ASX ANNOUNCEMENT

1 May 2007

HeartWare Moves Towards NASDAQ Listing

HeartWare today filed its registration statement, or Form 10, with the US Securities and Exchange Commission (SEC). The Form 10 is one of our pre-cursor documents that is required in order to achieve registration of the Company's securities on a US Exchange. A copy of the HeartWare Form 10 is attached to this announcement.

Having filed the Form 10, HeartWare is in the process of establishing a Level II American Depository Receipt (ADR) program on the NASDAQ Exchange. The Level II ADR is a mechanism that will essentially enable investors anywhere in the world to buy or sell HeartWare shares on the NASDAQ Exchange. HeartWare expects to complete the US listing requirements and to begin trading its ADR during the third quarter of 2007.

HeartWare Chief Executive Officer, Mr Doug Godshall commented:

"*The filing of our Form 10 is an important first step towards HeartWare being able to access the considerable medical technology investment community in the United States. With the growing recognition that Left Ventricular Assist Devices (LVADs) are the only viable option for treating tens of thousands of patients with heart failure, the US financial community has become increasingly interested in the considerable benefits offered by HeartWare's HVAD™ system and in the Company as a potential investment. Our forthcoming listing on NASDAQ will enable these investors to transact in HeartWare stock as they would in any other NASDAQ listed security. We look forward over time to establishing meaningful liquidity in the US market and to attracting new US investors to our share register.*"

HeartWare has appointed Citigroup to act as the Depository Bank for its ADR program.

About ADRs

An ADR is a US-dollar denominated security that represents a specified number of underlying shares in a non-US company. ADRs are traded in the US and treated in the same manner as other US securities for clearance, settlement, transfer, and ownership purposes.

An ADR is issued by a US depositary bank when the underlying shares are deposited in a local custodian bank, usually by a broker who has purchased the shares in the local market. Once issued, the ADR may be freely traded in the US. When the ADR holder sells, the ADR can either be sold to another US investor or it can be canceled and the underlying shares then sold in the local market. This ability to buy or sell in either market tends to ensure a close alignment in the pricing of the securities in the local and the US markets respectively.

There are broadly three types of ADR programs, namely Level I, II and III.

Under a Level I program, ADRs are traded in the US over-the-counter ("OTC") market with prices published in the Pink Sheets. A Level I program does not require full SEC registration and the company does not have to report its accounts under US Generally Accepted Accounting Principles ("GAAP") or provide full Securities and Exchange Commission ("SEC") disclosure. Since the ADR does not trade on an exchange, liquidity may be limited.

Under a Level II program, ADRs are freely traded on a US stock exchange (NASDAQ, American or New York). A Level II program requires SEC registration and adherence to US GAAP. Since these ADRs trade in precisely the same manner as shares in a listed US company, Level II ADR programs may attract substantial liquidity.

A Level III program differs from a Level II program only in that new capital is raised at the time of the issue and certain additional registration documents are therefore required. Once issued, the ADRs trade on a US exchange in precisely the same way as those issued under a Level II program.

There are currently some 2,000 ADR programs in the US. Demand by investors for ADRs has been growing by over 30% per year, driven in part by the increasing desire of US investors to diversify their portfolios globally. Many of these investors typically do not, or cannot, invest directly outside of the US and ADRs have become the primary means by which they can gain exposure to targeted non-US companies.

About HeartWare

HeartWare is developing a family of proprietary circulatory assist devices to treat patients with heart failure. HeartWare's lead device, the HVAD™ pump, is currently progressing through an international clinical trial. With a volume of 45cc, the HVAD™ pump is the smallest "3rd generation" pump and the only full output device implantable routinely within the thoracic cavity.

HeartWare's miniaturization platform enables the development of smaller devices, potentially implantable by minimally invasive surgical techniques. Pre-clinical studies are underway for HeartWare's MVAD™ pump, a pump one-third the size of the HVAD™ pump. HeartWare's IV-VAD, a pump one-tenth the size of the HVAD™ pump, is at early prototype stage.

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

FORM 10

GENERAL FORM FOR REGISTRATION OF SECURITIES
Pursuant to Section 12(b) or (g) of The Securities Exchange Act of 1934

HEARTWARE LIMITED

(Exact name of registrant as specified in its charter)

State of Victoria, Australia	**98-0498958**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

Suite 4, Level 46, 2 Park St.
Sydney NSW
Australia 2000
+61 2 8215 7600

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

Securities to be registered pursuant to Section 12(b) of the Act: None

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

Ordinary Shares, No Par Value
(Title of class)

References

Unless the context requires otherwise, references in this registration statement to:

- "HeartWare," "the Company," "Successor", "we," "us" and "our" refer to HeartWare Limited and its consolidated subsidiary.
- "HeartWare, Inc." and "Predecessor" refer to HeartWare, Inc., a Delaware corporation incorporated on April 3, 2003. HeartWare, Inc. was acquired by HeartWare Limited on January 24, 2005.
- We use HeartWare, HVAD, MVAD and IV VAD as trademarks in the United States, Australia and other countries. All other trademarks and tradenames mentioned in this registration statement are the property of their respective owners.

Forward-Looking Statements

This registration statement contains forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to our management. The forward-looking statements are contained principally in the sections entitled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." Forward-looking statements include, but are not limited to, statements about:

- 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 products;
- our ability to develop and commercialize new products; and
- our estimates regarding our capital requirements and our need for additional financing.

In some cases, 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. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking

statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this registration statement, particularly in the "Risk Factors" section, that could cause actual results or events to differ materially from the forward-looking statements that we make.

You should read this registration statement and the documents that we have filed as exhibits to this registration statement completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements.

Corporate Information

We were registered on November 26, 2004 under the laws of the state of Victoria, Australia. We further discuss our corporate history under "Business—Corporate History". Our principal executive offices are located at Suite 4, Level 46, 2 Park Street, Sydney NSW, Australia 2000. Our telephone number is 011-61-2-8215-7600. Our website address is www.heartware.com. We have included our website address in this registration statement as an inactive textual reference only. The information on, or that can be accessed through, our website is not part of this registration statement.

US Dollars

Unless indicated otherwise in this registration statement, all references to $ or dollars refer to US dollars. References to AU$ mean the lawful currency of the Commonwealth of Australia.

ITEM 1. BUSINESS

Overview

We are 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. Using our proprietary technology, we develop blood pumps, which are also known as left ventricular assist devices, or LVADs, or circulatory assist devices, that are significantly smaller and are designed to be more reliable than those that are currently available. We believe that the unique design, smaller size and increased reliability of these pumps will enable physicians to treat a wider range of patients using less invasive surgical techniques. We also believe that our blood pumps have the potential to provide significant clinical benefits to patients suffering from advanced heart failure, leading to fewer complications and improved outcomes.

Our proprietary technology has been in development for over ten years. Key features of our technology include:

- small device size which allows for routine implantation in the space immediately surrounding the heart, known as the pericardial space in all patients, directly adjacent to the heart, unlike other full-output LVADs that are currently available;
- a hybrid magnetic and hydrodynamic impeller suspension system which eliminates the need for mechanical bearings, providing a "wearless mechanism";
- a wide-bladed impeller which facilitates clear blood flow paths through the pump;
- an integrated inflow cannula which optimizes blood flow characteristics and facilitates pericardial placement;
- dual motor stators and related circuitry which enhance system reliability; and
- efficient coupling and motor design to maximize power efficiency and enable the delivery of up to ten liters per minute of blood flow.

We are currently conducting a combined European and Australian human clinical trial for our lead device, the HeartWare Ventricular Assist Device, or HVAD pump, which is aimed at receiving European and Australian regulatory approval in late 2007 or early 2008. The trial began in March 2006 and calls for the implantation of the device in 20 patients with advanced heart failure. The endpoint for the trial is patient survival to the earlier of 180 days or transplantation. As of April 19, 2007, we have completed implants in 13 patients with a cumulative support duration of more than 1,500 days. The first three patients have reached successful completion of the endpoint, with one patient having exceeded one year of support. We intend to aggregate the Australian and European clinical trial results into a single data set for European and Australian regulatory approval submissions and to use this data to support an application for approval of the HVAD pump by the US Food and Drug Administration, or FDA.

We believe that the HVAD pump is the smallest full-output LVAD, which is an LVAD with the capacity to pump blood at the rate of up to and exceeding 8 liters of blood per minute, that is currently in clinical trials or in the marketplace and is the only centrifugal LVAD designed to be implanted above the diaphragm in all patients.

Our next generation device, the Miniaturized Ventricular Assist Device, or MVAD, is based on the same technology platform as the HVAD pump but adopts an axial flow, rather than a centrifugal flow, configuration. The MVAD, which is currently at the prototype stage and undergoing animal studies, 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 expect to initiate human clinical trials for the MVAD in mid-2009.

In parallel with our development of the MVAD, we have commenced design work on our third generation blood pump, which we currently call the IV VAD. The IV VAD will rely on the same underlying technology platform and will be a smaller version of the MVAD. Unlike the

HVAD pump or the MVAD, the IV VAD is intended to be positioned within the body's vascular network and implanted by minimally invasive catheter-based techniques. Once the IV VAD is fully developed, we expect the IV VAD to be about one-tenth the size of the HVAD pump.

Market Opportunity

Heart Failure

Heart failure is one of the leading causes of death in the developed world, affecting over 20 million people globally and 5 million people in the United States alone. Heart failure is one of the only cardiovascular diseases with both an increasing incidence and death rate. Each year, approximately 550,000 new cases are diagnosed and 300,000 patients die from advanced heart failure. According to 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, the five-year survival rate for patients suffering from heart failure is 50% and the one-year survival rate for those affected by advanced heart failure is approximately 25%. The majority of patients with heart failure have underlying cardiovascular disorders that are often the precursors to heart failure, the most common of which are atherosclerosis, myocardial infarction, hypertension, cardiomyopathy and arrhythmia. These conditions generally initiate heart failure because they either damage the muscle of the left ventricle or cause it to pump inefficiently.

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. The human body generally tries to compensate when one of its parts is not working properly, and the heart is no exception: 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. Unfortunately, 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, increased effort and further dilation of the ventricle. This degenerative process generally continues until the patient becomes debilitated and eventually dies from inadequate clearing of the lungs and inadequate flow of oxygenated blood to the organs. The inadequate lung clearance or lung congestion is why the advanced stages of heart failure are called congestive heart failure, or CHF. When someone dies from "multi-organ failure" it is generally because the heart failed to provide adequate blood supply to the organs. Patients can spend months or years of near complete debilitation because of their heart failure before death. The symptoms of heart failure can be treated by pharmaceuticals or pacemaker technology but the underlying process is largely irreversible.

A commonly accepted method for categorizing the stages of heart failure is the New York Heart Association, or NYHA, functional classification system, which identifies four levels of heart failure in a steady progression of the disease by relating symptoms to everyday activities and the patient's quality of life. These classes are:

Class	Patient Symptoms
Class I (Mild)	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation or dyspnea (shortness of breath).
Class II (Mild)	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation or dyspnea.
Class III (Moderate)	Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation or dyspnea.
Class IV (Severe)	Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased.

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. 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." In addition, a recent study conducted at the Harefield Hospital in the United Kingdom and cited in a November 2006 article in *The New England Journal of Medicine* has also shown that the one-year survival rate for patents suffering from advanced heart failure increases from 25% to over 50% when a circulatory assist device is implanted.

A large population of end-stage heart failure patients can benefit from LVAD therapy, such as our HVAD pump. Within this population there are 3 different indications of use of LVADs, which are "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. At present, there are approximately 3,000 heart transplant procedures conducted each year. The median time spent on the transplant waiting list is nine months, but patients sometimes wait as long as two years. 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 to increase as surgeons become more familiar 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 80%. 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. Since we believe that our devices will offer superior durability and reliability, we expect that the HVAD pump will be primarily used in destination therapy.

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 over 80% 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 expected to occur 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 HVAD pump 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.

LVAD technology can be categorized in broad "generations." The first generation circulatory assist devices, which were first introduced in the 1960's, were pulsatile pumps, meaning they were designed to replicate the heart's normal mechanical or contraction activity. These volume displacement pumps are relatively large and mechanically complex. They are implanted in the abdomen, with inflow and outflow cannulae routed through the diaphragm to the patient's heart. As such, they are the most invasive LVADs. We believe that the size, weight and limited durability of these LVADs have limited their utilization as destination therapy devices and that cardiologists have remained cautious about referring patients for LVAD implants because they are skeptical about the merit and reliability of the current devices. First generation devices are the only ones currently available for sale in the United States.

A range of second generation pumps is being developed. These are rotary, continuous flow devices within which a spinning impeller, or rotor, is held in place by mechanical contact bearings. These pumps are non-pulsatile, do not require valves and have fewer moving parts. They are smaller than the first generation volume-displacement pumps, have lower energy

requirements, are expected to have a lower risk of mechanical failure and are less invasive than the first generation devices. However, these second generation devices still require abdominal surgery for implantation. In addition, we believe that the use of mechanical bearings might limit the reliability of these devices over the long term. As bearings wear over time, they typically diminish LVAD performance and can ultimately cause an LVAD to fail.

Third generation pumps eliminate the use of mechanical contact bearings by introducing magnetic or hydrodynamic "bearings" to suspend the impeller. The absence of any points of mechanical contact within these devices is expected to improve system longevity. We believe our HVAD pump is the smallest third generation device in development and the only one that can be implanted in the pericardial space. We believe that the combination of our HVAD pump's wearless suspension and its small size will give us a significant and sustainable advantage over our competitors' devices. In addition, the early results from our clinical trial highlight the benefits of the key features of our HVAD pump which we believe will offer additional advantages such as ease of implantation, device reliability and energy efficiency.

Most of the data currently available analysing the benefits of LVAD therapy are based on studies of first generation pumps, which represent relatively old technology. These devices are perceived to be less reliable than the second and third generation pumps. Further, the more recent clinical success of second and third generation circulatory assist devices manufactured by companies such as Thoratec Corporation and Ventracor Limited leads us to believe that these more reliable devices are likely to gain wider physician acceptance. These devices both appear to offer substantial advantages relative to the first generation devices currently available for sale in the United States. However, we believe that even these devices lack the considerable size and ease of use advantages of the HVAD pump.

Our Target Markets—Class III and Class IV Patients

Our devices will be targeted primarily to Class III and Class IV heart failure patients and their physicians, which include the cardiologists who refer patients for implantation as well as heart surgeons who conduct the actual implantation of the device. We estimate that that the number of Class III or Class IV heart failure patients worldwide is approximately seven 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 LVADs that are smaller, easier to use and more reliable than the devices that are currently available.

We estimate that there are approximately five million Class III heart failure patients worldwide. Of these five million patients, we estimate that approximately one 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 open chest procedure required for the placement of the HVAD pump or other LVADs. We believe that up to one-third of these one 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 referring physicians comfortable with the benefits of the implant because of the potential for reduced surgical risk and shorter post-operative recovery periods.

We expect the IV VAD to address the clinical needs of the balance of these one million Class III patients. The IV VAD will be a catheter-delivered implantable pump, requiring minimal surgery and convalescence time. The pump will be aimed at treating Class III patients whose quality of life is impacted by their condition but whose illness does not yet warrant the implantation of a full-output pump.

Other Treatment Options and Their Limitations

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 the disease. 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. A drug regimen of beta-blockers, diuretics, digitalis and angiotensin-converting enzymes, or ACE inhibitors, aim to improve the effectiveness of the heart's contractions and slow CHF progression. Some investigations have suggested that the increase in survival is limited and that drug treatments merely delay the advance of CHF.

Biventricular pacing, or BVP, devices are designed to stimulate both sides of the heart electrically such that the contractions of the left and right ventricles are re-synchronized. A 2002 article in *The New England Journal of Medicine* discussing the Multicenter InSync Randomized Clinical Evaluation (MIRACLE) trial demonstrated that, of the eligible CHF patients, almost one third showed no improvement or became worse after treatment using a BVP device. In those patients who responded positively, the heart's pumping ability improved only minimally by approximately 5%. Like drugs, pacing has not been shown to halt or reverse disease progression.

Coronary artery bypass graft surgery is a surgical procedure designed to route blood flow around a blockage or narrowing of an artery located on the heart. This procedure is considered in heart failure patients primarily when there is evidence of "hibernating" heart muscle that will exhibit improved function with restoration of normal blood flow. Improvements have resulted following bypass in such cases; however, the inability to accurately identify suitable patients limits the applicability of the procedure.

Heart restraint devices are investigational devices placed either inside or outside of the dilated heart, which are intended to reduce the size of the enlarged heart, lower wall stress and improve cardiac function. The use of a device inside the heart involves surgeons removing sections of the heart thereby allowing the reduced heart to pump more effectively. In the alternative, outside-the-heart approaches involve a sock-like device that is designed to reduce the heart's size by physically pushing inwards on it. The first such device from Acorn Cardiovascular recently failed to meet its clinical study endpoint, and the FDA has denied approval for this device at this stage.

Cell-based therapies are currently at an early research stage. Although cell-based therapies may ultimately provide a cure for the underlying myocardial dysfunction in CHF, we believe that viable cell-based CHF therapies are at least a decade away from receiving FDA approval.

Intra-aortic balloon pumps have been in clinical use since the late 1960's and are inserted by a cardiologist or surgeon to reduce acute heart failure symptoms or improve cardiac output. A balloon-tipped catheter is placed in the aorta, where the balloon inflates and deflates in counter-pulsation to the heart's natural contractions. Clinically, these pumps are used for temporary support in patients with acute reversible heart failure and are not perceived as a curative therapy for advanced heart failure.

Extra-aortic balloon pumps are devices are applied to the external surface of the ascending aorta, with advantages of ease of surgical implantation and no contact with circulating blood. Several of these devices are in or expected to enter clinical trials. We believe these devices do not provide sufficient blood flow augmentation for patients in end-stage heart failure.

Total artificial hearts are implanted to replace the patient's native heart, similar to heart transplantation therapy. Artificial hearts are large, highly complicated devices requiring extensive surgical procedures, and we believe they will be used only in a very minor subset of end-stage CHF patients.

Our Solution and Products

Proprietary Pump Technology

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.

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 magnetic or hydrodynamic forces alone face various physical constraints that may limit their ability to downsize.

The HeartWare HVAD pump

The first product in our portfolio, the HVAD pump, is a small, permanently implantable LVAD capable of generating up to ten liters per minute of blood flow. With a displaced volume of only 45 cubic centimeters and a mass of 145 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. The reduced surgical complexity involved in implanting the HVAD pump in the pericardial space should lead to shorter surgery time and a less invasive procedure relative to alternative devices, which are generally implanted in the abdomen in a surgically created pump "pocket".

