2007 have performance conditions consistent with the performance ESOP shares mentioned above. The RSU's granted in May 2008 have different performance conditions. The Company currently estimates that the RSU's will vest over a period of 16 to 54 months commencing on the grant date. Any RSU's not vested after five years from the date of grant automatically expire.

On August 13, 2008, the Company also approved the issuance of approximately 96,000 RSU's under its annual equity award grant. The RSU's with original issuance dates of August 2008 vest in three tranches, the first being 50% and the remaining two equal and are contingent upon the achievement of pre-determined corporate milestones. The Company currently estimates that the performance rights will vest over a period of 22 to 43 months commencing on the grant date. Any performance rights not vested after five years from the date of grant automatically expire.

At December 31, 2008, the Company has determined that only the first tranche of awards issued under the RSUP (19,639) related to the original issuances from November 2007 through May 2008, issued with performance criteria, meet the definition of "probable" under SFAS No. 5. As such, share-based compensation expense has only been recorded for the first tranche of awards. At the end of each reporting period, the Company will review the likelihood that the tranches will vest and if the vesting is deemed probable, the Company will 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.

Information in US$, as converted from AU$ at the then year-end spot rate, related to the RSU at December 31 is as follows:

	Shares	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2007	58,567		$ 994,004
Granted	95,707		
Exercised	—		
Forfeited	(11,428)		
Expired	—		
Outstanding at December 31, 2008	142,846	9.32	$ 2,078,238
Exercisable at December 31, 2008	—	—	$ —

The aggregate intrinsic value in the table above represents the quoted market value times the number of RSU awards outstanding.

The weighted average grant date fair value per share of options granted during the years ended December 31, 2008 and 2007 was $14.40 and $23.14, respectively.

The fair value of each RSU award is estimated on the date of grant using the Black-Scholes option pricing valuation model using the assumptions in the following table. Compensation is recognized on an accelerated accrual method over the estimated vest period.

Weighted Average Black-Scholes Option Pricing Assumptions

	2008	2007
Dividend yield	0%	0%
Estimated annual volatility	58.23%	53.24%
Risk-free interest rate	6.22%	6.00%
Estimated forfeiture rate	12.50%	12.50%
Estimated holding period (years)	6.22	6.63

At December 31, 2008, the Company had approximately $1.7 million of unrecognized compensation cost related to non-vested RSU awards, including awards not yet deemed probable of vesting that is expected to be recognized over a weighted average period of 2.11 years.

Non-Plan Options

The Company has also granted an aggregate of 68,438 options outside of any formal plan. Of these options, 28,569 were granted to 3 non-executive directors and 39,869 were granted to third parties for services rendered to the Company.

The options granted to the non-executive directors had three-year vest plans and were fully vested as of January 31, 2008. The options granted to third parties prior to 2007 had immediate vesting. The third party options granted in 2007 vest in three tranches; 40% on the first anniversary, 40% on the second anniversary and 20% on the third anniversary of the date of grant.

Information, in US$ as converted from AU$ at the then year-end spot rate for non-plan options, at December 31 is as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2005	58,439	$ 19.07		$ 11,064
Granted	—			
Exercised	—			
Forfeited	—			
Expired				
Outstanding at December 31, 2006	58,439	$ 20.55		$ —
Granted	9,999	$ 23.14		
Exercised	—			
Forfeited	—			
Expired	—			
Outstanding at December 31, 2007	68,438	$ 22.93		$ —
Granted	—			
Exercised	—			
Forfeited	—			
Expired	—			
Outstanding at December 31, 2008	68,438	$ 18.03	2.17	$ —
Exercisable at December 31, 2008	62,438	$ 18.02	1.53	$ —

The aggregate intrinsic value in the table above represents the quoted market value less the weighted average exercise price at year end times the number of options outstanding. As the weighted average exercise price was above the quoted market price on December 31, 2008, 2007 and 2006, there was no aggregate intrinsic value on those dates.

The fair value of each non-plan option award is estimated on the date of grant using the Black-Scholes option pricing valuation model using the assumptions in the following table. Compensation is recognized on an accelerated accrual method over the vest period.

The weighted average grant date fair value per share of non-plan options granted during the years ended December 31, 2007 was $16.49. There were no non-plan options granted during 2008 or 2006.

At December 31, 2008, the Company had approximately $34,000 of unrecognized compensation cost related to non-vested share non-plan option awards that is expected to be recognized over a weighted average period of 1.21 years.

Weighted Average Black-Scholes Option Pricing Assumptions

	2008	2007	2006
Dividend yield	—	0%	—
Estimated annual volatility	—	53.24%	—
Risk-free interest rate	—	6.00	—
Estimated forfeiture rate	—	12.50%	—
Estimated holding period (years)	—	10	—

HeartWare International, Inc. 2008 Stock Incentive Plan

On August 5, 2008, the Company adopted the HeartWare International, Inc. 2008 Stock Incentive Plan. The 2008 Stock Incentive Plan allows for the issuance of awards representing up to 469,140 shares of the Company's common stock. As of December 31, 2008, there have been no awards granted under this plan.

Summary

The following table summarizes information about all outstanding awards, including the ESOP, RSU and non-plan options, as of December 31, 2008:

	Awards Outstanding			Awards Exercisable		
Range of Exercise Prices	Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)
$0.00 - $0.00	142,846	$ —	9.32	—	$ —	—
$0.24 - $17.94	279,524	9.83	4.72	162,396	7.43	1.74
$18.19 - $33.95	399,365	23.80	7.10	187,281	24.58	5.90
$34.19 - $36.37	19,485	36.37	1.11	8,569	36.37	1.00
	841,220	$ 15.41	6.55	358,246	$ 17.09	3.89

We generally recognize compensation expense for our share awards deemed probable of vesting using an accelerated accrual method over the substantive vesting period. The Company allocates expense to general and administrative expense, the cost of manufacturing and research and development expense based on the award holders' employment function.

We recognize share-based compensation for the value of the portion of awards that are ultimately expected to vest. Statement No. 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The term "forfeitures" is distinct from "cancellations" or "expirations" and represents only the unvested portion of the surrendered award. We have applied an annual forfeiture rate of approximately 12.5% to all unvested share awards as of December 31, 2008, which represents the portion that we expect will be forfeited each year over the vesting period. We will re-evaluate this analysis periodically and adjust the forfeiture rate as necessary. Ultimately, we will only recognize expense for those shares that vest.

For the years ended December 31, 2008, 2007 and 2006, the Company recorded share-based payment expenses as follows:

(in thousands)	2008	2007	2006
General and administrative	$ 1,026	$ 1,365	$ 293
Cost of product sold	37	—	—
Research and development	89	900	597
	$ 1,152	$ 2,265	$ 890

Note 9 Income Taxes

At December 31, 2008 and 2007, the Company had gross deferred tax assets in excess of deferred tax liabilities of $26.4 million and $17.6 million, respectively. The Company determined that it is not more likely than not that such assets will be realized, and as such has taken a valuation allowance of $26.4 million and $17.6 million as of December 31, 2008 and 2007, respectively. The Company evaluates its ability to realize its deferred tax assets each period and adjusts the amount of its 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. The Company operates within multiple taxing jurisdictions and is subject to audit in those jurisdictions. Because of the complex issues involved, any claims can require an extended period to resolve.

SFAS No. 109 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. The Company has applied a 100% valuation allowance against its net deferred tax assets as of December 31, 2008 and 2007.

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

	For the Year Ended December 31,		
	2008	2007	2006
United States	$(24,679,024)	$(17,354,330)	$(13,467,250)
Non-US	915,403	(4,584,669)	(3,959,458)
	$(23,763,621)	$(21,938,999)	$(17,426,708)

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 has increased by approximately $8.8 million, $7.3 million and $6.0 million for the years ended December 31, 2008, 2007 and 2006, respectively.