Device reliability is also 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 help minimize the risk of pump-induced haemolysis, which refers to damage to blood cells, or thrombus, which means blood clotting.

Upon commercialization, we intend to provide the HVAD pump and its related components in one of three separate "kits" to be purchased in combination or separately, depending upon intended use. One kit will be a patient kit that will include the HVAD pump, a patient control unit, a battery pack, a battery charger and an AC power supply, and also the necessary surgical implant tools. Another kit will be a center support kit designed for each implantation facility that will include a clinical monitor, backup controller, batteries and accessories. The third kit will be a center implementation kit for facilities initiating HVAD pump implant programs that will include a contracted number of patient kits, a center support kit and associated training materials.

Transcutaneous Energy Transfer System

Currently, the HVAD pump 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 a transcutaneous energy transfer, or TET, system, which will be compatible across the HeartWare family of pumps. This system will be designed to enable a fully implanted battery pack to be periodically recharged using induction across the skin, eliminating the need for a driveline and allowing complete implantation of the LVAD system, including the controller and batteries. TET systems are already used to power pacemakers and other implantable electronic devices.

We believe that a TET 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 more easily to engage in normal daily activities and further improving their quality of life. We are beginning to selectively recruit personnel who have previously developed TET systems for other companies. We anticipate that our ongoing development efforts in this area, aided by the continuing improvements in electronics and battery technologies, will result in our development of a TET 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 our HVAD pump as compared with others' devices.

The HeartWare MVAD

The MVAD 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 should support the human heart's full cardiac output. The MVAD is expected to require only minimally invasive surgery to implant by avoiding the need 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 pacemaker market was the elimination of the sternotomy. We are hopeful that this will hold true for LVADs when the MVAD is introduced. It is likely that many more patients and the physicians who refer them will be willing to undergo a minimally invasive surgical procedure than are currently comfortable with the full sternotomy required for LVAD implantation. 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 HVAD pump to approximately 300,000.

The first MVAD preclinical trials began in August 2005. Animal studies are on-going with the recent focus being on novel, less invasive implantation techniques.

The HeartWare IV VAD

Our IV VAD, which is currently at the early prototype stage, is an axial flow pump which is approximately one-tenth the size of the HVAD pump. The IV VAD is being designed to be delivered via a catheter and implanted fully within the patient's aorta. The initial prototype and design work suggests that this pump will have a three liter per minute output, making it ideal for Class III patients who do not need the full output of the MVAD or HVAD pump but who also are not sufficiently advanced in their disease to warrant thoracic, or chest, surgery. The IV VAD will likely be either fully percutaneous or will only require a small "cut down" in the patient's iliac artery. We believe that this reduction in procedural invasiveness will vastly expand the potential pool of IV VAD patients. We estimate that one million of the five million patients in the United States who suffer from Class III heart failure would be potential candidates for the IV VAD. Catching patients early in the progression of their heart failure would halt disease progression earlier and improve the possibility that the heart would fully recover.

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 LVAD market. To capitalize on that advantage our strategy is to obtain regulatory approval for our initial product, the HVAD pump, and begin commercial HVAD pump sales, while at the same time develop new products. Our plan includes:

Obtaining regulatory approval and commercially launching the HVAD pump — Our first priority is to obtain regulatory approval, internationally and in the United States, for the HVAD pump and to launch the HVAD pump commercially. We are currently conducting a combined European and Australian clinical trial which we expect to be completed by mid-2007. This trial is aimed at achieving European and Australian regulatory approval for the HVAD pump which is targeted for the end of 2007 or early 2008. If we complete the trial successfully, we intend to use the trial results to support pilot and pivotal human trials of the HVAD pump in the United States. We expect that the first trial would be a multi-center pilot trial for bridge-to-transplant patients. If that trial is successful, we would then submit for approval to commence a multi-center pivotal trial for bridge-to-transplant patients, followed by a second multi-center destination therapy trial.

Commencing our sales and marketing activities — Once we obtain regulatory approval to sell our product commercially, we intend to develop a network of training centers at the sites where our clinical trials are being conducted. We intend to work with a broad spectrum of physicians and key opinion leaders to promote the clinical benefits of our device. We also plan to recruit and train a direct sales force to market our product in the United States, Canada, Australia and some European countries and engage distributors elsewhere, particularly in the Asia-Pacific region.

Focusing on continuous product development — In parallel with the clinical development of the HVAD pump, we plan to advance the development of our next generation products, such as our MVAD and IV VAD. Our first MVAD animal trials began in August 2005 and our first IV VAD animal trial is scheduled to begin in the first quarter of 2008. We are also developing a prototype of a transcutaneous energy transfer system, or TET system, that will improve a patient's quality of life by allowing our devices to be recharged through skin induction without the need for a separate line that connects the pump to an externally-worn controller and battery pack. We expect our TET system prototype to be available during the third quarter of 2007. We are also developing enhancements to our existing HVAD pump 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 HVAD pump system that we believe will lead to enhancing market acceptance.

Partnering with leading professionals in the fields of cardiovascular surgery and heart centers around the world — Our Advisory Board is composed 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.

Clinical Trials and Pre-Clinical Studies

International Clinical Trial

We are currently conducting a combined European and Australian human clinical trial which is aimed at receiving European and Australian regulatory approval for the HVAD pump in late 2007 or early 2008. Implants are being conducted at a maximum of five centers, being the Vienna General Hospital in Austria, Royal Perth Hospital in Australia, Harefield Hospital in the United Kingdom, Hannover Medical Centre in Germany and St. Vincent's Hospital in Australia. The endpoint for the trial is patient survival to the earlier of 180 days or transplantation. The trial began in March 2006 and calls for the implantation of the device in twenty patients with advanced heart failure. As of April 19, 2007, we have completed implants in 13 patients with cumulative support duration of more than 1,500 days. The first three patients have reached successful completion of the study end point, with one patient having exceeded one year of support.

We initiated this pilot bridge-to-transplant trial, which has been designed in accordance with FDA protocols, at the Vienna General Hospital under the supervision of Dr Georg Wieselthaler, a member of our Advisory Board. This trial has since expanded into the Royal Perth Hospital in Australia, Harefield Hospital in the United Kingdom, the Hannover Medical Centre in Germany and St. Vincent's Hospital in Australia. This trial is designed to enable us to commence bridge-to-transplant clinical trials as soon as possible in the United States. A successful US bridge-to-transplant clinical trial will be a prerequisite for the commencement of a destination therapy trial, and we believe that the results achieved so far in our international trial

will favorably affect our ability to begin human implantation in the United States. Since Australian regulations are comparable to those in Europe, we intend to aggregate the Australian and European clinical trial results into a single data set for European and Australian regulatory approval submissions. This data will also be used to support FDA regulatory applications.

Pre-Clinical Studies

Prior to the commencement of our international clinical trial for the HVAD pump, we were required to complete a series of formal animal trials under "good laboratory practice," or GLP, guidelines. These studies were conducted successfully over a period of approximately six months during 2005 at the Texas Heart Institute, one of the world's leading heart facilities. Under the GLP study, six sheep were implanted with the HVAD pump for a period of approximately 90 days. At the end of the 90-day implant period, the HVAD pumps were explanted and detailed pathology conducted at the Texas Heart Institute. The study results demonstrated that the pumps performed according to design, with minimal hemolysis and no evidence of pump-related thrombosis. Data from the study formed the basis of our technical submissions to regulatory bodies and ethical committees prior to beginning our international clinical trial.

Prior to the GLP study, we conducted a series of pre-GLP trials of the HVAD pump in vitro and in animals. These trials were essentially design development animal trials for the HVAD pump and they were conducted to assess anatomical fitting, design, pump mechanics and long-term compatibility with blood components.

In 2005, we commenced a series of similar design development animal trials for the MVAD. These studies are continuing in 2007 with the recent focus of animal studies concentrating on innovative cannulation techniques which we expect to lead to less invasive surgical techniques.

Sales and Marketing

Cardiologists manage patients using medicines and work with interventional cardiologists and heart surgeons to ensure continuity of care for those patients who could benefit from device treatments. Cardiologists are the main source of patient referrals for surgeons and interventionists. Heart surgeons implant circulatory assist devices and, as such, they represent our primary target market for the HVAD pump. Interventional cardiologists typically work with specialized catheter-mounted instruments, which they thread through the vasculature in order to perform cardiovascular treatments. We anticipate that interventional cardiologists will become a key target market for our miniaturized devices, particularly the IV VAD, which is designed to be implanted via catheter.

Once we obtain regulatory approval to sell our product commercially, we intend to develop a network of training centers for our products. We plan to use selected trial centers in Australia, Europe and the United States as training centers and the participating physicians as advocates for the HVAD pump implantation procedure.

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. The responsibility for ordering, paying for, stocking and generally managing our devices will rest with individual hospitals. While we do not expect hospitals to be responsible for deciding which device to purchase, they will be important in the broader decision making processes. 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 the United States, Canada, Australia and some European countries and engage distributors elsewhere, particularly in the Asia-Pacific region. We expect that our Australian operations center will serve as a base of operations to enter the Asian market for the HVAD pump.

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 15 issued US patents and 10 issued Australian patents, 3 issued patents in each of Germany, the United Kingdom and France, as well as patents issued in the Netherlands, Spain, Italy, Korea, Canada and Israel. We also have 17 pending US patent applications and a number of international patent applications filed under the Patent Cooperation Treaty, as well as in Japan, Europe and Australia.

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; and
- flow estimation based on impeller speed and viscosity.

Major patents and pending patent applications covering technologies for our HVAD pump system are scheduled to expire at various times between 2016 and 2027. Pending patent applications covering technologies for our MVAD are scheduled to expire in 2024 and 2025.

Pending patent applications covering technologies for our IV VAD are scheduled to expire in 2025 and 2028.

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, 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.

We own a registered trademark in the United States and Australia for HEARTWARE. In addition, we are seeking ownership of the HEARTWARE mark in Europe. In addition, we have filed applications for certain other trademarks that are currently pending in the United States, Europe and Australia.

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 prior pre-market approval 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 pre-market approval (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.

Pre-market Approval

Each of our devices will be regulated as a Class III medical device. FDA approval of a PMA 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 to the FDA's satisfaction the safety and effectiveness of the device. 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 activities 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. Because there is no FDA-approved second or third generation LVAD, a review panel may be convened as part of any FDA review of our HVAD pump. In addition, the FDA will conduct a pre-approval inspection of our and our suppliers' facilities to evaluate compliance with the quality system regulation. Under the Medical Device User Fee and Modernization Act of 2002, the fee to submit a PMA can be up to $259,600 per PMA, but certain companies, like HeartWare, may qualify for a small business exemption. New PMAs or supplemental PMAs are required for significant modifications to the manufacturing process, labeling, use and design of a device that is approved through the pre-market approval process. Pre-market approval 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 almost always required to support a PMA. Clinical trials for a "significant risk" device such as ours require submission of an application for an investigational device exemption, or IDE, to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Clinical trials for a significant risk device may begin once the IDE application is allowed to proceed by the FDA and the institutional review boards overseeing the clinical trial at the various investigational sites. We will obtain all such required approvals for our US clinical trial prior to enrolling patients at our investigational 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 25 countries encompassing nearly all the major countries in Europe. The EU has adopted two directives that cover medical devices—Directive 93/42/EEC covering medical devices generally and Directive 90/385/EEC for 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 intend to apply for CE marking approval for our HVAD pump and expect to have final CE marking approval at the end of 2007. The method of assessing conformity with applicable regulatory requirements varies depending on the class of the device, but for our HVAD pump, the method involves a combination of self-assessment by the manufacturer of the safety and performance of the device, and a third party assessment by a Notified Body, usually of the design of the device and of the manufacturer's quality system. A Notified Body is a private commercial entity that is designated by the national government of a member state as being competent to make independent judgments about whether a product complies with applicable regulatory requirements. The manufacturer's assessment will include a clinical evaluation of the conformity of the device with applicable regulatory requirements. We intend to use BSI Management Systems America, Inc. as the Notified Body for our CE marking approval process.

Australia

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

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

In order for the Australian trials to satisfy FDA requirements, we will remain responsible for implementing the Australian trial protocol and investigational brochure, as well as maintaining clinical quality systems.

TGA approval is expected to follow receipt of CE Mark in Europe.

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 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 that covers heart transplantation. Using the new published payment rates, the base Medicare payment to CMS-certified centers increased to $136,000, with $76,000 typically assigned for each pump. 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 two separate DRG 103 payments.

We believe that our products will be Medicare-eligible and therefore that they should be entitled to reimbursement. Reimbursement is expected to apply during US clinical trials once an IDE has been approved. Several insurance providers have also implemented US policies for circulatory assist devices, including Blue Cross and Blue Shield. We believe that most 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, there is adequate budget 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 CHF.

Our principal competitors include Thoratec Corporation, World Heart Corporation, Arrow International, Jarvik Heart, MicroMed Technology, Inc, Ventracor Limited, Berlin Heart AG, Abiomed, Inc. and Terumo Heart, Inc.

AbioMed's AbioCor, Thoratec's HeartMate I LVAS and WorldHeart's Novacor LVAS are all "first generation" devices. We believe that the size, weight and limited durability of these LVADs have limited their utilization as destination therapy devices.

Examples of "second generation" devices include the HeartMate II LVAS produced by Thoratec and is expected to gain approval in 2007, the Jarvik 2000 FlowMaker pump produced by Jarvik Heart and MicroMed's Debakey VAD pump. These devices are less invasive than first generation devices but, with the exception of the Jarvik 2000, all require abdominal surgery to implant.

Research and development

From the date of our inception, we have incurred approximately $22.3 million on research and development of our LVAD technologies. For each of the years ended December 31, 2006 and 2005, we incurred research and development expenses of $11.6 million and $10.7 million, respectively. 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. We expect our research and development expenses to increase significantly as we continue the development of our HVAD pump, initiate commercialization activities, research the application of, and develop our miniaturized heart pump technology, conduct additional clinical trials and hire additional employees.

Facilities

As of December 31, 2006, we leased an approximately 30,000 square foot technology development and manufacturing center in Miramar, Florida, which includes electronics, mechanical and quality assurance laboratories as well as controlled manufacturing space, a clean room and our research and development operations. This lease expires in April 2008, and we are in negotiations with the landlord to extend the lease term. While we believe we can renew this lease on terms acceptable to us, there is no assurance that we will be able to do so.

We also lease 2,900 square-feet of office space in Sydney, Australia, where our corporate headquarters is located. This lease expires in June 2008, and we have a right to renew this lease for a further three-year period. We also lease small offices in Pleasanton, California and Framingham, Massachusetts.

We believe that our current facilities will be sufficient to meet our needs now and for the foreseeable future.

Employees

As of December 31, 2006, we had 69 employees, 13 of whom hold masters or doctorate degrees. Approximately 54 employees are engaged in research and development including manufacturing and operations, 3 in clinical and 12 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

From time to time, we may be involved in litigation relating to claims arising out of our operations. However, we are not currently involved in any legal proceedings.

Corporate History

HeartWare Limited was registered under the laws of the state of Victoria, Australia on November 26, 2004. On January 24, 2005, HeartWare Limited acquired all of the voting stock of HeartWare, Inc. in exchange for the issuance by HeartWare Limited of 88 million ordinary shares and a convertible note in the principal amount of $1.1 million.

Our operating subsidiary, 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 HVAD pump 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. HeartWare, Inc. continued to operate as an independent entity until it was acquired by HeartWare Limited.

ITEM 1A. RISK FACTORS

Our business faces many risks. We believe the risks described below are the 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 ordinary 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 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 $19.2 million in 2006 and $15.5 million in 2005. As of December 31, 2006, our accumulated deficit was $34.7 million. We do not currently have any products that have been approved for marketing, and we continue to incur research and development and general and administrative expenses related to our operations. We expect to continue to incur significant and increasing operating losses for the foreseeable future as we incur costs associated with the conduct of our clinical trials, continue our product research and development programs, seek regulatory approvals, expand our sales and marketing capabilities, increase our manufacturing operations and comply 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 conducting clinical trials, obtaining regulatory approvals and manufacturing, marketing and selling commercial products. We may never succeed in these activities, and we may never generate revenues sufficient to achieve profitability. If we do achieve profitability, we may not be able to sustain it.

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.

Currently, we have no products available for commercial sale, and to date we have not generated any product revenue. We believe our cash and cash equivalents on hand and expected cash flows from operations will not be sufficient to fund our operations for at least the next twelve months unless we obtain additional funding. In addition, the report of our independent registered public accounting firm contains a going concern opinion in connection with its audit of our financial statements for the fiscal year ended December 31, 2006. Our continued

operations are dependent on our ability to obtain additional funding during 2007. However, 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 ordinary shares may suffer dilution. If we are unable to secure additional funding, our product development programs and our commercialization efforts would be delayed, reduced or eliminated.

We have no products approved for commercial sale, and our success will depend heavily on the success of our international clinical trial for our lead device, the HVAD pump. If we are unable to complete this trial or if we experience significant delays in the trial, our ability to obtain regulatory approval to commercialize our products and to generate revenues will be harmed.

Our lead device, the HVAD pump, is currently undergoing a clinical trial at sites in Austria, Australia, the United Kingdom and Germany. Our international clinical trial protocol requires us to obtain clinical data from at least 20 patients to meet our primary safety and efficacy endpoints. As of April 19, 2007, 13 patients have been enrolled in the trial. While we hope to conclude the trial by June 30, 2007, completion could be delayed or adverse events during the trial could cause us to repeat or terminate the trial. If our clinical trial is delayed, if it must be repeated or if it is terminated, our costs associated with the trial will increase, and it will take us longer to obtain regulatory approvals and commercialize the product. 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 products candidates could harm our financial results and the commercial prospects for our products candidates.

The completion of our international clinical trial could be substantially delayed or prevented by several factors, including:

- slower than expected rates of patient recruitment and enrollment;
- failure of patients to complete the clinical trial;
- 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.

If our international clinical trial does not demonstrate the safety and efficacy of the HVAD pump or if we do not receive regulatory approval in Europe and Australia, we will be unable to commercialize our product and generate revenues.

Before we can obtain regulatory approval to commercialize the HVAD pump in Europe and Australia, which are the first places where we intend to seek such approval, we must be able to demonstrate the safety and efficacy of our product by meeting the endpoint of the trial. The endpoint is that 20 patients with advanced heart failure shall have been implanted with the HVAD pump and shall have survived to the earlier of 180 days or to the time that they have received a heart transplant. Despite the encouraging results that we have observed to date, we may not be able to demonstrate the safety and efficacy of the HVAD pump by meeting the endpoint of the trial. Even if we complete our international clinical trial successfully, we may not receive regulatory approval in Europe and Australia. If we are unable to meet the endpoint or we do not obtain regulatory approval, we will be unable to commercialize our product and generate revenues.

Even if our international clinical trial is successful and we obtain foreign regulatory approvals, we will need to obtain FDA approval to commercialize our product in the United States, which will require us to receive FDA approval to conduct clinical trials in the United States and to complete those trials successfully. If we fail to obtain approval from the FDA, we will not be able to market and sell our products in the United States.

We do not have the necessary regulatory approvals to commercialize our HVAD pump, or any of our other products, in the United States. Although we intend to use the data from our international clinical trial to support an application for approval of the HVAD pump by the FDA, we can offer no assurance that our HVAD pump, or any of our future products, will obtain FDA approval.

In order to obtain FDA approval for our HVAD pump, we will be required to receive PMA from the FDA. A PMA must be supported by pre-clinical and clinical trials to demonstrate safety and efficacy. A clinical trial will be required to support an application for a PMA, but before we can commence a clinical trial, we will first be required to apply for and receive an investigational device exemption, or IDE, which must be supported by appropriate data showing that it is safe to test the device in humans. We do not know whether our IDE for our products or the protocols for any of our clinical trials will be accepted by the FDA. We do not know if our clinical trials will begin or be completed on schedule or at all. Even if completed, we do not know if these trials will produce clinically meaningful results sufficient to show the safety and efficacy of our products so as to support an application for a PMA.

The process of obtaining marketing approval or clearance from the FDA for our HVAD pump, 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. The failure to receive product approval clearance by the FDA could 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 unforeseen 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 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. If we do not comply, the FDA or European Union organizations may withdraw clearance to market, require a product recall or take other enforcement action.

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

Even if we obtain regulatory approvals to commercialize the HVAD pump 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 LVADs may never achieve market acceptance even if we obtain regulatory approvals.

Even if we obtain regulatory approvals to commercialize the HVAD pump 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;
- the strength of marketing and distribution support; and
- sufficient third party coverage or reimbursement.

If our HVAD pump, 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 in international markets 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 international reimbursement or pricing approvals in a timely manner, if at all. Our failure to receive international reimbursement or pricing approvals would negatively impact market acceptance of our products in the international 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, if any, would be adversely affected.

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

If hospitals do not conduct destination therapy procedures using our LVADs, 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 significant negative impact on our future results.

We have limited sales, marketing and distribution experience.

To develop and increase internal 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 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 that we have never faced, 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 manufacturing 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 LVAD at our facilities in Miramar, 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 LVAD 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 LVADs for use in our current and planned clinical trials, or if our manufacturing process yields substandard LVADs, 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 the production process by a significant factor over the current level of production. There are technical challenges to increasing manufacturing capacity, and developing commercial-scale manufacturing facilities would require the investment of substantial 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 manner or at all. If we are unable to do so, we may not be able to produce our LVADs 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 supply of our LVADs, or if we cannot do so efficiently, our revenues, business and financial prospects would be adversely affected.

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. 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 and record-keeping and quality assurance efforts and subject us and our suppliers to potential regulatory inspections and stoppages. We and our suppliers may not satisfy these requirements. If we or our suppliers do not achieve required regulatory approval 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 our products. If any critical suppliers do not deliver for any reason, contractual or otherwise, our business may be seriously harmed financially. While we have sought-out second-source suppliers where possible, we obtain some critical components from sole suppliers that we could not replace without significant effort and delay. 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.

Additionally, we may experience problems or delays in our own manufacturing process, which again may be significantly 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 effectively to 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 March 31, 2007, we owned 15 issued patents in the United States and 18 patent applications in the United States, as well as 15 patents and 28 patent applications in foreign jurisdictions. 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 out 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.

In recent years, there has been significant litigation involving medical device patents and other intellectual property rights. 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 or 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 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. 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 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, Inc. and Ventracor Limited, as well as several smaller specialized private companies, such as Jarvik Heart, Inc. Some of these 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. 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;
- success and timing of new product development and introductions; and
- intellectual property protection.

Amortization of our intangible assets, which represent a significant portion of our total assets, will adversely affect our net income and we may never realize the full value of our intangible assets.

A substantial portion of our assets is composed of goodwill and identified intangible assets, which we recorded as a result of our acquisition of HeartWare, Inc. on January 24, 2005. We may not receive the recorded value for our intangible assets if we sell or liquidate our business or assets. The material concentration of intangible assets increases the risk of a large charge to operations if the revenue or recoverability of these intangible assets is impaired. Such a charge to operations could adversely affect our financial results.

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 nonprofit 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 a limited amount of product liability insurance. However, we cannot be certain that our insurance policies 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. Any 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.

We will incur increased costs as a result of being a US reporting company and we have no experience as a US reporting company.

As of December 31, 2006, we are no longer a "foreign private issuer" as such term is defined under the US securities laws and have thus become subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Although the existing listing of our ordinary shares on the Australian Stock Exchange Limited (ASX) requires us to file financial information and make certain other filings with the ASX, our status as a reporting company under the Exchange Act will cause us to incur additional legal, accounting and other expenses that we have not previously incurred, including costs related to compliance with the requirements of the Sarbanes-Oxley Act of 2002. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We also expect these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers. We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

Investors could lose confidence in our financial reports, and the value of our ordinary 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.

In the near future, Section 404 of the Sarbanes-Oxley Act of 2002 requires us to include an internal control report with our Annual Report on Form 10-K. The internal control report must include management's assessment of the effectiveness of our internal controls over

financial reporting as of the end of the fiscal year. Additionally, our independent registered public accounting firm will be required to issue a report on management's assessment of our internal control over financial reporting and a report on their evaluation of the operating effectiveness of our internal control over financial reporting.

In connection with our fiscal year 2006 audit, our accounting firm informed us that they had identified significant deficiencies in our internal controls. No material weaknesses were identified. A significant deficiency is defined as a control deficiency that adversely affects a company's ability to initiate, authorize, record, process or report financial data reliably in accordance with generally accepted accounting principles such that there is more than a remote likelihood that a misstatement of the company's financial statements that is more than inconsequential will not be prevented or detected by the company's internal control. The audit identified significant deficiencies related to the lack of segregation of duties surrounding journal entries and the physical protection of assets against environmental threats.

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 may have to design enhanced processes and controls to address issues identified through this review. Remediating any deficiencies, significant deficiencies or material weaknesses that we or our independent registered public accounting firm may identify 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 material weaknesses could affect the accuracy and timing of our financial reporting. Investors could lose confidence in our financial reports, and the value of our ordinary 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.

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. Currently, all of our clinical activities occur outside of the United States though most of our expenditures are incurred in US dollars. We may, but do not currently, try to mitigate our exposure to currency exchange rate risks by using hedging transactions or holding funds in US dollars. We may suffer losses as a result of exchange rate fluctuations.

Risk Factors Related to Our Ordinary Shares

There is no current trading market for our ordinary shares in the United States and no such market may develop.

Although our ordinary shares are currently listed on the ASX in Australia, there is not any current trading market for our ordinary shares in the United States. In the future, we may seek to list our ordinary shares or American Depositary Receipts on a US securities exchange; however, there is no certainty that we would be successful in achieving a listing. As a result, no trading market for the ordinary shares may develop in the United States and you may not be able to transfer or resell your shares at their fair value or at all.

Conversion of our outstanding convertible note or other future issuances of our ordinary shares will dilute the ownership interests of existing shareholders.

As of December 31, 2006, we had an AU$1,475,396 convertible note outstanding with a conversion price of AU$1.00 which may be converted into 1,475,396 ordinary shares. The conversion of this convertible note, together with interest accrued to the date of conversion, will dilute the ownership interest of our existing shareholders, and any subsequent sales in the public market of the ordinary shares issuable upon this conversion could adversely affect prevailing market prices of our ordinary shares. Further, the existence of the convertible note may encourage short selling of our ordinary shares by market participants because the conversion of the convertible note could depress the price of our ordinary shares. In addition, future sales of substantial amounts of our shares, or the perception that such sales could occur, could adversely affect the market price of our shares. Sales of our shares and the potential for such sales could cause our share price to decline.

The price of our ordinary shares may fluctuate significantly.

Our ordinary shares have been traded on the ASX since January 31, 2005. The price of our ordinary shares 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, our closing share price has ranged from AU$0.64 to AU$1.40 in the 12 months ended December 31, 2006. The price of our ordinary shares 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; and
- fluctuations in the economy, world political events or general market conditions.

In addition, stock markets in general and the market for shares of health care stocks in particular, have experienced extreme price and volume fluctuations in recent years, fluctuations that frequently have been unrelated to the operating performance of the affected companies. These broad market fluctuations may adversely affect the market price of our ordinary shares. The market price of our ordinary 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 controlling shareholder.

As of December 31, 2006, Apple Tree Partners I, L.P., or Apple Tree, owned approximately 49% of our outstanding ordinary shares, without giving effect to the conversion of a convertible note held by Apple Tree. As a result, Apple Tree has and will continue to have control over the outcome of any matter, including a change of control, requiring approval of holders of ordinary shares under Australian law and the rules of any stock exchange on which our ordinary shares may be listed. 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 control over us and our subsidiaries may delay or prevent a change in control even if desired by the other holders of ordinary shares, which could adversely affect the trading price of the ordinary shares.

If there are substantial sales of ordinary shares, our share price could decline.

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

We do not intend to pay cash dividends on our ordinary shares in the foreseeable future.

We have never declared or paid any cash dividends on our ordinary 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 ordinary shares appreciates.

We are currently classified as a PFIC for US federal income tax purposes. As long as we remain a PFIC, US holders of our ordinary shares may be subject to adverse tax consequences.

We are currently classified as a passive foreign investment company, or PFIC, for US federal income tax purposes because all of our income is currently derived from interest on our cash balances. As a result, for so long as we remain a PFIC, US holders of our ordinary shares could be subject to substantially increased US tax liability, including an interest charge upon the sale or other disposition of their ordinary shares or upon the receipt of "excess distributions" from us. These investors may be able to avoid some of their increased tax liability by electing to treat the Company as a qualified electing fund, or QEF. However, in order for US investors to be able to make such an election, we would be required, among other things, to provide certain information to them on an annual basis regarding the US shareholder's pro rata share of capital gain and ordinary income for the year and the amount of cash and property distributed to the shareholder. Due to the time and expense required to provide such information, we do not currently intend to provide it. US investors should consult their own tax advisors concerning the US federal income tax consequences that would apply to their investment in our ordinary shares.

Some provisions of Australian law have anti-takeover effects that could discourage or prohibit the acquisition of us by others, even if such an acquisition would be beneficial to our shareholders.

Entities wishing to acquire us will need to comply with Australian laws, including the Corporations Act and the Foreign Acquisition and Takeover Act. These laws prescribe the steps that an acquirer must undertake in order to acquire a significant interest, being greater than 20%, in the Company. A summary of these requirements are set out under Item 11 "– Acquisition of the Company" and "– Foreign Acquisition and Takeover Act". These laws may discourage or prohibit the acquisition of us by others, even if such an acquisition would be beneficial to our shareholders.

We may be subject to arbitrage risks.

Investors may seek to profit by exploiting the difference, if any, in the price of our ordinary shares on the ASX and the price of our ordinary shares available for sale in the United States, whether such sales would take place on a US securities exchange or in the over-the-counter market or otherwise. Such arbitrage activities could cause our share price in the market with the higher value to decrease to the price set by the market with the lower value.

ITEM 2. FINANCIAL INFORMATION

SELECTED CONSOLIDATED FINANCIAL DATA

The selected consolidated statement of operations data for the years ended December 31, 2006, 2005 and 2004 and for the period from November 26, 2004 (inception) to December 31, 2006 and the balance sheet data as of December 31, 2006 and 2005 (referred to as "Successor") have been derived from our consolidated audited financial statements included elsewhere in this registration statement. The selected consolidated balance sheet data as of December 31, 2004 have been derived from our audited consolidated financial statements which are not included in this registration statement. 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 registration statement.

On January 24, 2005, we acquired all of the voting stock of HeartWare, Inc., the Predecessor. Our consolidated financial statements reflect the results of HeartWare, Inc. for all periods after January 24, 2005. The selected financial data for the Predecessor are derived from the audited financial statements included elsewhere in this registration statement.

	Successor				Predecessor		
	Years Ended December 31,			Cumulative Period from November 26, 2004 (Inception) Through December 31,	Years Ended December 31,		Cumulative Period from April 8, 2003 (Inception) Through December 31,
(In thousands, except per share data)	2006	2005	2004	2006	2004	2003	2004
Statement of Operations:							
Revenues	$ —	$ —	$—	$ —	$ —	$ —	$ —
General and administrative expenses	6,024	4,312		10,336	138	166	304
Research and development expenses	11,633	10,722		22,355	4,795	1,271	6,066
Amortization of purchased intangible assets	1,788	1,629		3,417			
Depreciation					88	35	123
In process research and development expensed when acquired					—	3,984	3,984
Other income (expense)	246	1,211		1,457	(982)	(248)	(1,230)
Provision for income taxes	—	—		—			
Net loss	(19,199)	(15,452)		(34,651)	(6,003)	(5,704)	(11,707)
Basic and diluted loss per share	(0.11)	(0.11)					
	As of December 31,				As of December 31,		
	2006	2005	2004		2004	2003	
Balance Sheet Data:							
Cash and cash equivalents	$ 16,698	$ 10,039	$ 1		$ 139	$ 197	
Intangible assets, including goodwill	32,063	33,816			—	—	
Total assets	52,088	45,588			372	419	
Total liabilities	2,779	2,245			12,027	6,070	
Total shareholders' equity	49,309	43,342	1		11,654	5,651	

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements and related notes appearing elsewhere in this registration statement. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. You should review the "Risk Factors" section of this registration statement 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 described in the following discussion and analysis.

Overview

We are 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. Heart failure is one of the leading causes of death in the developed world, affecting over 20 million people globally.

HeartWare Limited was registered in the state of Victoria, Australia on November 26, 2004. On January 24, 2005, HeartWare Limited acquired all of the outstanding voting stock of HeartWare, Inc. in exchange for the issuance by HeartWare Limited of 88 million ordinary shares and a convertible note in the principal amount of $1.1 million. The total consideration for the acquisition was valued at approximately $35 million, including the convertible note. The purchase price was allocated, based on an independent valuation, to the fair value of the assets of HeartWare, Inc. We recorded $15.4 million of goodwill and $19.9 million of intangible assets.

The initial application of our blood pump technology is our HeartWare Ventricular Assist Device, or HVAD pump, which we believe is the smallest full-output left ventricle assist device, or LVAD that is currently in clinical trials or in the marketplace. We believe the HVAD pump is the only centrifugal LVAD designed to be implanted above the diaphragm in all patients.

For more than ten years, we have conducted a series of trials of our HVAD pump in vitro, in animals and, more recently, in humans pursuant to an international clinical trial. The design development animal trials for the HVAD pump were conducted to assess anatomical fitting, design, pump mechanics and long-term compatibility with blood components and were completed in 2001. From 2002 until 2004, we conducted other animal studies which culminated in the commencement of "good laboratory practice", or GLP, animal trials in early 2005. Our GLP animal trials were completed in September 2005, and we commenced our international human clinical trial in Vienna, Austria in March 2006.

Beyond the HVAD pump, 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 HVAD pump but adopts an axial flow, rather than a centrifugal flow, configuration. The MVAD, which is currently at the prototype stage and undergoing animal studies, 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 expect to initiate human clinical trials for the MVAD during mid-2009.

In parallel with the MVAD project, we have commenced design work on our third generation blood pump, which we currently call the IV VAD. The IV VAD will rely on the same underlying technology platform and will be an even miniature version of the MVAD. Unlike the HVAD pump or the MVAD, the IV VAD is intended to be positioned within the vasculature and implanted by minimally invasive catheter-based techniques. Once the IV VAD is fully developed, we expect the IV VAD to be about one-tenth the size of the HVAD pump.

We are a development stage company with a limited operating history, and we currently have no products approved for sale. To date, we have not generated any significant revenue, and we have incurred net losses in each year since our inception. The only revenue we have generated has been from interest. We expect our losses to continue and to increase as we expand our clinical trial activities and initiate commercialization activities.

We have financed our operations primarily through our January 2005 initial public offering of ordinary shares in Australia and concurrent US private placement of ordinary shares which raised aggregate net proceeds of approximately $23.4 million and a private placement of ordinary shares in May 2006 which raised net proceeds of approximately $23.4 million from both US and Australian investors.

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 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: the valuation of identifiable intangible assets acquired in business combinations, useful lives assigned to identifiable intangible assets, translation of foreign currency, accounting for research and development costs and accounting for share based payments. 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.

Valuation of Business Combinations

We record intangible assets acquired in recent business combinations under the purchase method of accounting. Amounts paid for each acquisition are allocated to the assets acquired and liabilities assumed are based on their fair values at the dates of acquisition. We then allocate the purchase price in excess of net tangible assets acquired to identifiable intangible assets. The fair

value of identifiable intangible assets is based on detailed valuations that use information and assumptions provided by management. We allocate any excess purchase price over the fair value of the net tangible and intangible assets acquired to goodwill.

Amortization and Impairment of Intangible Assets

We record intangible assets at historical cost. We amortize intangible assets using the straight-line method over their estimated useful lives, from five to fifteen years. In accordance with SFAS No. 142, "Goodwill and Other Intangible Assets," we do not amortize goodwill.

We review goodwill and intangible assets subject to amortization quarterly to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment or a change in the remaining useful life. Conditions that would indicate impairment and trigger a more frequent impairment assessment include, but are not limited to, a significant adverse change in legal factors or business climate that could affect the value of an asset or an adverse action or assessment by a regulator. If the carrying value of an asset exceeds its fair value, we write down the carrying value of the intangible asset to its fair value in the period identified. We generally calculate fair value of intangible assets as the present value of estimated future cash flows to be generated by the asset using a risk-adjusted discount rate. If the estimate of an intangible asset's remaining useful life is changed, we amortize the remaining carrying value of the intangible asset prospectively over the revised remaining useful life.

We completed an impairment test of goodwill and other intangible assets subject to amortization as required by SFAS No. 142 and SFAS No. 144. Upon completion of our impairment tests as of the end of fiscal 2006, we determined that neither goodwill nor intangible assets were impaired.