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

	At December 31,	
	2008	2007
Net operating loss and other carryforwards	$ 26,418,604	$ 17,649,460
Total deferred tax assets	26,418,604	17,649,460
Valuation allowance	(26,418,604)	(17,649,460)
Net deferred tax assets	$ —	$ —

At December 31, 2008, the Company had net operating loss carryforwards of approximately $64.9 million for US federal income tax purposes and $5.8 million for non-US income tax purposes. Non-US losses have an unlimited carry forward period and the US operating losses expire as follows:

Year of Expiration	Year Generated	US Losses	Foreign Losses
unlimited	2005	—	$ (422,443)
unlimited	2006	—	(3,069,139)
unlimited	2007	—	(2,320,105)
2025	2005	$ (9,433,864)	—
2026	2006	(13,467,250)	—
2027	2007	(17,354,330)	—
2028	2008	(24,679,024)	—
		$(64,934,468)	$ (5,811,687)

Uncertain tax positions

At January 1, 2007, the Company adopted the provisions of FASB Interpretation No. 48, "*Accounting for Uncertainty in Income Taxes*" (FIN No. 48). At the adoption date, the Company applied FIN No. 48 to all tax positions for which the statute of limitation remained open. No liabilities for resulting unrecognized tax benefits were identified in connection with the implementation of FIN No. 48. The amount of unrecognized tax benefits as of January 1 and December 31, 2007 and December 31, 2008 was $0. There have been no material changes in unrecognized tax benefits through December 31, 2008. The fiscal years 2005, 2006, 2007 and 2008 are considered open tax years in state, federal and Australian tax jurisdictions. We currently do not have any audit investigations in any jurisdiction.

Note 10 Commitments and Contingencies

The Company has the following contingent liabilities resulting from the acquisition by HeartWare, Inc. of a business that previously held the Company's technology:

- a milestone payment of $750,000 within 6 months of the date when the first circulatory assist device is approved for sale in Europe, provided that the Company has at least $15,000,000 in cash on hand and, if the Company does not have $15,000,000 at that time, then the payment is deferred until such time that the Company has $15,000,000 in cash on hand;
- a milestone payment of $1,250,000 within 6 months of the date when the first circulatory assist device is approved for sale in the United States, provided that the Company has at least $25,000,000 in cash on hand and, if the Company does not have $25,000,000 at that time, then the payment is deferred until such time that the Company has $25,000,000 in cash on hand; and
- a special payment of up to $500,000 upon a sale of HeartWare, Inc. if such sale generates proceeds in excess of the aggregate liquidation preferences of all of HeartWare, Inc.'s then outstanding preferred stock.

On January 30, 2009, the Company received approval to sell its first circulatory assist device in Europe and as such recorded a liability related to the first milestone payment listed above as of that date, which could be paid as early as July 2009 if the Company has $15,000,000 in cash on hand at that time.

At December 31, 2008, we had purchase order commitments of approximately $2.6 million related to product costs and property, plant and equipment purchases.

In addition to the above, the Company has entered into employment agreements with all of its executive officers, including the Chief Executive Officer and the Chief Financial Officer who is also the 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 in control of the Company, as defined in such agreements.

Note 11 Guarantees

On December 16, 2008, the Company entered into a Deed of Cross Guarantee (the "Deed") by and among the Group's entities; HeartWare International, Inc. 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 the Company from the requirement to prepare and lodge audited accounts for HeartWare Limited in Australia. HeartWare International, Inc. is the holding entity, HeartWare, Inc. is the alternative Trustee and HeartWare Limited is a member of the Closed Group for purposes of the Class Order.

Note 12 Shareholders' Equity

Preferred Stock

The Company is authorized to issue up to 5,000,000 shares of preferred stock, $.001 par value per share. The Company's 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

The Company is authorized to issue up to 25,000,000 shares of common stock, $.001 par value per share. As of December 31, 2008, the Company had an equivalent of 8,866,702 shares outstanding. Holders are entitled to one vote for each share of common stock (or its equivalent).

See the Consolidated Statement of Stockholders' Equity for detail related to the Company's equity transactions.

Note 13 Retirement Savings Plan

We have established a 401(k) plan and 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. We have not made any contributions to the plan during any of the periods presented.

Note 14 Net Loss Per Share

Basic earnings (loss) per share is computed by dividing net income (loss) applicable to common shares by the weighted-average number of common shares outstanding during the period. Diluted earnings (loss) per share adjusts basic earnings (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. The following securities have been excluded from the calculation of diluted loss per share, as their effect would be anti-dilutive.

Common shares issuable upon:	2008	2007
Exercise of share-based payment awards	841,220	766,563
Conversion of convertible note	—	43,005

Note 15 Subsequent Events

Proposed Acquisition by Thoratec Corporation

On February 12, 2009, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") and Loan Agreement with Thoratec Corporation ("Thoratec"). Also, in connection with the Merger Agreement, Apple Tree Partners I, L.P., a beneficial owner of approximately 30.2% of the Company's common stock, and all of the directors and certain executive officers of the Company, entered into support agreements with Thoratec (each, a "Support Agreement") pursuant to which such stockholders have agreed to vote the shares of the Company's common stock held by them to adopt the Merger Agreement and, subject to certain exceptions, not to dispose of their shares prior to the date of the Company's stockholder vote. The Support Agreements terminate upon termination of the Merger Agreement.

Concurrent with the Merger Agreement, Thoratec entered into a Loan Agreement with HeartWare pursuant to which Thoratec has agreed to loan HeartWare up to $28 million through one or more term loans subject to the terms and conditions set forth in the Loan Agreement. Thoratec has deposited $20 million into an escrow account in order to support the loan. Beginning on May 1, 2009, HeartWare may borrow up to $12.0 million and beginning on July 31, 2009 HeartWare may borrow up to an aggregate of $20.0 million. In the event that all of the conditions to closing the Merger other than the receipt of regulatory approvals have been satisfied and Thoratec exercises an option under the Merger Agreement to extend the outside date for the completion of the Merger until January 31, 2010, HeartWare may borrow up to an additional $8.0 million, which Thoratec must deposit into the escrow account at the time it exercises its extension option.

The terms of the Merger Agreement, Loan Agreement and Support Agreements are disclosed on the Company's Current Report on Form 8-K as filed with the SEC on February 12, 2009.

Consummation of the Merger is subject to customary conditions, including adoption of the Merger Agreement by the Company's stockholders, the absence of legal impediments to consummation of the Merger and the expiration or termination of the required waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. Approval by Thoratec's shareholders is not required.

The financial statements as of December 31, 2008 do not reflect any adjustments related to these agreements.

NASDAQ Listing

On February 24, 2009, shares of our common stock commenced trading on the Nasdaq Global Market under the symbol of "HTWR". Our shares of common stock will continue to trade in the form of CHESS Depository 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".

CE Marking

On January 30, 2009, the Company received the necessary approvals to sell the HVAD pump in Europe. As a result, the milestone payment as described in Note 10 Commitments and Contingencies became payable. The Company has recorded the related liability as of January 30, 2009.

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

None.

Item 9A. CONTROLS AND PROCEDURES

The certifications of the Company's Chief Executive Officer and Chief Financial Officer are attached as Exhibits 31.1 and 31.2, respectively, to this Annual Report on Form 10-K include, in paragraph four of such certifications, information concerning the Company's disclosure controls and procedures, and internal control over financial reporting. Such certifications should be read in conjunction with the information contained in this Item 9A for a more complete understanding of the matters covered by such certifications.

Disclosure Controls and Procedures

The Company maintains disclosure controls and procedures designed to ensure information required to be disclosed in Company reports filed under the Securities Exchange Act of 1934, as amended ("the Exchange Act"), is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in Company reports filed under the Exchange Act is accumulated and communicated to management, including the Company's Chief Executive Officer and Chief Financial Officer and Chief Operating Officer, as appropriate, to allow timely decisions regarding required disclosure.

The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures as of December 31, 2008. Based on that evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures are effective as of December 31, 2008.