Translation of Non-US Currency

We translate all assets and liabilities of non-US entities at the year-end exchange rate and translate 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 financial statements as a component of shareholders' equity. Foreign currency transaction gains and losses are included in other, net in the consolidated statements of operations.

We have concluded that the functional currency of our Australian operations is the Australian dollar.

Research and Development

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

Share-Based Compensation

We elected to early adopt SFAS 123R effective January 1, 2005. We use a Black-Scholes option value method. Under the fair value recognition provisions of SFAS 123R, 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 assumptions, including an estimated expected life of the options, share price volatility and a forfeiture rate. We have used the contractual life of the option in determining the fair value.

We estimate the volatility of our ordinary shares on the date of grant based on the historical volatility of our publicly-traded ordinary shares. We estimate the forfeiture rate based on our historical experience of 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 use different assumptions, our stock-based compensation expense could be materially different in the future.

Fiscal Years 2006 and 2005

Revenue

We are a development stage company and have no revenues to date. We are currently conducting a combined European and Australian clinical trial with our first product, the HVAD pump, and will not generate revenue until we begin a US trial that qualifies for reimbursement or we receive regulatory approval and begin commercial sales of our product.

Cost of Goods Sold

There was no cost of goods sold recognized during the years ended December 31, 2006 or 2005, as we had no revenue from sale of products in those years.

General and Administrative

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.

During 2006, we experienced significant growth as we negotiated and obtained regulatory approvals to commence our international clinical trials, and successfully initiated the

trial by implanting the first patient with an HVAD pump. As a result, we experienced a significant expansion of our staff, including senior management, and a related expansion in infrastructure costs.

In 2006, general and administrative expenses were approximately $6.0 million, or 31% of operating expenses, compared to $4.3 million, or 26% of operating expenses, in 2005. The increase was primarily attributable to increased salaries and wages and related employee costs. Additional infrastructure costs associated with an expansion of our manufacturing facilities, accounting fees and travel also significantly contributed to the increase in general and administrative expenses.

Research and Development

Research and development expenses are the direct and indirect costs associated with developing our products. These expenses consist primarily of salaries and wages and related employee costs, external research and regulatory expenses, materials and costs associated with clinical trials. Additional costs include travel, facilities and overhead allocations. We expect that research and development expenses will continue to represent a significant portion of our operating expenses.

As discussed above, we experienced significant growth in 2006 and achieved significant research and development milestones, including the commencement of animal trials for our next generation heart pump, the MVAD. In 2006, research and development expenses were $11.6 million, or 60% of operating expenses, compared to $10.7 million, or 64% of operating expenses, in 2005. The increase of approximately $0.9 million was primarily attributable to increased salaries and wages and related employee costs, material costs and travel costs related to clinical trials, which was partially offset by a decrease of expenses related to external consultants.

Amortization of Intangible Assets

Amortization of intangible assets relates to the intangible assets purchased in connection with the acquisition of HeartWare, Inc. consisting mainly of patents, copyrights and non-compete agreements as well as intangible assets developed after the acquisition consisting mainly of patents. In 2006, amortization expense was $1.8 million, or 9% of operating expenses, as compared to $1.6 million, or 10% of operating expenses, in 2005. The increase of approximately $160,000 was primarily attributable to a full year of amortization in 2006 as the intangible assets were acquired on January 24, 2005.

Other Income

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

Interest income was approximately $844,500 in 2006 as compared to $717,000 in 2005. The increase was primarily due to increased average cash balances in 2006 as a result of our May 2006 private placement of ordinary shares in which we raised net proceeds of approximately $23.4 million.

Foreign exchange loss was approximately $584,000 in 2006 as compared to foreign exchange income of approximately $494,000 in 2005. 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. 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 deferred tax asset has not been recorded.

As of December 31, 2006, we did not have revenues or profit which would be sufficient to allow deferred tax assets to be accrued with a substantial degree of certainty. 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 2005 and 2004

HeartWare Limited was registered on November 26, 2004 for the sole purpose of acquiring HeartWare, Inc. The acquisition occurred on January 24, 2005. HeartWare, Inc. was incorporated on April 8, 2003 for the sole purpose of acquiring certain assets from Kriton Medical. The majority of operations, which consists primarily of research and development activities, prior to and post acquisition are contained within HeartWare, Inc. HeartWare Limited is a holding company that performs corporate and administrative functions.

For discussion purposes we are a providing a comparison of results of operations for the consolidated entity in 2005 versus HeartWare, Inc., our Predecessor, in 2004.

Revenue

The Company is a development stage company with no revenues to date.

Cost of Goods Sold

There was no cost of goods sold recognized during the years ended December 31, 2005 or 2004, as we had no revenue from sale of products in those years.

General and Administrative

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.

In 2005, general and administrative expenses were approximately $4.3 million, or 26% of operating expenses, compared to $138,000, or 3% of operating expenses, in 2004. The increase was primarily attributable to increased management personnel and other infrastructure costs associated with the Company's establishment of a professional management team and an initial public offering in January 2005.

Research and Development

Research and development expenses are the direct and indirect costs associated with developing our products. These expenses consist primarily of salaries and wages and related employee costs, external research and regulatory expenses, materials and costs associated with clinical trials. Additional costs include travel, facilities and overhead allocations. We expect that research and development expenses will continue to represent a significant portion of our operating expenses.

In 2005, research and development expenses were $10.7 million, or 64% of operating expenses, compared to $4.8 million, or 96% of operating expenses, in 2004. The increase of approximately $5.9 million was primarily attributable to increased salaries and wages and related employee costs, material costs and travel costs related to clinical trials incurred in 2005.

Amortization of Intangible Assets

Amortization of intangible assets relates to the intangible assets purchased in connection with the acquisition of HeartWare, Inc. consisting mainly of patents, copyrights and non-compete agreements as well as intangible assets developed after the acquisition consisting mainly of patents. In 2005, amortization expense was $1.6 million, or 10% of operating expenses. The were no intangible assets or related amortization in 2004.

Other Income

Other Income consists primarily of interest income and foreign exchange income (loss).

Interest income was approximately $717,000 in 2005 as compared to interest expense of $983,000 in 2004. The increase was primarily due to an increase cash balance due to the company's initial public offering in 2005. In 2004, interest expense related to a convertible note outstanding. The note was retired prior to the Company's acquisition of HeartWare, Inc.

In 2005, we generated foreign income of approximately $494,000 in 2005 as a result of 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. We did not generate foreign income in 2004 as all operations of the predecessor company were US based.

Liquidity and Capital Resources

At December 31, 2006, our cash and cash equivalents were $16.7 million as compared to $10 million at December 31, 2005. The increase was primarily due to the issuance, in a private placement, of ordinary shares in May 2006, which was offset in part by cash used in operations and the purchase of plant and equipment.

Cash used in operating activities for the year ended December 31, 2006 was approximately $15.9 million as compared to $11.2 million for the year ended December 31, 2005. In 2006 this amount included a net loss of $19.2 million, non-cash adjustments to net income of $3.1 million, primarily comprising $2.2 million of depreciation and amortization, and $890,000 of share-based payments, which was partially offset by a net increase in cash attributable to a change in current assets and liabilities. In 2005 cash used in operating activities included a net loss of $15.5 million, non-cash adjustments to net income of $4.0 million, primarily comprising $1.9 million of depreciation and amortization, and $1.9 million of share-based payments, which was partially offset by a net increase in cash attributable to a change in current assets and liabilities.

Investing activities used cash of approximately $1.7 million and $1.5 million for the years ended December 31, 2006 and 2005, respectively. The amounts in 2006 were primarily to acquire property, plant and equipment and software which related to our moving from research activities towards the development of manufacturing capabilities for our first product, the HVAD pump. The amounts in 2005 included purchases of plant and equipment of $1.4 million and additions to patents of $209,000 offset by net cash provided by our acquisition of HeartWare, Inc. of $126,380.

Cash provided by financing activities for years ended December 31, 2006 and 2005 was $23.5 million in each year from the net proceeds from the issuance of ordinary shares. We describe our issuances of ordinary shares under Item 10, “Recent Sales of Unregistered Securities.”

We will require additional funds to support our operations. We believe that cash and cash equivalents on hand and expected cash flows from operations will not be sufficient to fund our operations for the next twelve months unless we obtain additional funding. This means that we must raise capital in order to continue to moving toward commercialization of our products. There can be no assurance that we will be able to raise additional financing on terms that are acceptable to us, or at all.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as such term is defined in the rules promulgated by the SEC.

Contractual Obligations

The table below summarizes our commitments and contingencies at December 31, 2006. The information in the table reflects future unconditional payments and is based on the terms of the relevant agreements and appropriate classification of items under generally accepted accounting principles currently in effect.

	Payments due by period				
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Operating Leases Obligations	$1,346,927	$793,087	$471,620	$82,220	$ —
Total	$1,346,927	$793,087	$471,620	$82,220	$ —

We have entered into several operating lease agreements for facilities, primarily for our manufacturing facility in Miramar, Florida and our office building in Sydney, Australia. Terms of certain lease arrangements include renewal options, payment of certain costs such as insurance and common area maintenance.

In addition to the above, we have 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 when our first circulatory assist device is approved for sale in Europe, provided that we have at least $15,000,000 in cash on hand;
- a milestone payment of $1,250,000 when our first circulatory assist device is approved for sale in the US, provided that we have at least $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 outstanding preferred stock.

Recent Accounting Pronouncements

In June 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation Number 48, "Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109" ("FIN 48"). The interpretation contains a two-step approach to recognizing and measuring uncertain tax positions accounted for in accordance with SFAS No. 109. The first step is to evaluate the tax position for recognition by determining if the weight

of available evidence indicates it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement. The interpretation is effective for the first interim period beginning after December 15, 2006. We have not been able to complete our evaluation of the impact of adopting FIN 48 and as a result, we are not able to estimate the effect the adoption will have on our financial position and results of operations.

In September 2006, the SEC Office of the Chief Accountant and Divisions of Corporation Finance and Investment Management released SAB No. 108, "Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements" ("SAB No. 108"), that provides interpretive guidance on how the effects of the carry-over or reversal of prior year misstatements should be considered in quantifying a current year misstatement. SAB No. 108 states that registrants should quantify errors using both a balance sheet and an income statement approach and evaluate whether either approach results in quantifying a misstatement that, when all relevant quantitative and qualitative factors are considered, is material. This guidance is effective for fiscal years ending after November 15, 2006. The adoption of SAB No. 108 did not have a material impact on our financial position, results of operations or cash flows.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" ("SFAS No. 157"). This statement provides a single definition of fair value, a framework for measuring fair value and expanded disclosures concerning fair value. Previously, different definitions of fair value were contained in various accounting pronouncements creating inconsistencies in measurement and disclosures. SFAS No. 157 applies under those previously issued pronouncements that prescribe fair value as the relevant measure of value, except SFAS No. 123(R) and related interpretations and pronouncements that require or permit measurement similar to fair value but are not intended to measure fair value. This pronouncement is effective for fiscal years beginning after November 15, 2007. We do not expect the adoption of SFAS No. 157 to have a material impact on our financial position, results of operations or cash flows.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities". (SFAS 159). SFAS 159 allows an entity the irrevocable option to elect fair value for the initial and subsequent measurement for certain financial assets and liabilities on a contract-by-contract basis. Subsequent changes in fair value of these financial assets and liabilities would by recognized in earnings when they occur. SFAS 159 is effective for the Company's financial statements for the year beginning January 1, 2008, with earlier adoption permitted. The Company does not expect adoption of this statement to have an impact on its consolidated financial position and results of operations.

A variety of proposed or otherwise potential accounting standards are currently under study by standard-setting organizations and various regulatory agencies. Because of the tentative and preliminary nature of these proposed standards, management has not determined whether implementation of such proposed standards would be material to our condensed consolidated financial statements.

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 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.

Our convertible note does not bear interest rate risk as the note was issued at a fixed rate of interest.

Foreign Currency Rate Fluctuations

We conduct business in foreign countries. Our headquarters is located in Sydney, Australia and primarily comprises the executive functions of the Company. All of our trials are presently conducted outside of the United States, with trials within the United States expected to commence towards the end of 2007. Our manufacturing operations are located in Miramar, Florida.

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 financial statements as a component of stockholders' equity. Foreign currency transaction gains and losses are included in other, net in the consolidated statements of operations.

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 3. PROPERTIES

Our main operations facility is in Miramar, Florida, where we lease approximately 30,000 square feet of space. This lease expires in April 2008. We also have small satellite offices in California and Massachusetts. Our headquarters in Sydney, Australia consists of approximately 2,900 square feet, and our lease on this property expires in June 2008. We believe that our main facility located in Miramar, Florida and our other office spaces are suitable and adequate for our needs now and for the foreseeable future.

ITEM 4. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth, as of March 15, 2007, information regarding beneficial ownership of our ordinary shares by the following:

- each person, or group of affiliated persons, who is known by us to beneficially own 5% or more of any class of our voting securities;
- each of our directors;
- each of our named executive officers; and
- all current directors and executive officers as a group.

Beneficial ownership is determined according to the rules of the SEC. Beneficial ownership generally includes voting or investment power of a security and includes shares underlying options that are currently exercisable or exercisable within 60 days after the measurement date. This table is based on information supplied by officers, directors and principal shareholders. Except as otherwise indicated, we believe that the beneficial owners of the ordinary shares listed below, based on the information each of them has given to us, have sole investment and voting power with respect to their shares, except where community property laws may apply.

Unless otherwise indicated, we deem ordinary shares subject to options that are exercisable within 60 days of March 15, 2007 to be outstanding and beneficially owned by the person holding the options for the purpose of computing percentage ownership of that person, but we do not treat them as outstanding for the purpose of computing the ownership percentage of any other person.

As of March 15, 2007, there were 186,302,097 ordinary shares outstanding.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Shares Outstanding
5% Shareholders		
Apple Tree Partners I, L.P. 54th Floor, 405 Lexington Avenue, New York, NY 10174	91,588,782(1)	49.2%
Directors and Named Executive Officers		
Robert Thomas	2,540,102(2)	1.4%
Dr. Seth Harrison	91,588,782(3)	49.2%
Dr. Denis Wade	1,200,000(4)	*
Dr. Christine Bennett	200,000(5)	*
Robert Stockman	—	*
Douglas Godshall	37,305	*
David McIntyre	410,102(6)	*
Jeffrey LaRose	1,922,102(7)	1.0%
Dozier Rowe	260,000(8)	*
Jane Reedy	573,152(9)	*
William Rissman (10)	—	*
Stuart McConchie (11)	—	*
All directors and executive officers as a group (12 persons)	98,731,545(12)	53.0%

* Indicates less than 1%

(1) Includes 1,486,830 shares issuable upon conversion of a convertible note.

(2) Includes 782,102 shares subject to options exercisable within 60 days of March 15, 2007 and 950,000 shares held in trust.

(3) Represents shares held by Apple Tree Partners I, L.P., the Company's largest shareholder. Dr. Harrison is Managing General Partner in Apple Tree Partners I, L.P. Dr. Harrison disclaims beneficial ownership of such shares, except to the extent of his pecuniary interest therein.

(4) Represents 1,000,000 shares held by a family trust and 200,000 shares subject to options exercisable within 60 days of March 15, 2007.

(5) Represents shares subject to options exercisable within 60 days of March 15, 2007.

(6) Represents 382,102 shares subject to options exercisable within 60 days of March 15, 2007 and 28,000 shares held by Mr. McIntyre's spouse.

(7) Represents shares subject to options exercisable within 60 days of March 15, 2007.

(8) Includes 250,000 shares subject to options exercisable within 60 days of March 15, 2007.

(9) Represents shares subject to options exercisable within 60 days of March 15, 2007.

(10) Mr. Rissmann was our Vice President, Manufacturing and Product Development, until his resignation effective May 13, 2006.

(11) Mr. McConchie was our Chief Executive Officer until his resignation effective September 4, 2006.

(12) Includes 4,309,458 shares subject to options exercisable within 60 days of March 15, 2007.

ITEM 5. DIRECTORS AND EXECUTIVE OFFICERS

Our directors and executive officers and their respective ages are as follows:

Name	Age	Position
DIRECTORS:		
Robert Thomas	62	Chairman, Non-Executive Director
Dr. Seth Harrison	46	Deputy Chairman, Non-Executive Director
Douglas Godshall	42	Executive Director, Chief Executive Officer
Dr. Christine Bennett	51	Non-Executive Director
Dr. Denis Wade, AM	69	Non-Executive Director
Robert Stockman	53	Non-Executive Director
EXECUTIVES:		
Douglas Godshall	42	Managing Director, Chief Executive Officer
David McIntyre	36	Chief Financial Officer, Company Secretary
Dozier Rowe	54	Chief Operating Officer
Jeffrey LaRose	45	Chief Scientific Officer
Jane Reedy	47	Vice President, Clinical and Marketing
Barry Yomtov	51	Vice President, Engineering
Jennifer Foley	48	Vice President, Clinical and Regulatory Affairs

Biographical Summaries

Robert Thomas. Mr. Thomas has been our director and non-executive chairman since November 2004. Since October 2004, Mr. Thomas has been a consultant to Citigroup Corporate and Investment Bank. He is also currently a director of a number of Australian public companies, including Virgin Blue Holdings Limited and Australian Wealth Management Limited. Between March 2003 and September 2004, Mr. Thomas was the Chairman, Global Corporate and Investment Bank, Australia and New Zealand of Citigroup Global Markets Australia Pty Limited. Prior thereto, Mr. Thomas was CEO of Citigroup's (formerly known as Salomon Smith Barney) Corporate and Investment Bank, Australia and New Zealand from October 1999 until February 2003. Mr. Thomas holds a Bachelor of Economics from Monash University, Australia. He is a Master Stockbroker and has also been a member of the Securities Institute of Australia for almost four decades and a Fellow for a decade.

Dr. Seth Harrison. Dr. Harrison has been a director and deputy chairman and non-executive director since November 2004 and was Chief Executive Officer of HeartWare, Inc. from July 2003 through November 2004. Since September 1999, Dr. Harrison has been Managing General Partner of Apple Tree Partners I, L.P., an early stage life sciences venture capital firm, which is our major shareholder. Prior to September 1999, he held senior executive positions with Oak Investment Partners, Sevin Rosen Funds and Nazem & Company. Dr. Harrison received a Bachelor of Arts from Princeton University. He received his medical degree and a Masters of Business Administration from Columbia University and completed a surgery

internship at Columbia Presbyterian Hospital in New York. He serves on the board of and chairs the Finance Committee of the International Partnership for Microbicides, a Rockefeller Foundation/Gates Foundation-sponsored public-private partnership engaged in the development of anti-HIV microbicides. Dr. Harrison is also Vice Chairman of the Board of Trustees of the New York Studio School for Drawing, Painting and Sculpture.

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 five years as Vice President, Business Development, at Boston Scientific, where he was focused on acquisition strategies for the cardiology, electrophysiology, neuroradiology and vascular surgery divisions. Mr. Godshall has a Bachelor of Arts in Business from Lafayette College and Masters of Business Administration from Northeastern University in Boston, Massachusetts.

Robert Stockman. Mr. Stockman has been a director since December 2006. Since 1999, Mr. Stockman has been the President and CEO of Group Outcome LLC, a U.S.-based merchant banking firm which deploys its capital and that of its financial partners in private equity and venture capital investments in medical technology companies. He is also the co-founder and Chairman of REVA Medical, Inc, an interventional coronary medical device company. Prior to establishing Group Outcome LLC, Mr. Stockman spent eighteen years with Johnston Associates and Narragansett Capital Corporation, where he focused on venture capital investments in healthcare. Mr. Stockman holds a Bachelors Degree from Harvard College and a Master in Business Administration from The Tuck School at Dartmouth College.

Dr. Denis Wade, AM. Dr. Wade has been a director since December 2004. From 1998 until his retirement in 2003, Dr. Wade was Managing Director of Johnson & Johnson Research Pty Ltd, a research arm of Johnson & Johnson. Dr. Wade is the former Foundation Professor of Clinical Pharmacology at the University of New South Wales in Australia. Dr. Wade also serves on industry bodies in Australia, is a former President of the Australian Society of Clinical and Experimental Pharmacology and has held senior positions in the International Union of Pharmacology, serving as Chairman of the Clinical Pharmacology Section. Dr. Wade holds a Bachelor degree in Medicine and Surgery from the University of New South Wales (Australia) and a Doctorate in Philosophy from Oxford (in the United Kingdom). He was awarded an Honorary Doctorate in Science from the University of New South Wales. He is a Fellow of the Royal Australasian College of Physicians, the Australian Institute of Company Directors and the Australian Academy of Technological Sciences and Engineering.

Dr. Christine Bennett. Dr. Bennett has been a director since December 2004. In May 2006, Dr. Bennett was appointed as Group Executive, Health and Financial Solutions and Chief Medical Officer of MBF Australia Limited, Australia's second largest national health insurer. Prior thereto, Dr. Bennett held the position of Chief Executive Officer and Managing Director of Research Australia, a national body of Australian organizations and companies that are committed to making health and medical research a higher national priority in Australia and

globally, from September 2002 to May 2006. Dr. Bennett has also been the Chief Executive Officer and Managing Director of Total Healthcare Enterprises Limited from September 2001 to August 2002, a partner of KPMG Australia in the health and life sciences area from May 2000 to September 2001 and Chief Executive Officer of Westmead Hospital and Health Service in Sydney from May 1997 to May 2000. Dr. Bennett has over twenty years experience in the Australian health sector in senior executive, strategic and clinical roles. Specifically, Dr. Bennett brings substantial experience as a specialist clinician, strategist and planner and chief executive in both the public and private sectors. Dr. Bennett holds a Bachelor of Medicine and Surgery (from the University of Sydney, Australia), Master of Paediatrics (from the University of New South Wales, Australia) and is a Fellow of the Royal Australasian College of Physicians.

David McIntyre. Mr. McIntyre has been our Chief Financial Officer and Company Secretary since February 2005. 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 and, 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.

Dozier Rowe. Mr. Rowe joined HeartWare in April 2006 as our Chief Operating Officer. Prior to joining us, Mr. Rowe was the President / Managing Director of D. Rowe Consulting, Inc., a manufacturing consulting company, from March 2005 to April 2006. Prior to this Mr. Rowe had over twenty-five years of experience in the medical device, pharmaceutical and diagnostic industry, having held senior positions at Boston Scientific Corporation between September 1998 and December 2004, including the positions of Vice President / General Manager Miami Operations from April 2002 to December 2004 and Vice President Fremont Operations from October 2001 to April 2002. Mr. Rowe has also held various other senior roles with St. Jude Medical Inc. and Baxter Healthcare Corporation.

Jeffrey LaRose. Mr. LaRose is our Chief Scientific Officer and has been with the Company since its inception. Prior to joining HeartWare, since April 1999, he was involved in the development of HeartWare's technology through his employment with Kriton Medical, which the Company acquired in 2003. He is responsible for all aspects of the design and physiological controls for HeartWare's left ventricular assist device, the HVAD pump. 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.

Jane Reedy. Ms. Reedy joined HeartWare in May 2005 as Vice President, Clinical and Marketing. Ms. Reedy has over twenty years of experience in directing clinical affairs, sales and marketing in the circulatory assist device industry. Prior to joining HeartWare, Ms. Reedy was an independent consultant advising a variety of medical device companies from March 2003 to May 2005. Ms. Reedy was also employed by Thoratec Corporation from November 1993 to March 2003 in a variety of roles, including Director of Market Development from 1999 to 2003. Ms. Reedy has developed clinical and regulatory strategies for complex medical products, designed and directed multi-centre studies, formulated and executed global sales and marketing strategies and managed a network of distributors and clinical specialists worldwide. Ms. Reedy has a Master of Science in nursing from St. Louis University and has served as Department Head of Cardiothoracic Services at St. Louis University Hospital.

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 twenty-eight 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 nine patents issued, two patents pending and ten publications in the field of medical devices.

Jennifer Foley. Ms. Foley joined HeartWare in January 2007 as Vice President, Clinical & Regulatory Affairs. Ms. Foley has more than twenty years of experience in clinical trial management and regulatory activities. Prior to joining HeartWare, Ms. Foley was Vice-President, Clinical Sciences, Clinical Program Management and Operations at Boston Scientific from February 2002 to December 2006. Prior thereto, Ms. Foley was Senior Director, Clinical Affairs at The Medicines Company from July 2000 to February 2002. Ms. Foley also spent five years in various leadership positions at Parexel International Corporation, one of the world's largest contract research organizations, from July 1995 to July 2000. Before that, Ms. Foley was Clinical Program Manager at GlaxoSmithKline from April 1991 to June 1995. Ms. Foley holds a Masters of Business Administration from Boston University.

ITEM 6. EXECUTIVE COMPENSATION

The following discussion and analysis of compensation arrangements of our named executive officers for 2006 should be read together with the compensation tables and related disclosures set forth below. This discussion contains forward looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt may differ materially from currently planned programs as summarized in this discussion.

Role of the Compensation Committee

Our named executive officer compensation program is overseen and administered by the Nomination and Remuneration Committee ("Compensation Committee") of the Board of Directors. The members of this Committee are Mr. Robert Thomas (Chairman), Dr. Seth Harrison, Dr. Denis Wade and Dr. Christine Bennett.

The Compensation Committee advises the Board on compensation policies and practices generally. In addition, the Compensation Committee makes specific recommendations on compensation packages and other terms of employment for our senior executives and non-executive directors and considers recommendations from senior management regarding amendments to existing employee entitlements. In order for the Compensation Committee to make recommendations to the Board of Directors regarding compensation and incentive packages, the Compensation Committee requests that senior management obtain information for the Compensation Committee in order to assist the Compensation Committee with its decision-making process.

Philosophy

The market for medical device employees is highly competitive and, accordingly, employees in the medical device sector are generally relatively highly compensated, particularly in the United States. Because we do not currently have revenue or significant levels of detailed long-term human data for our products, potential new employees may perceive us as having a higher risk profile than other established medical device companies. Therefore, our executives are compensated in line with our perception of wider medical device industry compensation practices, especially with those of development-stage companies.

While equity-based compensation has been and remains a strong financial motivator for employees, the Board of Directors recognizes that the salary component of each employee's compensation will, in the short term, constitute the vast majority of an employee's total compensation. To that end, all options granted to employees during 2006 carried exercise prices significantly above market prices of our ordinary shares on the relevant grant date with this "premium-to-market" ranging between 14% and 43%.

We believe that this philosophy of emphasizing cash compensation in the short term and granting premium options is currently appropriate if we are to attract and retain key executives to manage the business and affairs of the Company, be a significant player in the growing circulatory assist market and increase shareholder value. We continue to monitor both our cash and option compensation approaches to ensure that they are competitive and motivating.

Compensation Objectives and Principles

We believe that our compensation policies and practices are central to our ability to attract and retain our employees. In particular, we recognize that employee attraction and retention are of the utmost importance as we transition from a development company to an early-stage manufacturer of implantable circulatory assist devices. Moreover, on a global basis, there are a limited number of individuals with significant mechanical circulatory assist experience or related medical device experience, such as pacemaker or defibrillator experience, and competition for executives with relevant experience is intense. We also recognize that because our facilities are located in the southeastern United States, in many instances potential new employees must consider the additional burden of relocation.

During this period of growth and development, we depend on a concentrated pool of employees who, consequently, are imparted with a wider set of responsibilities and obligations than would normally be expected in larger, more mature organizations. For this reason, the retention of these employees, together with their accumulated knowledge and experiences, are of great significance and directly impact on our ability to achieve our corporate objectives in a timely manner.

Our compensation policies are therefore designed to attract, retain and motivate executive officers and to align compensation and related financial incentives with the interests of shareholders.

The key principles of our compensation policies are as follows:

- offer sufficient rewards to attract and retain executives in light of current employment market conditions in our industry;
- link rewards for executives to the achievement of corporate goals thereby aligning the interest of our executives and our shareholders;
- ensure parity in terms of compensation among executives; and
- assess and reward executives using a variety of measures of performance.

Elements of Compensation

Compensation packages are set at levels that are intended to attract and retain executives capable of managing our diverse operations and achieving our strategic objectives in a timely manner.

Base Salary

For the short term, the base salary component will be the dominant factor in executive compensation. Base salaries are set by reference to the scope of the executive's responsibilities, the nature of the relevant individual's role and the extent of the executive's ongoing contributions to our strategic direction. Other relevant considerations include perceived long-term value to HeartWare, succession planning and retention.

Salaries are typically reviewed annually. Each of Mr. Godshall, Mr. Rowe and Mr. Yomtov commenced their employment with us during 2006; thus, their base salaries did not increase during the year. The base salaries of Mr. McIntyre, Mr. LaRose and Ms. Reedy did not increase during 2006 due to constraints on our time and resources. We expect to undertake a formal review for all executives for the twelve month period ending June 30, 2007.

Bonus

Sign-on bonus and performance-based bonuses are an important element of our compensation strategy. These bonuses are used to attract new executives and to reward the achievement of significant corporate milestones in circumstances where this can be linked to the delivery of improved shareholder value, subject to corporate cash flow and general working capital considerations.

We use sign-on bonuses as an additional incentive for potential executives to join us because we believe that this element of compensation often significantly influences the potential executive's decision-making process. The decision to offer such bonuses generally evolves as part of the employment negotiation process.

In 2006, we hired Mr. Godshall to be our new Chief Executive Officer and President, and Mr. Godshall was paid a sign-on bonus of $75,000 upon the commencement of his employment on September 18, 2006. This bonus was paid on the basis that we determined that it was imperative that we attract a new Chief Executive Officer with the appropriate skills, experience and qualifications to lead the Company through an important growth stage. We paid this bonus in order to ensure that we retained the services of Mr. Godshall as Chief Executive Officer and President.

The Compensation Committee and the Board of Directors also determined to pay a discretionary bonus on June 30, 2006 in recognition of the substantial achievements and progress made by the Company over a period of more than twelve months. Specifically, this discretionary bonus reflected the fact that the Company had been able to expedite the finalization of the development of the HVAD pump, successfully and quickly commence and complete GLP animal trials, negotiate and obtain regulatory approvals to commence a human clinical trial in Europe (Germany, Austria and the United Kingdom) and Australia, and importantly, to successfully initiate the Company's international human clinical trial by implanting the first patient with a HVAD pump in March 2006. These accomplishments were achieved through an

enormous contribution and personal sacrifice by the Company's executives over an extended period of time and the Company determined that the payment of this bonus to executives was appropriate in the circumstances.

All of our executives who were employed by us prior to December 1, 2005 were eligible to receive this discretionary bonus. The bonus of each individual executive was determined in conjunction with our annual performance review process. The executives who received this bonus were:

- David McIntyre, who received $35,000;
- Jeff LaRose, who received $45,000;
- Jane Reedy, who received $25,000; and
- Stuart McConchie, who received $45,200.

Option Awards

We have adopted the HeartWare Limited Employee Share Option Plan, or ESOP. The ESOP is utilized for the purpose of attracting new executives, retention and as a long-term incentive program. We perceive that it is a generally accepted practice in the medical device industry that potential employers offer senior executives compensation packages that include a significant option component. In line with this perception, we often make an initial grant of options to an incoming senior executive with effect from the commencement of employment, with subsequent awards being given at the sole discretion of the Board of Directors.

In the interest of promoting long-term shareholder value, we presently grant options that progressively vest in four annual tranches, commencing on the first anniversary of the date of employment. Further, all options granted under the ESOP in 2006 were granted at a premium to the then-current market price.

See "—HeartWare Limited Employee Share Option Plan" below for further information on our option awards.

Pensions

All executives receive retirement benefits.

In the United States, our executives are eligible to participate in a 401(k) retirement plan after 90 days of employment. We do not provide matching funds.

In Australia, we are legally obliged to contribute "superannuation", at the rate of 9% of the relevant annual gross salary, with respect to each Australian employee. Superannuation is a

retirement or pension contribution that is made to a pension fund selected by the employee. The amount is not available to the employee until retirement. As an Australian, Mr. McIntyre was entitled to this benefit until his transfer to the United States with effect from May 1, 2006.

Perquisites and Other Benefits

In the United States, we maintain health, dental and life insurance plans for the benefit of eligible executives. Each of these benefit plans requires the executive to pay a portion of the premium, with the Company paying the remainder of the premiums. These benefits are offered on the same basis to all employees. As noted above, we also maintain a 401(k) retirement plan that is available to all eligible US employees.

Life, accidental death, dismemberment and disability, and short and long-term disability insurance coverage is also offered to all eligible executives, and we pay these premiums in full. No other voluntary benefits, such as vision insurance, supplemental life and specific coverage insurance supplements, tuition assistance and work-life balance programs are currently made available to any executive.

Australian employees are not eligible to receive any of the above benefits. If Australian executives receive a benefit under their employment agreement, such as a car parking space, or other perquisites, then we are required to gross-up the cost of the benefit and to pay fringe benefits tax on this grossed-up amount to the Australian Taxation Office. The amount of any fringe tax benefits paid by us in this regard is included in the relevant employees' reported earnings. As an Australian, Mr. McIntyre received a fringe benefit in the form of a parking space and a maintained motor vehicle until his transfer the United States, with effect from May 1, 2006. The Company paid fringe benefit tax on these benefits to the Australian Taxation Office as required under Australian law and this amount is reflected in Mr. McIntyre's reported earnings.

Some executives may, generally on commencement of employment with us, be required to relocate residences in order to fulfill their job responsibilities. In this case, we negotiate a relocation allowance with the relevant executive on a case-by-case basis, and this allowance may include our making contributions toward the cost of relocation, establishment of housing and utilities, travel and, in rare cases, rental assistance.

We also provide Blackberry communication devices to various executives at no cost to the executive in circumstances where we consider that it is reasonable to do so.

HeartWare Limited Employee Share Option Plan

We have adopted the ESOP which allows us to grant options to purchase our ordinary shares to employees and directors. The ESOP is primarily designed to provide employees and directors with the opportunity to participate in our growth and success and to provide an incentive for such participants to have a greater involvement with, and to focus on, our long-term

goals. We believe that this is an important component of executive retention and central to our long-term development.

Each option issued under the ESOP allows the holder to subscribe for and be issued one of our ordinary shares. In accordance with the Company's ESOP rules (as adopted by shareholders on May 23, 2006), all ESOP options issued after we became listed on the ASX must have an exercise price which is not less than the weighted average sale price of ordinary shares sold during the five days (or such other period as our Board may determine) prior to the issue of the ESOP option.

Options may generally be exercised after they have vested and prior to the specified expiration date if the applicable exercise conditions are met. The expiration date can be for periods of up to ten years after the grant of the option.

Exercise conditions, if any, are determined by the Board and may include performance criteria set by the Board. No exercise conditions, other than continued employment, have been applied to any grants of options to executives at this stage. In addition and subject to the approval by the Board, options may be exercised at any time if we enter into a scheme of arrangement or a takeover occurs, or if an entity acquires a relevant interest in sufficient number of our ordinary shares to enable them to replace all or a majority of the Board.

There are a number of events that may cause options to lapse under the ESOP including, for example, where a participant ceases to be an employee or director of ours, for whatever reason. If we issue our ordinary shares as a share dividend, the number of ordinary shares which an option holder is entitled to receive upon the exercise of the option will be adjusted accordingly.

ESOP options are not listed for quotation on the ASX. Options issued under the ESOP are not transferable, except during a takeover in which case the options can be transferred to the bidder.

Options are typically granted upon hiring and annually based on performance thereafter.

We made the following grants of options to our executives during 2006:

- On April 20, 2006, we granted 1,000,000 options to Mr. Rowe on commencement of his employment with us and otherwise in accordance with the terms of his employment agreement. The exercise price of these options was AU$1.41, which constituted a 15% premium to the share price at the date of grant, which was AU$1.23.
- On September 27, 2006, we granted 5,581,264 options to Mr. Godshall on commencement of his employment with us and otherwise in accordance with the terms of his employment agreement. The exercise price of these options was AU$1.10, which constituted a 43% premium to the share price at the date of grant, which was AU$0.77.

- On October 28, 2006, we granted an aggregate of 800,000 options to the following executives: Mr. McIntyre, Mr. LaRose, Ms. Reedy and Mr. Rowe each received 200,000 ESOP options. The exercise price of these options was AU$1.10, which constituted a 41% premium to the share price at the date of grant, which was AU$0.78. We had previously in 2006 deferred the consideration of a grant of options to these executives as part of the annual review process until later in 2006 and this grant was therefore made following reconsideration of the issue.

As noted above, each of the above options was granted with an issue price of AU$1.10 per option. The Compensation Committee determined to apply this exercise price as this was the same price at which we completed a capital raising in May 2006.

The Board considers potential options grants to executives upon commencement of employment and as part of our annual employee performance review process that is completed in May and June each calendar year.