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 principal executive officer and our principal financial officer, management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2008 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, 2008.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Our internal control over financial reporting was not subject to attestation by our independent registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only management's report in this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

There were no changes in the Company's internal control over financial reporting during the Company's fiscal quarter ended December 31, 2008, that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

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	44	Managing Director [(1)], Chief Executive Officer
David McIntyre	38	Chief Financial Officer and Chief Operating Officer, Company Secretary
Jeffrey LaRose	47	Chief Scientific Officer
David Hathaway	61	Chief Medical Officer
Lauren Farrell	41	Vice President, Finance
Ramon Paz	51	Vice President, Quality Assurance
James Schuermann	41	Vice President, Sales and Marketing
Barry M. Yomtov	53	Vice President, Product Development

(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 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 in private practice as a senior attorney with KPMG Legal from May 2003 to October 2003 and Legal and Business Affairs Manager with Bulldogs League Club Limited from November 2001 to April 2003. Prior thereto, he was a senior attorney in private practice specializing in corporate, mergers and acquisitions and capital markets with Baker & McKenzie. 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, and strategic financial and mergers and acquisition consulting. 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 holds a Bachelors of Science in Accounting and a Masters of Business Administration from Bentley College.

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.

Barry Yomtov. Mr. Yomtov joined HeartWare in July 2006 as Vice President, Product Development and is responsible for the design and development of new products. He has over thirty years experience in the medical device industry specializing in Class III implantable medical devices. Prior to joining HeartWare, Mr. Yomtov held senior management positions as follows: Director, Engineering at Massachusetts Eye and Ear Infirmary from January 2005 to July 2006 and Director, Engineering at MicroCHIPS, Inc. from October 2001 to October 2004. Prior thereto, Mr. Yomtov was Director, Systems Integration at Abiomed, Inc. In addition, from 1978 to 1988, Mr. Yomtov held various positions in the design of pacemakers, neuro-stimulators and defibrillators at Cordis Corporation. Mr. Yomtov holds a Masters of Engineering in Biomedical Engineering from Rensselaer Polytechnic Institute. He has ten patents issued and ten publications in the field of medical devices.

Ramon Augusto 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.

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 2009 annual meeting of stockholders to be filed with the Securities and Exchange Commission, including the information set forth under the captions "Election of Directors," "Compliance with Section 16(a) of the Exchange Act" and "Audit Committee," 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 by reference to the applicable information in our definitive proxy statement for our 2009 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.

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 2009 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.

Australian Disclosure Requirements

The Company is listed for quotation on the Australian Securities Exchange ("ASX") and trades under the symbol of "HIN". As part of its ASX listing, the Company is required to comply with various disclosure requirements as set out under the ASX Listing Rules. The information in this section is not intended to fulfill information required by Part III of this Annual Report on Form 10-K.

In accordance with those requirements, the Company provides the information below.

Substantial Shareholders

The number of CHESS Depositary Instruments ("CDIs") held by the substantial shareholders and their associated interests are set out below:

	Number of Ordinary CDIs	Percentage %
Apple Tree Partners	93,588,782	30.2
Mr. Muneer A. Satter	48,000,000	15.5
FMR LLC and FIL Limited	29,112,558	9.4
Deephaven Capital Management LLC	20,515,180	6.6

Shareholder Information as at 20 February 2009.

Distribution of equity security holders

	CDIs		Options (unlisted)	
	Number of holders	Number of CDIs	Number of holders	Number of options
1 – 1,000	100	80,529	—	—
1,001 – 5,000	259	831,680	—	—
5,001 – 10,000	256	2,208,883	—	—
10,001 – 100,000	525	18,406,445	31	1,653,050
100,001 – and over	124	287,272,073	45	27,789,650
	1,264	308,799,610	76	29,442,700

The number of shareholders holding less than a marketable parcel was 455.

No.	Holder	Number of CDIs held	% of CDIs Outstanding
1.	Apple Tree Partners I LP	90,234,235	29.220
2.	HSBC Custody Nominees (Australia) Limited-GSCO ECA	48,105,000	15.580
3.	HSBC Custody Nominees (Australia) Limited	26,508,450	8.580
4.	ANZ Nominees Limited <Cash Income A/C>	21,344,828	6.910
5.	JP Morgan Nominees Australia Limited	12,770,800	4.140
6.	Citicorp Nominees Australia Limited	10,031,508	3.250
7.	National Nominees PTY Limited	7,363,488	2.380
8.	HSBC Custody Nominees (Australia) Limited – A/C 2	7,194,621	2.330
9.	Phillip Asset Management Ltd <IB AUS Bioscience Fund I A/C>	5,633,330	1.820
10.	Mr. Jon B Platt	5,197,500	1.680
11.	Warman Investments PTY Ltd	4,749,990	1.540
12.	Merrill Lynch (Australia) Nominees PTY Limited	3,870,965	1.250
13.	Mr. Jon Benjamin Platt	2,802,485	0.910
14.	UBS Nominees PTY Ltd	2,283,417	0.740
15.	Mr. Matthew Rosenthal	2,247,945	0.730
16.	Mr. Seth Garrison <Apple Tree Partners I LP A/C>	1,999,970	0.650
17.	Warman Investments PTY Ltd	1,649,970	0.530
18.	Mr. Robert Thomas and Mrs. Kyrenia Thomas <Rob Thomas Super Fund A/C>	1,549,975	0.500
19.	Nickeli Holdings PTY Limited <Wade Family S/Fund A/C>	1,451,310	0.470
20.	Fitel Nominees Limited	1,435,788	0.460
Total CDIs held by top 20 shareholders		258,425,575	83.687
Total CDIs held by all other shareholders		50,374,035	16.313

Options Unlisted

The Company has 772,782 options on issue under the Employee Share Option Plan ("ESOP"), the Restricted Stock Unit Plan or by way of Incentive Options. These options are held by 76 individuals.

The Company has an additional 68,438 options on issue, with 44,157 of these being held by 3 directors and the balance being held by 2 individuals.

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.

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 US 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 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 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 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, 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 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 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 US 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. David John McIntyre.

The address of the principal registered office in Australia is Level 57, MLC Centre, 19-29 Martin Place, Sydney NSW 2000, telephone (02) 9238 2064.

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 CDIs on of the Australian Securities Exchange 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" ("ASX Governance Recommendations"), other than as set out below. To this end, the Company provides below a review of its 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 during 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 are predominantly "US-focused".

Principle 1 – Lay solid foundations for management and oversight

Principle 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. Copies of the Charter of the Board of Directors may be downloaded from 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.

Principle 1.2 – Disclose the process for evaluating the performance of senior executives

The Company's 2007 Annual Report 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 December 31, 2008, as required by Item 11, is incorporated by reference to the applicable information in our definitive proxy statement for our 2009 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.

Reporting Requirement

The Company fully complied with Principle 1.1 and 1.2 during the year ended 31 December 2008.

Principle 2 – Structure the Board to add value

Principle 2.1 – A majority of the Board of Directors should be independent

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 Chairman	26 Nov 2004	4.1 years	Yes
Seth Harrison	Non-executive Deputy Chairman	26 Nov 2004	4.1 years	No
Denis Wade	Non-executive director	15 Dec 2004	4.0 years	Yes
Christine Bennett	Non-executive director	15 Dec 2004	4.0 years	Yes
Bob Stockman	Non-executive director	11 Dec 2006	1.1 years	Yes
Ray Larkin Jr	Non-executive director	3 Oct 2008	0.2 years	Yes
Tim Barberich	Non-executive director	29 Apr 2008	0.7 years	Yes
Doug Godshall	Chief Executive Officer / President / Executive Director	28 Oct 2006	1.2 years	No

* Calculated at as at 31 December 2008.

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.

Principle 2.2 – The Chair should be an independent director

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

Reporting Requirement

The Company fully complied with Principle 2.1 to 2.3 during the year ended 31 December 2008.