Employment Agreements and Severance Arrangements

All of our named executive officers have employment agreements, including the Chief Executive Officer and the Chief Financial Officer. These contracts do not have a fixed term, and the executives serve on an "at will" basis. The employment agreements of Douglas Godshall, David McIntyre, Dozier Rowe and Jane Reedy contain provisions which will entitle these executives to certain payments or benefits if their employment is terminated under certain circumstances, including after a "change in control" of the Company occurs.

The material terms of each named executive officer's employment agreement, and the payments or benefits which the named executive officers would receive under different termination circumstances, are set forth below in "—Employment Agreements" and "—Potential Post-Employment Payments", respectively.

Material Change

Except as set out below, since December 31, 2006, there has been no material change to the compensation arrangements of the named executive officers:

- On January 2, 2007, Ms. Foley was appointed Vice President, Clinical and Regulatory Affairs, and Ms. Reedy assumed the responsibilities of Vice President, Sales and Marketing, from that date.
- As a consequence of her assuming new responsibilities, Ms. Reedy's salary was increased from $200,000 to $220,000 per annum.

Share Ownership

We do not have share ownership guidelines or requirements for employees or directors.

Compensation Components of Named Executive Officers

The following summary compensation table sets forth compensation information for our last fiscal year with regard to (i) our Chief Executive Officer, (ii) our Chief Financial Officer, (iii) our other three most highly compensated executive officers during fiscal 2006 and (iv) two additional individuals for whom disclosures would have been provided but for the fact that the individuals were not serving as executive officers at the end of fiscal 2006, to whom we refer collectively as the "named executive officers."

SUMMARY COMPENSATION TABLE
For the Year Ended December 31, 2006

Name and Principal Position	Salary ($)	Bonus ($)	Option Awards (1) ($)	Change in Pension Value and Nonqualified Deferred Compensation Earnings (2) ($)	All Other Compensation ($)	Total ($)
Douglas Godshall Chief Executive Officer	87,500	75,000(3)	2,217,984	—	—	2,380,484
David McIntyre Chief Financial Officer	186,834(4)	35,000(5)	79,367	5,003	111,127(6)	417,331
Dozier Rowe Chief Operating Officer	147,212	—	79,367	—	—	226,579
Jeffrey LaRose Chief Scientific Officer	211,539	45,000(5)	79,367	—	—	335,906
Jane Reedy Vice President, Clinical and Marketing	200,000	25,000(5)	79,367	—	—	304,367
William Rissmann (7) Former Vice President, Manufacturing and Product Development	226,534	—	—	—	—	226,534
Stuart McConchie (8) Former Chief Executive Officer	567,813	45,200(5)	—	50,368	39,667(9)	703,048

(1) All option awards are issued with an exercise price in AU$. Amounts were converted using the exchange rate at December 31, 2006 of AU$1.00 = US$.7913. The amount referenced is calculated using the Black-Scholes valuation model.

(2) Statutory payments for superannuation (i.e., pension) fund equal to 9% of annual salary. This only applies to Australian employees.

(3) Represents a sign-on bonus upon commencement of employment in September 2006.

(4) Mr. McIntyre's base salary includes AU$73,333 paid in Australian dollars while Mr. McIntyre resided in Australia. Amounts were converted using the average exchange rate during the year.

(5) Represents a cash bonus paid on June 30, 2006 as part of a Company-wide bonus in recognition of our progressing into human clinical trials.

(6) Includes a one-time payment of $27,750 as a relocation allowance and seven monthly after-tax payments of approximately US$6,000 (gross cost US$9,000) for the purposes of assisting Mr. McIntyre with the provision of comparative housing, financing of motor vehicles, rental shortfall on his Australian residence and other incremental recurring costs associated with his relocation to this United States. As of December 31, 2006, a pre-tax amount of US$80,077 (AU$105,647) has been paid to Mr. McIntyre in this regard. Also includes $3,300 related to the cost of providing a maintained motor vehicle and car parking space during his employment in Australia.

(7) Mr. Rissmann was our Vice President, Manufacturing and Product Development, until his resignation effective May 13, 2006.

(8) Mr. McConchie was our Chief Executive Officer until his resignation effective September 4, 2006.

(9) Represents payments to Mr. McConchie in the form of a relocation allowance that assisted Mr. McConchie with costs associated with him relocating his family from the United Kingdom to Australia.

The following table lists all options granted to named executive officers during 2006:

GRANTS OF PLAN-BASED AWARDS
For the Year Ended December 31, 2006

Name and Position	Grant Date	Estimated Future Payouts Under Non-Equity Incentive Plan Awards			All Other Option Awards: Number of Securities Underlying Options (#)	Exercise Price of Option Awards ($/Sh)	Grant Date Fair Value of Option Awards ($)
		Threshold ($)	Target ($)	Maxium ($)			
Douglas Godshall Chief Executive Officer	09/27/06	75,000	75,000	75,000	5,581,264(1)	0.00	— —
David McIntyre Chief Financial Officer	10/28/06	—	—	—	200,000(2)	0.00	—
Dozier Rowe	10/28/06	—	—	—	200,000(2)	0.00	—
Chief Operating Officer	04/20/06	—	—	—	1,000,000(1)	0.00	—
Jeffrey LaRose Chief Scientific Officer	10/28/06	—	—	—	200,000(2)	0.00	—
Jane Reedy Vice President, Clinical and Marketing	10/28/06	—	—	—	200,000(2)	0.00	—

(1) Options granted upon commencement of employment in accordance with employment agreement.

(2) Options granted pursuant to annual review process.

Options are granted with exercise prices in Australian dollars (i.e., AU$). The exercise price per share and the calculated Black-Scholes value at option grant date per share in the table above has been converted to US dollars using the exchange rate at December 31, 2006 of AU$1.00 = US$.7913. Under the terms of the Company's ESOP rules, all options issued after we became listed on the ASX must have an exercise price which is not less than the weighted average sale price of our ordinary shares sold during the five days (or such other period as our Board may determine) prior to the time of the issuance of the option.

The following table sets forth all option exercises during 2006 by named executive officers:

OPTION EXERCISES

Name	Option Awards	
	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise ($)
William Rissmann (1) Former Vice President, Manufacturing and Product Development	191,151	40,921

(1) Mr. Rissmann was the Company's Vice President, Manufacturing and Product Development, until his resignation effective May 13, 2006.

The following table summarizes all outstanding equity awards for the named executive officers as of December 31, 2006:

OUTSTANDING EQUITY AWARDS
AT DECEMBER 31, 2006

	Option Awards				
Name and Position	Number of Securities Underlying Unexercised Options (# Exercisable)	Number of Securities Underlying Unexercised Options (# Unexercisable)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($) (1)	Option Expiration Date
Douglas Godshall	—	5,581,264	—	0.87	09/04/16
Chief Executive Officer					
David McIntyre	191,051			0.47	01/31/10
Chief Financial Officer		191,051	—	0.59	01/31/10
		191,051		0.79	01/31/10
		191,051		1.19	01/31/10
		764,204		0.59	11/30/12
		200,000		0.87	10/18/16
Dozier Rowe	—	1,000,000	—	1.12	04/20/16
Chief Operating Officer		250,000		0.87	10/18/16
Jeffrey LaRose	1,540,000	—	—	0.16	01/31/10
Chief Scientific Officer	191,051	—		0.40	04/27/15
		573,153		0.40	04/27/15
		250,000		0.87	10/18/16
Jane Reedy	286,576	859,730	—	0.40	04/27/15
Vice President, Clinical and Marketing		250,000		0.87	10/18/16
William Rissmann (2)	—	—	—	—	—
Former Vice President, Manufacturing and Product Development					
Stuart McConchie (3)	1,146,307	—	—	0.47	01/31/10
Former Chief Executive Officer		1,146,307		0.59	01/31/10
		1,146,307		0.79	01/31/10
		1,146,307		1.19	01/31/10

(1) Options are granted with exercise prices in AU$. Amounts referenced are converted to US$ at the spot rate in effect at December 31, 2006.

(2) Mr. Rissmann was the Company's Vice President, Manufacturing and Product Development until his resignation effective May 13, 2006.

(3) Mr. McConchie was the Company's Chief Executive Officer until his resignation effective September 4, 2006.

Deferred Compensation

We do not have any deferred compensation arrangements.

Employment Agreements

We have entered into employment agreements with all of our named executive officers. These agreements do not have a fixed term of employment.

Employment agreements with our named executive officers generally include certain restrictive covenants, including a confidentiality covenant that will apply during each officer's employment with us and thereafter. In the case of Mr. Godshall, Mr. McIntyre, Mr. LaRose and Ms. Reedy, their employment contracts also include a non-solicitation covenant for the duration of their employment and one year thereafter and a non-competition covenant for the duration

of their employment and one year thereafter.

Those named executive officers with a "technical competence" also enter into a Proprietary Information, Confidentiality and Inventions Assignment Agreement whereby the relevant employee, amongst other things, assigns all rights, including all intellectual property rights, to us without further compensation.

Below is a summary of each named executive officer's employment agreement.

Doug Godshall, President, Chief Executive Officer and Executive Director

As Chief Executive Officer, Mr. Godshall is responsible for our day-to-day management, as well as for planning and directing all of our policies, objectives and initiatives. Key elements of Mr. Godshall's employment agreement include:

- Annual salary of $350,000.
- A sign-on bonus of $75,000 paid upon commencement of employment.
- An annual performance bonus of $75,000 subject to satisfaction of agreed annual performance hurdles.
- Full participation in our employee benefits program, including life and disability insurance (short and long term), health and group dental.
- Upon commencement of employment, and pursuant to the terms of his employment agreement, Mr. Godshall was granted 5,581,264 options under our ESOP, with an exercise price of AU$1.10 per share.

Mr. Godshall's employment agreement does not include a fixed term. Mr. Godshall is entitled to a period of notice on termination in various circumstances, including where we terminate Mr. Godshall's employment "without cause". Mr. Godshall does not receive any additional compensation, except as provided above, for his role as an executive director of the Company.

David McIntyre, Chief Financial Officer and Company Secretary

As Chief Financial Officer and Company Secretary, Mr. McIntyre is responsible for directing our financial, taxation, compliance (non-clinical), risk and company secretarial functions.

Until April 30, 2006, Mr. McIntyre resided in Sydney, Australia and traveled frequently to the United States. As of May 1, 2006, Mr. McIntyre has temporarily relocated to our operations facility located in Miramar, Florida, in order to assist with, among other things, the management of our growth and development.

Mr. McIntyre has an employment agreement with HeartWare Limited that has been temporarily suspended as of April 30, 2006. Key elements of this agreement include:

- Annual salary of AU$220,000.
- Superannuation calculated at the statutory rate of 9% per annum.
- Provision of one car parking space and a maintained motor vehicle.
- Upon commencement of employment, and pursuant to the terms of his employment agreement, Mr. McIntyre was granted an aggregate of 764,204 options under the ESOP, with exercise prices between AU$0.60 and AU$1.50 per share.

Mr. McIntyre's employment agreement does not contain a fixed term and may be terminated by either party on three months' notice. This employment agreement, including all accrued but unpaid leave entitlements, will resume upon Mr. McIntyre's return to Australia.

While serving us in the United States, and with effect from May 1, 2006, Mr. McIntyre is subject to a service agreement with HeartWare, Inc. The arrangements with Mr. McIntyre, including relocation benefits, were determined following a detailed external, independent review. This review, which was conducted by Ernst & Young, compared host country (Miami, Florida) and home country (Sydney, Australia) relativities incorporating a net income comparison, spending and housing cost differentials as well as standards of living comparatives. In addition, market data provided by recognized relocation experts were also assessed and consideration was given to the additional financial burden associated with an international relocation including, among other things, consideration of the loss of income for Mr. McIntyre's spouse as a certified practicing accountant. Set out below is an overview of the key elements of this service agreement:

- Annual salary of $225,000.
- Full participation in our employee benefits program, including life and disability insurance (short and long term), health and group dental.
- Relocation benefits as follows:

  (i) A one-time pre-tax relocation allowance of $27,750 upon commencement of assignment in the United States. The allowance is provided to assist Mr. McIntyre with meeting out-of-pocket expenses that are incurred on relocation to the United States, such as installation and purchase of electrical appliances, house cleaning, telephone installation etc, together with associated costs of leaving Australia (termination of services etc).

(ii) A monthly after-tax payment of approximately $6,000, with a gross cost to us of $9,000, for the purposes of assisting Mr. McIntyre with the provision of comparative housing, financing of motor vehicles, rental shortfall on his Australian residence and other incremental recurring costs associated with his relocation to the United States.

In addition, we have adopted an international relocation policy pursuant to which Mr. McIntyre's family is entitled to one return trip to Australia following each year of completed service in the United States. Further, Mr. McIntyre and his spouse are entitled to a return flight to Australia in the event of a death in their respective families.

Mr. McIntyre's service agreement does not contain a fixed term and may be terminated by either party at will.

Dozier Rowe, Chief Operating Officer

As Chief Operating Officer, Mr. Rowe is responsible for our manufacturing and operational processes including final product development, assembly methods, plant layout, workflow and workforce utilization. Mr. Rowe has an employment agreement with us. Set out below are the key elements of the terms of his employment agreement:

- Annual salary commenced at $205,000 and was revised to $225,000 on the completion of a ninety-day review.
- Full participation in our employee benefits program, including life and disability insurance (short and long term), health and group dental.
- Upon commencement of employment, Mr. Rowe was granted 1,000,000 options under our ESOP, with an exercise price of AU$1.41 per share.

Mr. Rowe's employment agreement does not contain a fixed term and may be terminated by either party at will.

Jeffrey LaRose, Chief Scientific Officer

As Chief Scientific Officer, Mr. LaRose is responsible for technology and intellectual property development.

Mr. LaRose has an employment agreement with HeartWare, Inc., the material terms of which are set out below:

- Annual salary of $225,000.
- Full participation in our employee benefits program, including life and disability insurance (short and long term), health and group dental.

Mr. LaRose's employment agreement does not contain a fixed term and may be terminated by either party at will.

Jane Reedy, Vice President Clinical and Marketing

As Vice President Clinical and Marketing, Ms. Reedy is responsible for global marketing, managing reimbursement systems in domestic and international markets, and directing clinical trials to support product registration.

Ms. Reedy has an employment agreement with us, the material terms of which are as follows:

- Annual salary of $200,000.
- A one-time payment of $40,000 as a sign-on bonus upon commencement of her employment, which bonus was paid in May 2005.
- Full participation in our employee benefits program, including life and disability insurance (short and long term), health and group dental.
- Upon commencement of her employment, Ms. Reedy was granted 1,146,306 options under our ESOP, with an exercise price of AU$0.50 per share.

Ms. Reedy's employment agreement does not contain a fixed term and may be terminated by either party at will.

Potential Post-Employment Payments

Under the employment agreements we have with our named executive officers, each is entitled to certain compensation from us in the event that his or her employment is terminated. The amount of compensation that each named executive officer would be entitled to receive depends on the circumstances in which the employment is terminated and the relevant terms of the individual named executive officer's employment agreement.

One or more of our named executive officers are entitled to post-termination benefits if their employment is terminated in one or more of the following circumstances:

- by the Company without cause;
- by the executive for "good reason";
- upon death or disability; and
- following a change in control.

The following sections discuss the estimated benefits that our named executive officers would receive as of December 31, 2006 in each of these termination circumstances, as applicable. The calculations set forth below are intended to provide reasonable estimates of the

potential benefits are based on a number of assumptions and may not represent the actual amount a named executive officer would receive if the executive's employment is terminated in any of these circumstances.

Termination Without Cause

If we terminate the employment of a named executive officer without cause, then that executive is entitled to receive his or her then-current base salary for six months following the date of termination. The above applies to each of our named executive officers except Mr. LaRose and Ms. Foley, who are not entitled to any further compensation if they are terminated without cause.

The following additional terms also apply to the named executive officers referred to below if we terminate their employment without cause:

- For Mr. Godshall, he is also entitled to:
  - a further three months notice in writing of such termination or payment of three months' salary in lieu of notice;
  - the continuation of all benefits provided to him and his family for six months following the date of termination; and
  - the acceleration of a pro-rata portion of the options that would otherwise vest on the next anniversary of Mr. Godshall's commencement date with the Company following the date of termination, calculated by multiplying the relevant number of options that would otherwise vest by a fraction, the numerator of which is the number of months Mr. Godshall has worked since the most recent anniversary of Mr. Godshall's commencement date and the denominator of which is 12.
- For Mr. McIntyre, he is also entitled to reimbursement of the reasonable costs of relocating him and his family from Miami to Sydney unless he accepts a new position with another employer that covers his relocation expenses, in which case the Company shall pay the excess of his relocation benefit over the expenses actually paid by such new employer.
- For Ms. Reedy, she is entitled to receive her then-current base salary for an additional six months following the date of termination of her employment.

Termination for Good Reason

If any of Mr. Godshall, Mr. McIntyre or Ms. Reedy terminates his or her employment for "good reason" (as defined in his or her employment agreement), the executive shall be entitled to receive the same benefits as are set out under the heading "Termination Without Cause" above.

If Mr. Rowe terminates his employment for "good reason" (as defined in his employment agreement), he shall be entitled to receive his then-current base salary for six months following the date of termination of his employment.

The following table shows the potential payments to each named executive officer if his or her employment was terminated without cause or for good reason as of December 31, 2006.

Termination Without Cause and Termination for "Good Cause"

Name	Severance Payment ($)	Payment in Lieu of Notice ($) (1)	Share Options ($) (2)	Benefits ($) (3)	Relocation ($)	Total ($)
Douglas Godshall	175,000	87,500	119,406	5,342	—	387,248
David McIntyre	166,500	—	—	—	67,750(4)	234,250
Dozier Rowe	112,500	—	—	—	—	112,500
Jane Reedy	220,000	—	—	—	—	220,000

(1) Assumes that the Company elects to make a payment in lieu of notice to the named executive officer instead of providing written notice of termination.

(2) Represents the Black-Scholes value of share options calculated as of December 31, 2006.

(3) Represents the cost to the Company of benefits for the named executive officer and his family.

(4) Represents the estimated cost to relocate Mr. McIntyre and his family from Miami to Sydney.

Death or Disability

Except for Mr. Godshall, none of our named executive officers have specific provisions in their employment agreements that govern termination in the event of death or disability.

For Mr. Godshall, the following provisions apply:

- If Mr. Godshall becomes incapacitated such that, in the opinion of an independent physician, the incapacitation prevents Mr. Godshall from performing his duties for three consecutive months or three months in aggregate in any twelve month period, then Mr. Godshall shall be entitled to receive his salary and health insurance benefits for three months following termination, and Mr. Godshall's options shall accelerate in the manner specified above under the heading "Termination Without Cause".