Principle 2.4 – The Board should establish a Nomination Committee

Reporting Requirement

The Company adopted a Nomination & Governance Committee on 9 December 2008 and therefore only partly complied with Principle 2.4 during the year ended 31 December 2008.

Principle 2.5 – Disclose the process for evaluating the performance of the Board, its committees and individual directors

Reporting Requirement

The Company is a developmental company with early-stage revenues and limited resources. As such, the Company has not undertaken any review of the performance of the Board, its committees and individual directors. The Company has not therefore complied with Principle 2.5 during the year ended 31 December 2008.

Principle 2.6 – Disclosure of information under Principle 2 of the ASX Governance Recommendations

Reporting Requirement

Information regarding Directors, including biographical information, as required by Item 12, is incorporated herein by reference to the applicable information in our definitive proxy statement for our 2009 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.

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 all other respects, the Company fully complied with complied with Principle 2.6 during the year ended 31 December 2008.

Principle 3 – Promote ethical and responsible decision-making

Principle 3.1 – Establish a Code of Conduct and disclose it

The Company has adopted a Code of Conduct and this was updated and replaced by a Code of Business Conduct and Ethics on 9 December 2008, a copy of which is available on the Company's website.

Principle 3.2 – Establish a policy concerning trading in Company securities by directors, senior executives and employees and disclose it

The Company has adopted a Securities Trading Policy, a copy of which is available on the Company's website.

Reporting Requirement

The Company fully complied with Principle 3.1 and 3.2 during the year ended 31 December 2008.

Principle 4 – Safeguard integrity in financial reporting

Principle 4.1 – The Board should establish an Audit Committee

Principle 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 (3) members

Principle 4.3 – The Audit Committee should have a formal charter

The Audit Committee met four times during 2008 with each of Mr. Thomas, Dr. Bennett (Chair) and Dr. Wade attending on all occasions. Mr. Stockman, who joined the Audit Committee during 2008, attended the two (2) meetings for which he was eligible to attend.

A copy of the Audit Committee Charter may be downloaded from the Company's website.

Reporting Requirement

The Company fully complied with Principle 4.1 to .3 during the year ended 31 December 2008.

Principle 4.4 – Disclosure of information under Principle 4 of the ASX Governance Recommendations

Reporting Requirement

Elsewhere in this Form 10-K, or included by reference herein, the Company has disclosed information regarding the skills, experience and expertise of directors, including audit committee members, in accordance with US disclosure requirements. 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.

The Company has not disclosed its policy for auditor rotation or selection.

In all other respects, the Company fully complied with complied with Principle 4.4 during the year ended 31 December 2008.

Principle 5 – Make timely and balanced disclosure

Principle 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

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 Principles 5.1 during the year ended 31 December 2008.

Principle 6 – Respect the rights of shareholders

Principle 6.1 – Design a communications policy for promoting effective shareholder communication and encourage their participation at general meetings and disclose those policies

The Company has implemented a number of measures so as to facilitate the effective and efficient exercise of the rights of shareholders. The Company communicates information to shareholders through a range of media including annual reports, newsletters, public (ASX) announcements and via the website. Key financial information and stock performance are also available on the Company's website. Shareholders can raise questions with the Company by contact the Company via telephone, facsimile, post or email, with relevant contact details being available on the 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 complies with Principles 6.1 for the year ended 31 December 2008.

Principle 7 – Recognise and manage risk

Principle 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 risks that the Company faces are continually changing in line with the development of the Company. The primary risks faced by the Company during 200 include 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.

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 therefore 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 complies with Principle 7.1 for the year ended 31 December 2008.

Principle 7.2 – Require management to design and implement the risk management and internal control system to manage the Company's material business risk and report to it whether those risks are being managed effectively (and makes disclosures therein)

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 Quality System, complaint handling processes, employee policies and standard operating procedures.

Principle 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 financials statements under US accounting prices and laws, management is required to provide sign-offs 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.

To this end, shareholders' attention is drawn to the certifications provided by the Chief Executive Officer and the Chief Financial Officer at the end of the Form 10-K.

The Company believes that the aforementioned reporting meets, or otherwise exceeds, the requirements of Principles 7.2 and 7.3 for the year ended 31 December 2008.

Principle 8 – Remunerate fairly and responsibly

Principle 8.1 – Establish a Remuneration Committee

The Board has established a Remuneration Committee and this was replaced by the Compensation Committee on 9 December 2008.

Principle 8.2 – Clearly distinguish the structure of non-executive directors' remuneration from that of executive directors and senior executives

The Board has established a Remuneration Committee and this was replaced by the Compensation Committee on 9 December 2008. A copy of the Charter is available on the Company's website.

The members of the Remuneration Committee are Mr. Thomas, Dr. Wade, Dr. Harrison, Mr. Barberich and Dr. Bennett.

As noted above in the discussion regarding Principle 1.2, the Company's 2007 Annual Report and the forthcoming 2008 proxy 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 and, with this exception, the Company complies with Principles 8.1 and 8.2 during the year ended 31 December 2008.

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

Rob Thomas
Chairman
Date 25 February 2009

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 2009 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 2009 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 AND 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 Shareholders' 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 Limited

Date: February 26, 2009

By: /s/ Douglas Godshall
Name: Douglas Godshall
Title: 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	Chief Executive Officer and Director (Principal Executive Officer)	February 26, 2009
/s/ David McIntyre David McIntyre	Chief Financial Officer, Chief Operating Officer and Secretary (Principal Financial and Accounting Officer)	February 26, 2009
/s/ Robert Thomas Robert Thomas	Chairman and Director	February 26, 2009
/s/ Seth Harrison Seth Harrison	Director	February 26, 2009
/s/ Christine Bennett Christine Bennett	Director	February 26, 2009
/s/ Denis Wade Denis Wade	Director	February 26, 2009
/s/ Robert Stockman Robert Stockman	Director	February 26, 2009
/s/ Timothy J. Barberich Timothy J. Barberich	Director	February 26, 2009
/s/ C. Raymond Larkin, Jr. C. Raymond Larkin, Jr.	Director	February 26, 2009

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	Convertible Note between HeartWare Limited and Apple Tree Partners I, L.P. dated December 15, 2004 (1)
10.02	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)
10.03	Lease Agreement, dated as of April 17, 2008, between JDRP Associates No. 1, Ltd. and HeartWare, Inc. (10)
10.04	Lease extension, dated as of February 23, 2004, between Sunbeam Properties, Inc. and HeartWare, Inc. (1)
10.05	Second lease extension, dated as of February 20, 2005, between Sunbeam Properties, Inc. and HeartWare, Inc. (1)
10.06	Sublease Agreement, dated June 1, 2006, between Starkey Laboratories, Inc. and HeartWare, Inc. (1)
10.07	Addendum to Sublease Agreement, dated as of June 1, 2006, between Starkey Laboratories, Inc. and HeartWare, Inc. (1)
10.08	Employment Agreement, dated as of December 5, 2008, between HeartWare International, Inc. and Douglas Godshall (5) +
10.09	Employment Agreement, dated as of December 5, 2008, between HeartWare International, Inc and David McIntyre (5) +
10.10	Employment Agreement, dated as of December 5, 2008, between HeartWare International, Inc. and Jeffrey LaRose (5) +
10.11	Employment Agreement, dated as of December 5, 2008, between HeartWare International, Inc. and James Schuermann (5) +
10.12	Employment Agreement, dated as of December 5, 2008, between HeartWare International, Inc. and Ramon Paz (5) +
10.13	Employment Agreement, dated as of December 5, 2008 between HeartWare Inc. and David R. Hathaway, M.D. * +
10.14	Separation Agreement between HeartWare, Inc. and Dozier Rowe dated May 13, 2008 (11) +
10.15	Clinical Investigation Agreement, dated as of March 21, 2006 between Medical University of Vienna and HeartWare, Inc. (1)
10.16	Clinical Investigation Agreement, dated as of February 17, 2006, between Royal Perth Hospital and HeartWare, Inc. (1)
10.17	Clinical Investigation Agreement, dated as of October 23, 2006, between Royal Brompton & Harefiled NHS Trust and HeartWare, Inc. (1)
10.18	Clinical Investigation Agreement, dated as of May 17, 2006, between Hannover Medical School and HeartWare, Inc. (1)
10.19	Production Services Agreement, dated August 17, 2006, between Minnetronix, Inc. and HeartWare, Inc. (2)
10.20	Servicing Agreement, dated August 17, 2006, between Minnetronix, Inc. and HeartWare, Inc. (1)
10.21	Sustaining Services and Clinical Support Agreement, dated August 17, 2006, between Minnetronix, Inc. and HeartWare, Inc. (1)

Exhibit No.	Description
10.22	Form of Deed of Indemnity, Access and Insurance Agreement for directors and executive officers (1) +
10.23	Letter of Appointment as a Director of the Company dated December 1, 2006 between HeartWare Limited and Robert Stockman (1) +
10.24	Letter of Appointment as a Director of the Company dated December 15, 2004 between HeartWare Limited and Robert Thomas (1) +
10.25	Letter of Appointment as a Director of the Company dated December 15, 2004 between HeartWare Limited and Christine Bennett (1) +
10.26	Letter of Appointment as a Director of the Company dated December 15, 2004 between HeartWare Limited and Denis Wade (1) +
10.27	Letter of Appointment as a Director of the Company dated September 3, 2008 between HeartWare International, Inc. and Ray Larkin * +
10.28	Letter of Appointment as a Director of the Company dated April 16, 2008 between HeartWare International, Inc. and Timothy J. Barberich * +
10.29	HeartWare Limited Employee Share Option Plan Rules (1) +
10.30	HeartWare Limited Share Performance Rights Plan — Plan Rules (3) +
10.31	Incentive Option Agreement between HeartWare Limited and Dr. Christine Bennett (12)
10.32	Incentive Option Agreement between HeartWare Limited and Dr. Denis Wade (12)
10.33	Incentive Option Agreement between HeartWare Limited and Inteq Limited (12)
10.34	Incentive Option Agreement between HeartWare Limited and Robert Thomas (12)
10.35	HeartWare International, Inc. 2008 Stock Incentive Plan (6)
10.36	HeartWare International, Inc. Employee Stock Option Plan (7)
10.37	HeartWare International, Inc. Restricted Stock Unit Plan (8)
10.38	Form of HeartWare International, Inc. Incentive Option Terms (9)
10.39	Business Lease, dated December 27, 2006, between HeartWare, Inc. and Atlantic-Philadelphia Realty LLC (12)
10.40	Loan Agreement, dated as of February 12, 2009, among HeartWare International, Inc., the Guarantors thereto and Thoratec Corporation (14)
10.41	Investor's Rights Agreement, dated as of February 12, 2009, between HeartWare International, Inc. and Thoratec Corporation (14)
21.1	List of Subsidiaries *
23.1	Consent of Independent Registered Public Accounting Firm *

Exhibit No.	Description
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 10.22 filed with Amendment No. 2 to the Company's Registration Statement on Form 10 (File No. 000-52595) filed with the Securities and Exchange Commission on July 13, 2007.

(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 99.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 15, 2008.

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

(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.

* Filed herewith

\+ Management contract or compensatory plan or arrangement.

Exhibit 10.13

5 December 2008

David R. Hathaway, MD
2 Windcrest Lane
Millis, MA 02054

Dear David:

In light of the fact that changes need to be made to your existing employment letter agreement in order to ensure compliance with Section 409A of the Internal Revenue Code of 1986, and to update the terms of your employment to reflect HeartWare, Inc.'s (the "Company") current employment practices, we set forth below the terms and conditions of your continuing employment with us:

1. Position. Your title will be Chief Medical Officer**.** As such, you will be responsible for, among other things, managing the overall clinical and regulatory affairs of the Company including establishing clinical and regulatory strategies, recruitment, administration, resource requirements, budgeting, oversight of all medical issues related to the Company's products, clinical trial data, post commercial complaints, data presentation, medical journal publications and participating in the senior management leadership team. You shall report directly to the President / Chief Executive Officer of the Company, and shall provide such other services as may be requested by the President or the Parent's (as defined below) Board of Directors (the "Board"), consistent with your position with the Company. Your usual place of business will be at the Company's offices in Framingham, Massachusetts. "Parent" shall mean the ultimate parent entity of the Company which at the above date is HeartWare International, Inc..

2. Compensation. Your base salary shall be at the annual rate of $250,000, payable in accordance with the Company's payroll policies as from time to time in effect ("Base Salary"). Your Base Salary will be reviewed annually by the Board and may be increased by the Board in its discretion. Your Base Salary shall not be subject to reduction without your prior written consent except that if the Board reduces the salary of all senior managers of the Company, the Base Salary shall be reduced by the same percentage as the percentage reduction in salary of such senior managers.

3. Annual Bonus. The Company may pay you an annual cash bonus based on your performance (which may be measured by specific goals), as determined by the Board in its discretion. The Company shall pay the annual cash bonus for a calendar year, if at all, on or after January 1st, but by no later than March 15th, of the next year. No annual cash bonus is guaranteed. Payment of all annual bonuses rests in the sole discretion of the Board regardless of the achievement of pre-specified goals, and you must be employed with the Company on the payment date in order to be eligible to receive any such annual bonus.

4. Vacation, Insurance and Benefits; Expenses.

(a) You shall be entitled to all legal holidays recognized by the Company, and 20 days of paid vacation per annum. Any unused vacation shall be subject to Company policy as from time to time in effect. Vacation days for the first fiscal year of your employment will be prorated.

(b) You shall be eligible for participation in any health, dental, and other insurance plans that may be established and maintained by the Company from time to time for its employees of your level, all as determined by the Board in its discretion. You shall also be entitled to participate in any employee benefit programs that the Board may establish for Company employees generally, including but not limited to health insurance, 401(k) Plan and stock purchase or option plans. The Company's employee benefit programs will be discussed during your orientation.

(c) The Company shall reimburse you for all usual and ordinary business expenses incurred by you in the scope of your employment hereunder in accordance with the Company's expense reimbursement policy as from time to time in effect.

5. Severance Pay.

The provisions of this Section 5 shall apply on and after January 1, 2009.

(a) If your employment is terminated by the Company without "Cause" (as defined below) or by you for "Good Reason" (as defined below) other than in connection with a Change in Control (as described below), and subject to the notice and release requirements described below, the Company shall pay, beginning within 15 days after your termination of employment, (i) your Base Salary for a period of 6 months, payable in accordance with the standard payroll practices then in effect for active senior executives; and (ii) the employee portion of your COBRA continuation coverage (to the extent that you elect coverage) for a period of 6 months or, if earlier, until you become entitled to participate in another employer's health plan.

(b) If your employment is terminated by the Company without "Cause" (as defined below) or by you for "Good Reason" (as defined below) coincident with or within 18 months after a Change in Control (as defined below), and subject to the notice and release requirements described below, the Company shall cause to be paid, on or beginning within 15 days after your termination of employment, (i) a lump-sum cash payment in an amount equal to one times your Base Salary; and (ii) the employee portion of your COBRA continuation coverage (to the extent that you elect coverage) for a period of 12 months or, if earlier, until you become entitled to participate in another employer's health plan. The severance pay provided under this Section 5(b) shall supersede, and not be in duplication of, the severance pay provided under Section 5(a).