- Upon Mr. Godshall's death, his estate shall be entitled to receive the benefits as set out under the heading "Termination Without Cause" above.

The following table shows the potential payments to Mr. Godshall if his employment was terminated in the event of death or disability, as of December 31, 2006.

	Death					Disability			
Name	Severance Payment ($)	Payment in Lieu of Notice ($)	Share Options ($) (1)	Benefits ($) (2)	Total ($)	Severance Payment ($)	Share Options ($) (1)	Benefits ($) (2)	Total ($)
Douglas Godshall	175,000	87,500	119,406	5,342	387,249	87,500	119,406	2,671	209,577

(1) Represents the Black-Scholes value of share options calculated as of December 31, 2006.

(2) Represents the cost to the Company of benefits for the named executive officer and his family.

Change of Control

Our employment agreements with each of Mr. McIntyre, Mr. Rowe and Ms. Reedy contain certain provisions that apply if the employment of these executives is terminated following a "change of control". The payments or benefits these executives shall be entitled to receive are in addition to those that the named executive officer would otherwise be entitled to receive if his or her employment were terminated under the same circumstance but for the change in control having occurred.

For Mr. McIntyre, if his employment is terminated by the Company without cause following a "change in control" and the Company does not provide him with three months notice of the termination, then he shall be entitled to a payment equal to an additional three months base salary. These provisions are in addition to the benefits that Mr. McIntyre would otherwise receive if his employment was terminated without cause by the Company.

For Mr. Rowe or Ms. Reedy, if either of their employment is terminated by the Company without cause or if he or she terminates his or her employment for good reason, and if such termination occurs within twelve months following the change in control, then all his or her options held by the executive on the date of and immediately prior to the transaction constituting the change in control and that would have vested on or before the date which is twelve months after the date on which the change in control occurs shall vest and be immediately exercisable.

Under each of the relevant employments agreements, a "change of control" occurs if:

- a person or entity becomes the owner, directly or indirectly, of more than fifty percent of the Company's voting power (except by way of a merger, consolidation or similar transaction);
- there is a merger, consolidation or similar transaction where the Company's existing shareholders do not own, directly or indirectly, more than fifty percent of the Company's voting power of the surviving entity in a merger, consolidation or similar transaction (except where these circumstances arise in the context of a public offering); or
- there is a consummated sale, lease, exclusive license or other disposition of the Company's consolidated assets.

The following table shows the potential incremental payments or benefits to each of Mr. McIntyre, Mr. Rowe and Ms. Reedy if his or her employment was terminated by the Company for cause or by the named executive officer for good reason following a change of control, as of December 31, 2006.

Change of Control (1)

Name	Severance Payment ($)	Payment in Lieu of Notice ($)	Share Options ($) (2)	Benefits ($)	Relocation ($)	Total ($)
David McIntyre	—	83,250	—	—	—	83,250
Dozier Rowe	—	—	92,886	—	—	92,886
Jane Reedy	—	—	102,805	—	—	102,805

(1) The benefits referred to above are the incremental benefits the named executive officer would receive upon a change of control in the event of a termination without cause or a termination for good reason, which are separately disclosed in a table preceding the above table.

(2) Represents the Black-Scholes value of share options calculated as December 31, 2006.

Non-Continuing Named Executive Officers

Our former Chief Executive Officer, Mr. McConchie, and our former Vice President, Manufacturing and Product Development, Mr. Rissmann, both resigned their positions in 2006.

The Company and Mr. McConchie entered into an agreement upon the termination of his employment pursuant to which Mr. McConchie provided various undertakings to the Company. Under this agreement, we agreed to pay Mr. McConchie a severance payment equal to twelve months salary, or $356,243, plus attorney's fees of approximately $6,000.

The Company also entered into an agreement with Mr. Rissmann upon the termination of his employment. In return for certain undertakings from Mr. Rissmann, the Company paid Mr. Rissmann severance payments equal to six months salary, or $112,500, plus benefits for the same period, the estimated value of which was $10,684.

DIRECTOR COMPENSATION

The following table sets out total compensation for the year ended December 31, 2006 to our non-executive directors. Executive directors do not receive compensation for their service as directors.

DIRECTOR COMPENSATION

Name and Position	Year Ended December 31,	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Change in Pension Value and Nonqualified Deferred Compensation Earnings ($) (1)	All Other Compensation ($)	Total ($)
Robert Thomas Chairman	2006	90,956	—	—	—	8,186	—	99,142
Seth Harrison, M.D. Deputy Chairman	2006	75,796	—	—	—	6,822	—	82,618
Dr. Christine Bennett Non-executive director	2006	45,478	—	—	—	4,093	—	49,571
Dr. Denis Wade Non-executive director	2006	26,529	—	—	—	23,042	—	49,571
Robert Stockman (2) Non-executive director	2006	—	—	—	—	—	—	—

(1) Statutory contributions of 9% of fees to a superannuation fund (i.e., pension) for Australian directors only.

(2) Mr. Stockman was appointed to the Board of Directors as of December 11, 2006 and has elected to not receive director's fees.

Compensation Components

The compensation for our non-executive directors was determined in late 2004 in consultation with our corporate advisers and by reference to what the Board of Directors then understood to be comparable levels of compensation for substantially similar entities. Compensation is paid to non-employee, or non-executive, directors only, and employee or executive directors do not receive any additional compensation for their directorships.

In the two-year period since our ordinary shares have been listed on the ASX, the compensation of our directors has not changed or otherwise increased. In addition, no incremental equity participation has been afforded to directors in this period. A review of the performance of individual directors has not been undertaken.

Compensation Committee Interlocks and Insider Participation

The Compensation Committee consists of four non-executive directors: Mr. Robert Thomas (Chairman), Dr. Seth Harrison, Dr. Denis Wade and Dr. Christine Bennett. None of the members of the Compensation Committee is a former officer of the Company. Dr. Harrison previously acted as Chief Executive Officer of the Company's subsidiary, HeartWare, Inc., prior to its acquisition by the Company in January 2005. Dr. Harrison was Acting Chief Executive Officer of HeartWare, Inc. between July 2003 and November 2004 and was not paid any compensation for the services that he rendered in this regard.

ITEM 7. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Certain Relationships and Related Party Transactions

Since January 2004, we have not been a party to, and we have no plans to be a party to, any transaction or series of similar transactions in which the amount involved exceeded or will exceed $120,000 and in which any current director, executive officer, holder of more than 5% of our capital stock, or entities affiliated with them, had or will have a material interest, except that in January 2005, we issued a convertible note in the principal amount of $1.1 million to Apple Tree Partners I, L.P., our largest shareholder, which note remains outstanding.

Corporate Governance

Our Board of Directors currently consists of six (6) members: Robert Thomas, Seth Harrison, MD, Douglas Godshall, Dr. Christine Bennett, Dr. Denis Wade and Robert Stockman. Our Board of Directors has determined that all of our directors, other than Dr. Harrison and Mr. Godshall, are "independent" within the meaning of applicable NASDAQ Global Select Market listing standards. In addition, Mr. McConchie was a member of our Board of Directors in 2006 until his resignation on September 4, 2006. Mr. McConchie was not deemed to be "independent" within the meaning of applicable NASDAQ Global Select Market listing standards.

ITEM 8. LEGAL PROCEEDINGS

None.

ITEM 9. MARKET PRICE OF AND DIVIDENDS ON THE REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

HeartWare's ordinary shares have been listed on the ASX under the trading symbol "HTW", since January 24, 2005.

Our high and low sales prices on the ASX for each quarter within the last two fiscal years are shown below, both in Australian dollars and in United States dollars.

Period	High (AU$)	Low (AU$)	High (US$)	Low (US$)
Fiscal Year 2006:				
First Quarter	1.25	0.73	0.89	0.52
Second Quarter	1.40	0.78	1.04	0.58
Third Quarter	1.10	0.76	0.82	0.57
Fourth Quarter	0.84	0.64	0.66	0.51
Fiscal Year 2005:				
First Quarter	0.49	0.38	0.38	0.29
Second Quarter	0.46	0.34	0.35	0.26
Third Quarter	0.47	0.37	0.36	0.28
Fourth Quarter	0.75	0.44	0.55	0.32

All currency conversions are based on the prevailing Australian dollar to US dollar rate applicable on the last day of each respective quarter.

As of December 31, 2006, 20,501,250 of our ordinary shares were subject to outstanding options.

As of December 31, 2006, there were approximately 1,556 holders of record of our ordinary shares.

Rule 144

In general, under Rule 144 under the Securities Act of 1933, as amended (the Securities Act), a person who acquires our ordinary shares in a transaction not registered under the Securities Act and has beneficially owned such shares for at least one year would be entitled to sell within any three-month period those shares subject to certain restrictions, including volume and manner of sale restrictions.

Under Rule 144(k) under the Securities Act, a person who is not deemed to have been one of our affiliates at any time during the 90 days preceding a sale, and who has beneficially owned the shares proposed to be sold for at least two years, is entitled to sell the shares without complying with the volume and manner of sale restrictions of Rule 144.

Of our ordinary shares outstanding, at least 91,500,000 were eligible for resale under Rule 144 as of January 31, 2007, subject to the volume and manner of sale restrictions thereof.

As of January 31, 2007, at least 67,735,000 of our ordinary shares were either freely tradable or eligible for resale under Rule 144(k).

Dividends

We have not paid any dividends on our ordinary shares, and we do not expect to pay dividends in the foreseeable future. We expect to retain all earnings to provide funds for the growth and development of our business. The declaration and payment of dividends in the future will be determined by the Board based upon our earnings, financial condition, capital requirements and such other factors as the Board may deem relevant at that time. We are not under any contractual restriction as to our present or future ability to pay dividends.

Equity Compensation Plan Information

The following table describes shares of our ordinary shares that are available for purchase as at December 31, 2006 under outstanding options:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	19,001,250	$0.64	1,487,581
Equity compensation plans not approved by security holders	1,500,000	$0.74	—
Total	20,501,250	$0.65	1,487,581

On exercise and payment of the relevant subscription monies, each of the above options entitles the holder to be issued one ordinary share in the Company for each option exercised.

Additional information required by this Item is contained under Item 11 "–Taxes" and "– Foreign Acquisition and Takeover Act".

ITEM 10. RECENT SALES OF UNREGISTERED SECURITIES

Since November 26, 2004, our inception, we have issued the following securities that were not registered under the Securities Act:

- In connection with our initial public offering in Australia, on January 27, 2005, we issued 55,838,000 ordinary shares. The aggregate offering price for this issuance was $21.6 million (AU$27.9 million), and we incurred underwriting commissions of $1.6 million (AU$2.1 million). Our principal underwriter was EG Capital. The sales of these ordinary shares were exempt from registration pursuant to Regulation S promulgated under the Securities Act.

- Also on January 27, 2005, we issued 9,000,876 ordinary shares, for an aggregate consideration of approximately $3.5 million (AU$4.5 million), in a private placement exempt from registration pursuant to Regulation D promulgated under the Securities Act and Section 4(2) of the Securities Act.
- Also on January 27, 2005, in connection with our acquisition of all of the common stock of HeartWare, Inc., we issued 88,000,000 ordinary shares and a $1.1 million (AU$1.42 million) note that is convertible into our ordinary shares at a conversion price of AU$1.00 per share. The issuance of these ordinary shares and note was exempt from registration pursuant to Section 4(2) of the Securities Act.
- On April 20, 2005, we issued 2,589,998 ordinary shares to Dr. Robert Fine, former CEO of Kriton Medical, Inc., upon the cashless exercise by Dr. Fine of three warrants to purchase 5,259,076 ordinary shares at an exercise price of AU$0.20 per share. These warrants had originally been issued to him by Kriton Medical's subsidiary, HeartWare, Inc., on October 3, 2003. The issuance of these ordinary shares was exempt from registration pursuant to Section 4(2) of the Securities Act.
- On May 23, 2006, we issued 29,679,220 ordinary shares in a private placement. The aggregate proceeds to us in connection with this offering were US$23.4 million. The issuance of these ordinary shares was exempt from registration pursuant to Regulation S and Regulation D promulgated under the Securities Act.
- On June 15, 2006, we issued 75,452 ordinary shares to our Australian shareholders pursuant to our Shareholder Share Purchase Plan for aggregate proceeds to us of AU$82,997. The issuance of these ordinary shares was exempt from registration pursuant to Regulation S promulgated under the Securities Act.
- From June 2005 to August 2006, we issued an aggregate of 806,552 ordinary shares pursuant to the exercise of options under our ESOP at exercise prices ranging from $0.16 to $0.36 (AU$0.20 to AU$0.50) for aggregate proceeds of $162,713 (AU$218,656) to five individuals. The issuance of these ordinary shares was exempt from registration pursuant to Rule 701 under the Securities Act.

ITEM 11. DESCRIPTION OF REGISTRANT'S SECURITIES TO BE REGISTERED

The rights of the holders of our ordinary shares are governed by our Constitution and the Australian Corporations Act 2001, or the Corporations Act. In addition, because our ordinary shares are listed on the ASX we are also subject to Australian securities laws and the ASX Listing Rules.

A summary of the principal rights attaching to our ordinary shares is as follows:

Rights affecting our ordinary shares and related matters

Issuance of shares

Australian law does not recognize the concepts of "authorized capital" or "par value". As such, we do not have an authorized capital and our ordinary shares do not have a par value. Pursuant to our Constitution and subject to various restrictions as set out under the ASX Listing Rules and the Corporations Act, the power to issue ordinary shares in the Company is vested in the Board of Directors and, as such, the Board may issue ordinary shares to any person on such terms and with such rights as the Board may determine. The Board may determine that ordinary shares are to be issued with preferred, deferred or other special rights or restrictions, whether in regard to dividends, voting, return of share capital, payment of calls or otherwise.

General meetings and voting

Under Australian law, our annual general meeting is required to be held within five months after the end of each financial year. For other general meetings, our directors are required to call a general meeting when requested to do so by shareholders holding at least 5% of the votes that may be cast at the meeting or being at least 100 in number, and such shareholders may propose a resolution for consideration at the next general meeting occurring more than two months' after the date of their notice.

Each shareholder is entitled to receive notice of, and to attend and vote at, general meetings of the Company. Notice of a general meeting of the Company must be given to shareholders at least 28 days before the date of the meeting. At a general meeting of shareholders, each shareholder has one vote for each ordinary share held. Two shareholders present in person or by proxy constitute a quorum for a general meeting.

Resolutions put to shareholders generally require the approval of a majority of votes cast by those present and voting. Super-majority approval is required under Australian law for certain special resolutions. Approval by special resolution of shareholders is required for actions such as modifying or repealing the Company's Constitution, changing the Company's name or type, selectively reducing or buying back capital (in some circumstances), giving financial assistance in connection with the acquisition of shares in the Company and undertaking a voluntary winding up of the Company.

Dividends

Subject to any special rights and restrictions attaching to an ordinary share, our Board may declare that dividends are payable to shareholders on each ordinary share.

Winding-up rights

If the Company is wound up, any property that remains after satisfaction of all debts and liabilities of the Company, the payment of the costs, charges and expenses of winding up and any

adjustment of the rights of the contributories among shareholders, must be distributed among the shareholders equally.

Directors and director remuneration

The Company must have at least three directors. At least two directors must ordinarily reside in Australia. A resolution of the Board must be passed by a majority vote. Under the ASX Listing Rules and our Constitution, the maximum amount which may be paid to non-employee directors for their services as directors may not exceed the amount approved by shareholders at a general meeting.

Australia has recently enacted legislation that gives shareholders of listed companies, such as holders of our ordinary shares, the right to participate in a non-binding vote, to be held at the annual general meeting, on the adoption of the remuneration report of the Company. The remuneration report is included in the Company's Annual Report and is to contain a discussion of the Board's policy in relation to remuneration of directors of the Company.

Transactions involving directors or officers

The Corporations Act prohibits us from giving directors a financial benefit unless we obtain the approval of our shareholders or the financial benefit is otherwise exempt. Exempt financial benefits include indemnities, insurance premiums and payments for legal costs that are not otherwise prohibited by the Corporations Act and benefits given on arms' length terms.

The ASX Listing Rules prohibit us from acquiring a substantial asset from, or disposing of a substantial asset to, one of our directors without shareholder approval. In addition, subject to certain exceptions, the ASX Listing Rules prohibit us from issuing shares to a director without shareholder approval.

Issues exceeding 15% of capital

Subject to certain exceptions, the ASX Listing Rules prohibit us from issuing or agreeing to issue ordinary shares or other equity securities in any 12-month period which amount to more than 15% of our ordinary shares without shareholder approval.

Minority shareholders

Under the Corporations Act, any shareholder can bring an action in cases of conduct which is either contrary to the interests of shareholders as a whole, or oppressive to, unfairly prejudicial to or unfairly discriminatory against, any shareholders in their capacity as a shareholder, or themselves in a capacity other than as a shareholder. Former shareholders can also bring an action if it relates to the circumstances in which they ceased to be a shareholder. A statutory derivative action may be instituted by a shareholder, former shareholder or person entitled to be registered as a shareholder. In all cases, permission of the court is required to bring a statutory derivative action.

Australian law does not provide for appraisal rights.

Right to inspect corporation books and records

Under Australian law, a shareholder may not obtain access to the Company's books and records unless the shareholder first obtains a court order to do so.

Acquisition of the Company

Australian law restricts a person acquiring interests in the voting shares of a company where, as a result of the acquisition, that person's or someone else's voting power in that company increases from 20% or below to more than 20%. Generally, such acquisitions cannot be made unless the person acquires 3% or less of the voting shares in a company in any six-month period, the acquisition is made with shareholder approval or the acquisition is made under a takeover bid made in accordance with Australian law. Takeover bids must treat all shareholders alike and must not involve any collateral benefits to certain shareholders which are not otherwise made generally available. Various restrictions about conditional offers exist, and there are also substantial restrictions concerning the withdrawal and suspension of offers.

In addition, the Corporations Act provides that if an offer is received for a specified proportion of the ordinary shares of a company, a resolution of "Eligible Shareholders", who are persons other than the bidder or an associate of the bidder, who, as at the end of the day on which the first offer under a bid was made, held ordinary shares in the class of ordinary shares to which the bid relates, must approve the takeover bid before it may take effect. If approval is obtained, the offer may proceed. If approval is not obtained, the offer will be taken to have been withdrawn. The rule does not apply to a takeover bid for all of the ordinary shares of the Company. The rule ceases to apply at the end of three years following its date of adoption or last renewal by shareholders of the Company by resolution at a general meeting.