(c) "Cause" means your: (i) material or persistent breach of this letter agreement; (ii) engaging in any act that constitutes serious misconduct, theft, fraud, material misrepresentation, serious dereliction of fiduciary obligations or duty of loyalty to the Company; (iii) conviction of a felony, or a plea of guilty or *nolo contendere* to a felony charge or any criminal act involving moral turpitude or which in the reasonable opinion of the Board brings you, the Board, the Company or any affiliate into disrepute; (iv) neglect of or negligent performance of your duties under this letter agreement; (v) willful, unauthorized disclosure of material confidential information belonging to the Company, or entrusted to the Company by a client, customer, or other third party; (vi) repeatedly being under the influence of drugs or alcohol (other than prescription medicine or other medically related drugs to the extent that they are taken in accordance with their directions) during the performance of your duties under this letter agreement, or, while under the influence of such drugs or alcohol, engaging in grossly inappropriate conduct during the performance of your duties under this letter agreement; (vii) repeated failure to comply with the lawful directions of your immediate supervisor or the Board that are not inconsistent with the terms of this letter agreement; or (viii) actual engagement in conduct that violates applicable state or federal laws governing the workplace that could reasonably be expected to bring the Company or any affiliate into disrepute. In order for the Company to terminate your employment for Cause under any of clauses (i), (iv), (vi) or (vii) in the preceding sentence, the Company must provide you with written notice of its intention to terminate employment for Cause and describing the acts or omissions upon which such termination for Cause is based, and you shall be provided a 30-day period from the date of such notice within which to cure or correct such acts or omissions if they are reasonably susceptible of cure or correction.

(d) "Good Reason" means the occurrence of any of the following without your consent:

(i) a material diminution in your Base Salary;

(ii) a material diminution in your authority, duties, or responsibilities;

(iii) a material diminution in the authority, duties, or responsibilities of the supervisor to whom you are required to report, including a requirement that you report to a corporate officer or employee instead of the Board;

(iv) a material diminution in the budget over which you retain authority; or

(v) any other action or inaction that constitutes a material breach by the Company of any agreement under which you provide services.

Notwithstanding the above, no "Good Reason" exists unless (I) you notify the Company in writing within 90 days after the initial existence of any condition listed above, and the Company fails to cure the condition within 30 days after receiving notice, and (II) you terminate employment by no later than 2 years after the initial existence of any condition listed above.

(e) A "Change in Control" means the earliest to occur of any of the following events, construed in accordance with section 409A of the Internal Revenue Code:

(i) Any one Person or more than one Person Acting as a Group (each as defined below) acquires, or has acquired during the 12-month period ending on the date of the most recent acquisition by such Person or Group, beneficial ownership of more than a majority of the total fair market value or total voting power of the then-outstanding securities of HeartWare International, Inc. (the "Parent"), a Delaware corporation that is the ultimate parent company of the Company;

(ii) Any one Person or more than one Person Acting as a Group (each as defined below) acquires, or has acquired during the 12-month period ending on the date of the most recent acquisition by such Person or Group, the assets of the Parent that have a total gross fair market value (as determined by the Board) of more than 50% of the total gross fair market value of all of the assets of, as applicable, the Parent immediately prior to the initiation of the acquisition; or

(iii) A majority of the members of the board of directors of the Parent is replaced during any 12-month period by directors whose appointment or election is not endorsed or approved by a majority of the members of the board who were members of the board prior to the initiation of the replacement.

For purposes of this Section 5(e), a "Person" means any individual, entity or group within the meaning of section 13(d)(3) or 14 (d)(2) of the Securities Exchange Act of 1934, as amended, other than (A) the Parent, (B) any trustee or other fiduciary holding securities under an employee benefit plan of the Parent, or (C) any corporation owned, directly or indirectly, by the stockholders of the Company Parent in substantially the same proportions as their ownership of stock of the Parent. Persons will be considered to be "Acting as a Group" (or a "Group") if they are owners of a corporation that enters into a merger, consolidation, purchase or acquisition of stock, or similar business transaction with the corporation. If a Person owns stock in both corporations that enter into a merger, consolidation, purchase or acquisition of stock, or similar transaction, such stockholder is considered to be Acting as a Group with other stockholders only with respect to the ownership in that corporation before the transaction giving rise to the change and not with respect to the ownership interest in the other corporation. Persons will not be considered to be Acting as a Group solely because they purchase assets of the same corporation at the same time or purchase or own stock of the same corporation at the same time, or as a result of the same public offering.

For purposes of this Section 5(e), section 318(a) of the Internal Revenue Code applies to determine stock ownership. Stock underlying a vested option is considered owned by the individual who holds the vested option (and the stock underlying an unvested option is not considered owned by the individual who holds the unvested option). For purposes of the preceding sentence, however, if a vested option is exercisable for stock that is not substantially vested (as defined by Treasury regulation section 1.83 3(b) and (j)), the stock underlying the option is not treated as owned by the individual who holds the option.

(f) Your right to receive severance pay under this Section 5 is conditioned upon (i) your signing and delivering to the Company, before any payment is due or scheduled to begin, a general release of claims, in form and substance reasonably acceptable to the Company, by which you release the Company from any claim arising from your employment by, or termination of employment with, the Company, in consideration for the payment; and (ii) your compliance with Sections 7, 8, and 9 of this letter agreement. The Company shall make no payment before the general release becomes effective upon the expiration of any applicable revocation period.

(g) Termination of employment, other than for Cause, by either you or the Company, requires 60 days' prior written notice. The Company reserves the right to pay the portion of your compensation attributable to the period for which the Company fails to satisfy the notice requirement described above. Any such payment of compensation in lieu of notice will be paid in accordance with the provisions of Section 5(a) or 5(b), as applicable.

(h) Notwithstanding the above, on termination of your employment (for whatever reason) you shall be entitled to receive the pro rata portion of your Base Salary through the date of your termination, together with such compensation or benefits to which you may be entitled by law or under the terms of the Company's compensation and benefit plans in effect including, without limitation, amounts owed to you for unpaid vacation leave accrued during the course of your employment with the Company.

6. At Will Employment.

(a) This letter agreement describes the compensation and benefits that you are entitled to receive for so long as you remain employed by the Company, but is not a contract or guarantee of employment for any particular period of time. At all times you will remain an employee at will, and you and the Company are free to terminate your employment at any time for any reason.

(b) Should your employment with the Company be terminated by the Company for Cause, by you without Good Reason, or as a result of your death or permanent disability or other physical or mental incapacity, you shall be entitled to receive only the prorated portion of your Base Salary through the date of your termination of employment, together with such other compensation or benefits to which you may be entitled by law, the terms of this letter agreement, or under the terms of the Company's compensation and benefit plans then in effect.

7. Nonsolicitation. During your employment with the Company and for 12 months after your termination of employment (for whatever reason), you shall not, directly or indirectly, on your own behalf or on behalf of any third party, without the express written consent of the Company or the Parent:

(a) canvass, solicit, target, induce or entice or endeavor to solicit, target, induce or entice away from the Company or the Parent, or attempt to divert, reduce or take away, the business or patronage (with respect to products or services of the kind or type developed, produced, marketed, furnished or sold by the Company with which you were substantively involved during the course of your employment with the Company) of, of any of the clients, customers, vendors, suppliers or accounts, or prospective clients, customers, suppliers, vendors or accounts of the Company or the Parent that you contacted, solicited or served while employed by the Company or supplier to or in the habit of dealing with the Company or the Parent;

(b) target, recruit, solicit, hire away, or otherwise interfere with the employment relationship of, or endeavor to entice away, any employee of the Company or the Parent, or otherwise induce any such employee to cease their relationship with the Company or the Parent; or

(c) counsel, procure or otherwise assist any person to do any of the acts referred to in Section 7(a) or (b).

8. Nondisparagement. You shall not, while employed by the Company or at any time after your termination of employment, directly, or through any other personal entity, make any public or private statements that are disparaging of the Company or the Parent, their respective businesses or employees, officers, directors, or stockholders. The Company agrees that, after your termination of employment with the Company for any reason, it will refrain from making any public statements that disparage you. The Company's obligations under this Section 8 extend only to the then-current officers and members of the Board, and only for so long as those individuals are officers or directors of the Company. Nothing herein shall be deemed to prevent you or the Company from complying with their respective legal obligations or responding to a subpoena or other court order.

9. Proprietary Information. Both during and after your employment with the Company, you will treat all proprietary or other confidential information as strictly confidential. Further, you agree to sign and comply with the terms and conditions of the enclosed Proprietary Information, Confidentiality, and Inventions Assignment Agreement, which is incorporated by reference into this letter agreement. This offer of continued employment is contingent upon your signing that agreement.

10. Injunctive Relief: Clawback. You recognize and acknowledge that it would be difficult to ascertain the damages arising from a breach or threatened breach of the covenants set forth in Sections 7 (nonsolicitation), 8 (nondisparagement), and 9 (proprietary information) and that any such breach or threatened breach could result in irreparable harm to the Company. You therefore agree that, notwithstanding anything in this letter agreement to the contrary, including but not limited to the forfeiture and clawback provision below, the Company shall have the right to an injunction or other equitable relief in any court of competent jurisdiction, enjoining any such breach, without prior notice to you and without the posting of a bond or other guarantee, to enforce this letter agreement. You hereby waive any and all defenses you may have on the ground of lack of jurisdiction or competence of the court to grant such an injunction or other equitable relief. The existence of this right shall not preclude any other rights and remedies at law or in equity that the Company may have. The provisions of Section 10 shall survive termination of this letter agreement and/or your employment with the Company. The existence of a claim or cause of action of any kind by you against the Company shall not constitute a defense to the enforcement by the Company of the rights provided in this Section 10 and shall not be a defense to any injunction proceeding. In addition, notwithstanding anything herein to the contrary, if the Board, in its discretion, determines that you have engaged in any activity that contravenes any covenant set forth in Section 7, 8, or 9, you shall forfeit any amount payable under Section 5 (severance pay), and you agree to repay the Company, within 30 days after you receive notice of the Board's determination, any amount previously paid by the Company under Section 5.

11. Blue Pencil; Severability. If any provision of this letter agreement is construed by a court of competent jurisdiction to be invalid or unenforceable, that construction does not affect the remainder of this agreement, which is to be given full force and effect without regard to the invalid or unenforceable provision. Any invalid or unenforceable provision is to be reformed to the maximum time, geographic and/or business limitations permitted by applicable laws, so as to be valid and enforceable.

12. Waivers. No delay or omission by the Company in exercising any right under this letter agreement operates as a waiver of that or any other right. The Company's waiver or consent on any one occasion is effective only for that occasion and is not be construed as a bar or waiver of any right on any other occasion.

13. Federal Employment Law. Please note that Federal law requires you to provide the Company with documentation of your identity and eligibility to work in the United States. In addition, the Company verifies the validity of social security numbers. Accordingly, this offer is further conditioned upon your providing the required documentation to the Company within three business days after your start date. A list of the required documentation will be provided during your orientation.

14. Prior Employers. By accepting this offer of employment, you are representing that you are not party to any agreement with any prior employer that prevents your working for the Company or that would prevent you from performing your assigned duties for the Company.

15. Background Check. The Company reserves the right to conduct a background check of its employees, and your employment may be conditioned on satisfactory results.

16. Tax Withholding. The Company may withhold from any amounts payable under this letter agreement such federal, state, local or foreign income and employment taxes as shall be required to be withheld under applicable law.

17. Section 409A Compliance. The following rules relate to section 409A of the Internal Revenue Code of 1986 and any regulations and Treasury guidance promulgated thereunder ("Section 409A"), which govern deferred compensation:

(a) This letter agreement is intended to comply with, or otherwise be exempt from, Section 409A.

(b) The Company shall undertake to administer, interpret, and construe this letter agreement in a manner that does not result in the imposition on you of any additional tax, penalty, or interest under Section 409A.

(c) The Company and you agree to execute any and all amendments to this letter agreement permitted under applicable law, as mutually agreed in good faith, as may be necessary to ensure that this letter agreement complies with Section 409A.

(d) The preceding provisions, however, shall not be construed as a guarantee by the Company of any particular tax effect to you under this letter agreement. The Company shall not be liable to you for any payment made under this letter agreement that is determined to result in an additional tax, penalty, or interest under Section 409A, nor for reporting in good faith any payment made under this letter agreement as an amount includible in gross income under Section 409A.

(e) For purposes of Section 409A, the right to a series of installment payments under this letter agreement shall be treated as a right to a series of separate payments.

(f) With respect to any reimbursement of expenses of, or any provision of in-kind benefits to, you, as specified under this letter agreement, such reimbursement of expenses or provision of in-kind benefits shall be subject to the following conditions: (i) the expenses eligible for reimbursement or the amount of in-kind benefits provided in one taxable year shall not affect the expenses eligible for reimbursement or the amount of in-kind benefits provided in any other taxable year, except for any medical reimbursement arrangement providing for the reimbursement of expenses referred to in section 105(b) of the Internal Revenue Code; (ii) the reimbursement of an eligible expense shall be made no later than the end of the year after the year in which such expense was incurred; and (iii) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit.

(g) "Termination of employment," or words of similar import, as used in this letter agreement means, for purposes of any payments under this letter agreement that are payments of deferred compensation subject to Section 409A, your "separation from service" as defined in Section 409A.

(h) If a payment obligation under this letter agreement arises on account of your separation from service while you are a "specified employee" (as defined under Section 409A and determined in good faith by the Board), any payment of "deferred compensation" (as defined under Treasury regulation section 1.409A-1(b)(1), after giving effect to the exemptions in Treasury regulation sections 1.409A-1(b)(3) through (b)(12)) that is scheduled to be paid within six months after such separation from service shall accrue without interest and shall be paid within 15 days after the end of the six-month period beginning on the date of such separation from service or, if earlier, within 15 days after the appointment of the personal representative or executor of your estate following your death.

18. Successors, Binding Agreement. This letter agreement shall not be assignable by you. This letter agreement may be assigned by the Company to any affiliate or to any other person that is a successor in interest to all or substantially all of the business operations of the Company. This letter agreement shall be binding upon, and inure to the benefit of, the parties hereto and their respective successors, heirs and permitted assigns.

19. Governing Law. This letter agreement shall be governed in all respects, including as to validity, interpretation and effect, by the laws of the Commonwealth of Massachusetts, without regard to its conflict of laws principles.

20. Entire Agreement, Amendments. This letter agreement, including the proprietary information, confidentiality, and inventions assignment agreement incorporated herein by reference, sets forth the entire agreement between you and the Company regarding your employment with the Company and supersedes all prior agreements or other understandings, whether written or oral, express or implied, between the parties to the extent that such agreements or understandings contain provisions addressed herein; provided, however, that the severance pay provisions under your employment letter agreement with the Company in effect as of the date of this letter agreement shall continue to apply, in lieu of the severance pay provisions set forth in this letter agreement, until January 1, 2009. This letter agreement may not be amended or modified except by a written agreement executed by the parties hereto or their respective successors and legal representatives.

* * * *

To indicate your acceptance of these updated terms and conditions of your employment, please sign and return the following to me no later than date that is one week after date of offer letter:

- one copy of this letter, and
- one copy of the Company's standard Proprietary Information, Confidentiality, and Inventions Assignment Agreement, the form of which is annexed hereto as Exhibit A.

This is a great opportunity for both you and the Company, and we look forward to having you continue as a member on our team.

Sincerely,

HEARTWARE, INC.

By: /s/ David McIntyre
Name: David McIntyre
Title: Chief Financial Officer

Agreed to and accepted:

/s/ David Hathaway MD
David Hathaway

Dated: December 5, 2008

EXHIBIT A

Form of Proprietary Information, Confidentiality, and Inventions Assignment Agreement

Exhibit 10.27

HEARTWARE LIMITED
ABN 34 111 970 257

Level 57
MLC Centre
19-29 Martin Place
Sydney NSW 2000
Ph: (+61 2) 9238 2064
Fax: (+61 2) 9238 2063
www.heartware.com.au

Mr Ray Larkin

September 29, 2008

Dear Ray

LETTER OF APPOINTMENT — BOARD OF DIRECTORS

As discussed at our recent meeting, I am very pleased to confirm our offer of a position as a Non-Executive Director of HeartWare Limited ("HeartWare" or "the Company"). We trust the association will be mutually rewarding and we look forward to a long and successful relationship.

This letter sets out the terms of your directorship. It is agreed that this is a contract for services and is not a contract of employment.

Appointment

Your appointment to the Board of Directors is for no fixed term and is otherwise in accordance with the Company's Constitution. Accordingly, your appointment will be confirmed by shareholders at the Company's next Annual General Meeting.

Time commitment

By accepting this appointment, you have confirmed that you are able to allocate sufficient time to meet the expectations of your role that is likely to be in the vicinity of about 1-2 days per month on average.

Role

The Board of Directors acts within a statutory framework — principally the *Corporations Act* and the ASX Listing Rules in Australia and the *Securities Exchange Act* in the United States of America — and also in accordance with the Constitution of HeartWare. Subject to this statutory framework, the Board has the authority and the responsibility to perform the functions, determine the policies and control the affairs of the Company.

The primary role of the Board is to provide effective governance over the affairs of HeartWare so that the interests of all stakeholders are protected.

Your role will have a strong emphasis on leadership and strategic guidance for HeartWare both in the short and long-term. Specifically, as a member of the Board of Directors you will:

- provide guidance, assistance and advice to the Chief Executive Officer on the overall direction of HeartWare as a whole;

- provide input on HeartWare's strategic aims; and
- endeavour to provide appropriate guidance on matters such as commercial opportunities, funding strategies, growth areas etc.

Director's Fee

As a director you will be entitled to directors' fees of US$60,000 per annum (excluding superannuation).

HeartWare will also grant you 200,000 options under the Company's Employee Share Option Plan, subject to shareholder approval as required under the ASX Listing Rules and other relevant legislation (or an equivalent amount following completion of the redomiciliation of the Company to the United States). These options shall vest in three annual tranches commencing on the first anniversary of the grant date. The options shall have an exercise price determined by the Board of Directors.

In addition to the above, reasonable out-of-pocket expenses incurred in the course of carrying out your role will be reimbursed by the Company. Approval of the Chairman or Chief Executive Officer should be obtained before traveling interstate or overseas on behalf of the Company.

Outside interests

It is accepted and acknowledged that you have business interests other than those of HeartWare and have declared any conflicts that are apparent at present. In the event that you become aware of any conflicts of interest, these should be disclosed to the Chairman as soon as apparent.

Confidentiality

All information acquired during your appointment is confidential to HeartWare and should not be released, either during your appointment or following termination (by whatever means), to third parties without prior clearance from the Chairman.

Your attention is also drawn to the requirements under both legislation and regulation as to the disclosure of price sensitive information. Consequently, you should avoid making any public statements that might risk a breach of these requirements without prior clearance from the Chairman.

* * * * *

It would be appreciated if you could complete, sign and return the attached consent in order to formalize your appointment.

The Board welcomes you as a member of the Board of Directors and trusts that the association will be one of mutual benefit, reward and enjoyment.

Yours sincerely

Rob Thomas
Chairman

Exhibit 10.28

HEARTWARE LIMITED
ABN 34 111 970 257

Level 57
MLC Centre
19-29 Martin Place
Sydney NSW 2000
Ph: (+61 2) 9238 2064
Fax: (+61 2) 9238 2063
www.heartware.com.au

Mr Tim J. Barberich
40 Elm Street
Concord, MA 01742

April 16, 2008

Dear Tim

LETTER OF APPOINTMENT — BOARD OF DIRECTORS

As discussed at our recent meeting, I am very pleased to confirm our offer of a position as a Non-Executive Director of HeartWare Limited ("HeartWare" or "the Company"). We trust the association will be mutually rewarding and we look forward to a long and successful relationship.

This letter sets out the terms of your directorship. It is agreed that this is a contract for services and is not a contract of employment.

Appointment

Your appointment to the Board of Directors is for no fixed term and is otherwise in accordance with the Company's Constitution. Accordingly, your appointment will be confirmed by shareholders at the Company's next Annual General Meeting that is presently scheduled for mid-May 2009.

Time commitment

By accepting this appointment, you have confirmed that you are able to allocate sufficient time to meet the expectations of your role that is likely to be in the vicinity of about 1-2 days per month on average.

Role

The Board of Directors acts within a statutory framework — principally the *Corporations Act* and the ASX Listing Rules in Australia and the *Securities Exchange Act* in the United States of America — and also in accordance with the Constitution of HeartWare. Subject to this statutory framework, the Board has the authority and the responsibility to perform the functions, determine the policies and control the affairs of the Company.

The primary role of the Board is to provide effective governance over the affairs of HeartWare so that the interests of all stakeholders are protected.

Your role will have a strong emphasis on leadership and strategic guidance for HeartWare both in the short and long-term. Specifically, as a member of the Board of Directors you will:

- provide guidance, assistance and advice to the Chief Executive Officer on the overall direction of HeartWare as a whole;
- provide input on HeartWare's strategic aims; and
- endeavour to provide appropriate guidance on matters such as commercial opportunities, funding strategies, growth areas etc.

Director's Fee

As a director you will be entitled to directors' fees of US$60,000 per annum (excluding superannuation).

HeartWare will also grant you 200,000 options under the Company's Employee Share Option Plan, subject to shareholder approval as required under the ASX Listing Rules and other relevant legislation. These options shall vest in three annual tranches commencing on the first anniversary of the grant date. The options shall have an exercise price determined by the Board of Directors.

In addition to the above, reasonable out-of-pocket expenses incurred in the course of carrying out your role will be reimbursed by the Company. Approval of the Chairman or Chief Executive Officer should be obtained before traveling interstate or overseas on behalf of the Company.

Outside interests

It is accepted and acknowledged that you have business interests other than those of HeartWare and have declared any conflicts that are apparent at present. In the event that you become aware of any conflicts of interest, these should be disclosed to the Chairman as soon as apparent.

Confidentiality

All information acquired during your appointment is confidential to HeartWare and should not be released, either during your appointment or following termination (by whatever means), to third parties without prior clearance from the Chairman.

Your attention is also drawn to the requirements under both legislation and regulation as to the disclosure of price sensitive information. Consequently, you should avoid making any public statements that might risk a breach of these requirements without prior clearance from the Chairman. To this end, a copy of *Guidance Note 8: Continuous Disclosure* from the ASX Listing Rules is included for your information.

* * * * *

It would be appreciated if you could complete, sign and return the attached consent in order to formalize your appointment.

The Board welcomes you as a member of the Board of Directors and trusts that the association will be one of mutual benefit, reward and enjoyment.

Yours sincerely

Rob Thomas
Chairman

Encl: Consent to Act as a Director
ASX Guidance Note 8

Exhibit 21.1

LIST OF SUBSIDIARIES

NAME OF SUBSIDIARY	STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION
HeartWare Limited	Australia
HeartWare, Inc.	Delaware

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We have issued our report dated February 25, 2009, with respect to the consolidated financial statements included in the Annual Report of Heartware International, Inc. on Form 10-K for the year ended December 31, 2008. We hereby consent to the incorporation by reference of said report in the Registration Statement of Heartware International, Inc. on Form S-8 (File No. 33-155359, effective November 13, 2008).

/s/ GRANT THORNTON LLP

Fort Lauderdale, Florida
February 25, 2009

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 26, 2009

/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 26, 2009

/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, 2008 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 26, 2009

/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, 2008 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned Chief Financial Officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that based on his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 26, 2009

/s/ David McIntyre
David McIntyre
Chief Financial Officer
(Principal Financial Officer)