If the acquisition of a security results in the purchaser acquiring a relevant interest in 5% or more of the total number of votes attached to voting shares in a company, the purchaser will also be required to make disclosures as to its substantial holdings under the Corporations Act. Disclosure obligations, including obligations on substantial shareholders, and limitations on acquisitions may, depending on the purchaser's interests in, or voting power in relation to, ordinary shares, apply to the purchaser in respect of acquisitions, continuing holdings, exercises and disposals of ordinary shares.

Foreign Acquisition and Takeovers Act

The Foreign Acquisition and Takeovers Act 1975, or FATA, empowers the Treasurer of Australia to prohibit a proposed acquisition of shares in a company where as a result of the acquisition a non-Australian person, together with its associates, would have an interest of at least 15% of the total issued shares in that company, or two or more foreign persons, together with their associates, would in the aggregate have an interest of at least 40% of the total issued shares in that company. However, FATA only applies where a company is valued, based upon the acquisition consideration to be paid in the transaction, at AU$100 million or more for acquirers that are non-US persons, and for acquirers that are US persons, a company must be valued at AU$871 million or more for FATA to apply.

Where an acquisition by a non-Australian person or persons has already occurred, the Treasurer has the power to order the acquirer to dispose of the shares. In addition, FATA requires certain persons who propose to make such acquisitions first to notify the Treasurer of their intention to do so. The concepts of acquisition, interest, associate and foreign person are broadly defined in FATA.

Rights of Non-Australian Holders of Ordinary Shares

Except with respect to restrictions under the Foreign Acquisition and Takeovers Act 1975 described above, neither our Constitution nor the laws of Australia restrict in any way the ownership, voting or other rights of our ordinary shares by non-residents or persons who are not citizens of Australia. See "—Foreign Acquisition and Takeovers Act".

Non-marketable parcels

Subject to certain limitations, we may sell the ordinary shares of a shareholder who holds less than a "marketable parcel" of ordinary shares by giving that shareholder written notice prior to the sale. The power may be invoked only once by the Company in any 12 month period. A "marketable parcel" of ordinary shares is generally construed to mean securities with a value of at least $500.

Taxation Considerations

Summary of Taxation Implications

The following is a general summary of the Australian taxation implications that may arise for certain shareholders in respect of holding and disposing of shares in the Company.

As taxation laws are complex, the following discussion is intended as a general guide to the Australian implications only. Shareholders should not rely on this discussion as advice in relation to their own affairs but should consult their own tax adviser applicable to their own needs and circumstances.

Dividends paid by HeartWare Limited

In respect of franked (Australian tax paid) dividends paid to non-residents of Australia (including US residents), no withholding tax applies.

In respect of unfranked dividends paid to non-residents of Australia (including US residents), the rate of Australian withholding tax, prima facie, shall be:

- US residents and residents of countries with which Australia has a double tax agreement (DTA) – 15%.
- US residents (also United Kingdom residents) that are a company which holds directly at least 10% of the voting power in the company paying the dividend – 5%.
- Tax residents of a country that does not have a DTA with Australia – 30%.

However, in respect of unfranked dividends, so much of the part of the distribution that HeartWare declares is 'conduit foreign income' is:

- Not assessable not exempt income of a foreign resident; and
- Not subject to Australian withholding tax.

Australian Capital Gains Tax ("CGT") on sale of ordinary shares in HeartWare Limited

Prior to December 12, 2006, a non-Australian resident holder of ordinary shares, including a US resident, would not be required to pay Australian CGT, provided the non-residents' interest represented less than 10% of the total number of our issued ordinary shares.

From December 12, 2006, Australian capital gains realized by non-Australian residents on the sale of ordinary shares shall be disregarded for CGT purposes, unless our real property assets exceed 50% of our total assets. As we do not, at this time, own any Australian real property, no Australian CGT shall apply to non-Australian residents, including US residents that sell ordinary shares.

ITEM 12. INDEMNIFICATION OF DIRECTORS AND OFFICERS

Under Australian law, we may not exempt a director from liability to the Company incurred in his or her capacity as a director. Further, we may not indemnify a director or officer against a liability owed to the Company or certain related entities. We are also not permitted to indemnify a director or officer against the cost of legal proceedings where such proceedings result in them being found to have a liability to the Company or certain related entities.

However, under Australian law, we may indemnify a director or officer against a liability owed to someone other than the Company or certain related entities (and also the cost of any related legal proceedings), provided the liability does not arise out of conduct involving a lack of good faith and is not a penalty or compensation order made under the Corporations Act.

Accordingly, we may indemnify each officer, director and company secretary out of the assets of the Company against any liability incurred or to be incurred by the officer, director or secretary in or arising out of the discharge of their duties. We may pay the insurance premium for an officer, director or company secretary in respect of a contract of insurance in relation to liability incurred by the officer, director or secretary arising out of the activities of the Company and their proper performance of any duty.

We have entered into a Deed of Indemnity, Access and Insurance pursuant to which each of the officers, directors and the company secretary are entitled, to the extent permitted by Australian law, to the benefit of certain indemnities from the Company. In addition, these persons have certain rights of access to our books and records.

We have also paid premiums to insure each of the directors and officers against all liabilities for costs and expenses incurred by them in defending any legal proceedings arising out of their conduct while acting in the capacity of director of the Company, other than conduct involving a willful breach of duty in relation to the Company.

ITEM 13. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements, and those of our predecessor together with the reports of our independent registered public accounting firm, appear on pages F-1 through F-37 of this registration statement.

ITEM 14. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 15. FINANCIAL STATEMENTS AND EXHIBITS

(a) Financial Statements

Our financial statements and those of our predecessor, appear at the end of this Form 10. Please see the table of contents to the financial statements on page F-1.

(b) Exhibits

3.01 Constitution

10.01 Convertible Note between HeartWare Limited and Apple Tree Partners I, L.P. dated December 15, 2004

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

10.03 Business Lease, dated as of March 1, 2001, between Sunbeam Properties, Inc. and Kriton Medical, Inc.

10.04 Lease extension, dated as of February 23, 2004, between Sunbeam Properties, Inc. and HeartWare, Inc.

10.05 Second lease extension, dated as of February 20, 2005, between Sunbeam Properties, Inc. and HeartWare, Inc.

10.06 Sublease Agreement, dated June 1, 2006, between Starkey Laboratories, Inc. and HeartWare, Inc.

10.07 Addendum to Sublease Agreement, dated as of June 1, 2006, between Starkey Laboratories, Inc. and HeartWare, Inc.

10.08 Employment Agreement, dated as of September 18, 2006, between HeartWare Limited, HeartWare, Inc and Doug Godshall

10.09 Employment Agreement, dated as of April 11, 2006, between HeartWare, Inc. and Dozier Rowe

10.10 Employment Agreement, dated as of May 1, 2006, between HeartWare, Inc. and David McIntyre

10.11 Employment Agreement, dated as of November, 2004, between HeartWare, Inc. and Jeff LaRose

10.12 Employment Agreement, dated as of April 14, 2005 and amended January 2, 2007, between HeartWare, Inc. and Jane Reedy

10.13 Employment Agreement, dated as of April, 2005 between HeartWare Limited and Howard Liebman

10.14 Employment Agreement, dated as of May 30, 2006, between HeartWare, Inc. and Barry Yomtov

10.15 Employment Agreement, dated as of January 1, 2007, between HeartWare, Inc. and Jennifer Foley

10.16 Employment Agreement, dated as of December 15, 2004 between HeartWare Limited and Stuart McConchie

10.17 Deed of Release, dated as of September 4, 2006, between HeartWare Limited and Stuart McConchie

10.18 Clinical Investigation Agreement, dated as of March 21, 2006 between Medical University of Vienna and HeartWare, Inc.

10.19 Clinical Investigation Agreement, dated as of February 17, 2006, between Royal Perth Hospital and HeartWare, Inc.

10.20 Clinical Investigation Agreement, dated as of October 23, 2006, between Royal Brompton & Harefiled NHS Trust and HeartWare, Inc.

10.21 Clinical Investigation Agreement, dated as of May 17, 2006, between Hannover Medical School and HeartWare, Inc.

10.22* Production Services Agreement, dated August 17, 2006, between Minnetronix, Inc. and HeartWare, Inc.

10.23 Servicing Agreement, dated August 17, 2006, between Minnetronix, Inc. and HeartWare, Inc.

10.24 Sustaining Services and Clinical Support Agreement, dated August 17, 2006, between Minnetronix, Inc. and HeartWare, Inc.

10.25 Form of Deed of Indemnity, Access and Insurance Agreement for directors and executive officers

10.26 Letter of Appointment as a Director of the Company dated December 1, 2006 between HeartWare Limited and Robert Stockman

10.27 Letter of Appointment as a Director of the Company dated December 15, 2004 between HeartWare Limited and Robert Thomas

10.28 Letter of Appointment as a Director of the Company dated December 15, 2004 between HeartWare Limited and Christine Bennett

10.29 Letter of Appointment as a Director of the Company dated December 15, 2004 between HeartWare Limited and Denis Wade

10.30 Clinical Trial Agreement, dated as of February 13, 2007 between HeartWare Limited and St. Vincent's Hospital, Sydney Limited

10.31 Employment Agreement, dated as of February, 2005 between HeartWare Limited and David McIntyre

10.32 HeartWare Limited Employee Share Option Plan Rules

21.01 List of Subsidiaries

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* Confidential treatment has been requested for certain provisions of this Exhibit pursuant to Rule 406 promulgated under the Securities Act.

SIGNATURES

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized.

HeartWare Limited
(Registrant)

Date: April 30, 2007

By: /s/ Douglas Godshall
Name: Douglas Godshall
Title: Chief Executive Officer

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED
PUBLIC ACCOUNTING FIRM

Board of Directors
Heartware Limited

We have audited the accompanying consolidated balance sheets of HeartWare Limited (a Development Stage Company) (the "Company") as of December 31, 2006 and 2005 and the consolidated statements of operations, shareholders' equity and cash flows for the years ended December 31, 2006 and 2005, the period from November 26, 2004 (date of inception) through December 31, 2004, and the cumulative period from November 26, 2004 (date of inception) through December 31, 2006. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes 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 financial statements referred to above present fairly, in all material respects, the consolidated financial position of HeartWare Limited (a Development Stage Company) as of December 31, 2006 and 2005, and the results of its operations and its cash flows for the years ended December 31, 2006 and 2005, the period from November 26, 2004 (date of inception) through December 31, 2004, and the cumulative period from November 26, 2004 (date of inception) through December 31, 2006, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred and expects to continue to incur significant costs in pursuit of the development of its products. There is no assurance that the Company's plans to raise capital will be successful. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are described in Note 2. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Grant Thornton LLP

Fort Lauderdale, Florida
March 5, 2007

HEARTWARE LIMITED
(A Development Stage Company)
CONSOLIDATED BALANCE SHEETS

	December 31, 2006	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,697,769	$ 10,036,941
Receivables	18,050	16,496
Prepaid expenses and other assets	598,793	345,514
Total current assets	17,314,612	10,398,951
Property, plant and equipment, net	2,710,870	1,372,399
Other intangible assets, net	16,691,701	18,445,103
Goodwill	15,371,221	15,371,221
Total Assets	$ 52,088,404	$ 45,587,674
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 308,364	$ 963,443
Accrued expenses and other current liabilities	1,287,142	195,268
Convertible note — related party	1,167,481	—
Total current liabilities	2,762,987	1,158,711
Long-term convertible note — related party	—	1,061,081
Other long-term payables	15,936	25,613
Shareholders' equity:		
Ordinary shares, no par value - 186,262,097 and 156,096,274 shares outstanding in 2006 and 2005 respectively	—	—
Additional paid-in capital	83,890,582	59,457,504
Deficit accumulated during the development stage	(34,650,726)	(15,452,199)
Accumulated other comprehensive income (loss):		
Cumulative translation adjustments	69,625	(663,036)
Total Shareholders' Equity	49,309,481	43,342,269
Total Liabilities and Shareholders' Equity	$ 52,088,404	$ 45,587,674

The accompanying notes are an integral part of these financial statements

HEARTWARE LIMITED
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		Period from November 26, 2004 (Inception) through December 31,	Cumulative Period from November 26, 2004 (Inception) Through December 31,
	2006	2005	2004	2006
Revenues	$ —	$ —	$ —	$ —
Operating expenses:				
General and administrative expenses	6,024,374	4,311,639	—	10,336,013
Research and development expenses	11,633,294	10,722,302	—	22,355,596
Amortization of intangibles	1,788,347	1,629,202	—	3,417,549
Total operating expenses	19,446,015	16,663,143	—	36,109,158
Loss from operations	(19,446,015)	(16,663,143)	—	(36,109,158)
Foreign exchange income (loss)	(583,805)	493,823	—	(89,982)
Interest income, net	844,522	717,121	—	1,561,643
Other, net	(13,229)	—	—	(13,229)
Loss before income taxes	(19,198,527)	(15,452,199)	—	(34,650,726)
Provision for income taxes	—	—	—	—
Net loss	$ (19,198,527)	$ (15,452,199)	$ —	$ (34,650,726)
Loss per ordinary share — basic and diluted	$ (0.11)	$ (0.11)	$ —	
Weighted average shares outstanding - basic and diluted	174,689,977	144,648,898	2,000	

The accompanying notes are an integral part of these financial statements

HEARTWARE LIMITED
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

	Ordinary Shares		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During Development Stage	Total
	Shares Issued	$				
Balance at November 26, 2004, (inception)	—	$ —	$ —	$ —	$ —	$ —
Issuance of founding ordinary shares	2,000	—	794	—	—	794
Net loss	—	—	—	—	—	—
Balance December 31, 2004	2,000	—	794	—	—	794
Issuance of ordinary shares pursuant to the acquisition of HeartWare, Inc.	88,000,000	—	34,012,000	—	—	34,012,000
Issuance of ordinary shares pursuant to initital public offering, net of offering costs	64,838,876	—	23,437,597	—	—	23,437,597
Issuance of ordinary shares pursuant to stock option exercise	395,400		59,576	—	—	59,576
Issuance of ordinary shares pursuant to cashless warrant exercise	2,859,998	—	—	—	—	—
Share based compensation	—	—	1,947,537	—	—	1,947,537
Net loss	—	—	—	—	(15,452,199)	(15,452,199)
Other accumulated comprehensive income (loss)						
Foreign currency translation adjustment	—	—	—	(663,036)	—	(663,036)
Balance December 31, 2005	156,096,274	—	59,457,504	(663,036)	(15,452,199)	43,342,269
Issuance of ordinary shares pursuant to private placement	29,679,220		23,378,369	—	—	23,378,369
Issuance of ordinary shares pursuant to shareholder purchase plan	75,452		61,254	—	—	61,254
Issuance of ordinary shares pursuant to stock option exercise	411,151		103,136	—	—	103,136
Share based compensation	—	—	890,319	—	—	890,319
Net loss	—	—	—	—	(19,198,527)	(19,198,527)
Other accumulated comprehensive income (loss)						
Foreign currency translation adjustment	—	—	—	732,661	—	732,661
Balance December 31, 2006	186,262,097	$ —	$83,890,582	$ 69,625	$(34,650,726)	$ 49,309,481

The accompanying notes are an integral part of these financial statements

HEARTWARE LIMITED
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		Period from November 26, 2004 (Inception) through December 31,	Cumulative Period from November 26, 2004 (Inception) Through
	2006	2005	2004	December 31, 2006
CASH FLOWS FROM OPERATING ACTIVITIES				
Net loss	$(19,198,527)	$(15,452,199)	$—	$(34,650,726)
Adjustments to reconcile net loss to net cash used in operating acitvities:				
Depreciation	371,497	247,229	—	618,726
Amortization	1,788,347	1,629,202	—	3,417,549
Share-based compensation expense	890,319	1,947,537	—	2,837,856
Loss on disposal of assets	13,229	—	—	13,229
Accrued interest, long-term	22,126	19,227	—	41,353
Lease incentive	(11,688)	25,613	—	13,925
Increase (decrease) in operating assets and liabilities, excluding the effect of acquisitions:	—	—	—	—
Accounts receivable	(259)	(16,496)	—	(16,755)
Prepaid expenses and other current assets	(229,430)	(29,743)	—	(259,173)
Note receivable, current	—	794	—	794
Accounts payable	(666,383)	149,241	—	(517,142)
Accrued expenses and other current liabilities	1,083,648	235,242	—	1,318,890
Net cash used in operating activities	(15,937,121)	(11,244,353)	—	(27,181,474)
CASH FLOWS FROM INVESTING ACTIVITIES				
Additions to property and equipment	(1,732,372)	(1,412,523)	—	(3,144,895)
Additions to patents	(34,945)	(209,242)	—	(244,187)
Net cash provided by acquisition	—	126,380	—	126,380
Proceeds from dispositions of assets	23,701	—	—	23,701
Net cash flows used in investing activities	(1,743,616)	(1,495,385)	—	(3,239,001)
CASH FLOWS FROM FINANCING ACTIVITIES				
Net proceeds from issuance of share capital	23,542,759	23,497,173	—	47,039,932
Net cash provided by financing acitivities	23,542,759	23,497,173	—	47,039,932
Effect of exchange rate changes on cash	798,806	(720,494)	—	78,312
INCREASE IN CASH AND CASH EQUIVALENTS	6,660,828	10,036,941	—	16,697,769
CASH AND CASH EQUIVALENTS — BEGINNING OF PERIOD	10,036,941	—	—	—
CASH AND CASH EQUIVALENTS — END OF PERIOD	$ 16,697,769	$ 10,036,941	$—	$ 16,697,769
Supplemental cash flow information:				
Cash paid during the year for:				
Interest	$ 22,496	$ 20,150	$—	$ 42,646

The accompanying notes are an integral part of these financial statements

Note 1 Description of Business

HeartWare Limited, referred to in these notes collectively with its subsidiary, 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 initial application of our blood pump technology is our HeartWare Ventricular Assist Device, or HVAD pump, which we believe is the smallest full-output left ventricle assist device, or LVAD, that is currently in clinical trials. The HVAD pump is the only centrifugal LVAD designed to be implanted above the diaphragm in all patients.

Beyond the HVAD pump, 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 HVAD pump but adopts an axial flow, rather than a centrifugal flow, configuration. The MVAD, which is currently at the prototype stage and undergoing animal studies, 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 that those required to implant the HVAD pump. We expect to initiate human clinical trials for the MVAD during mid-2009.

In parallel with our development of the MVAD, we have commenced design work on our third generation blood pump, which we currently call the IV VAD. The IV VAD will rely on the same underlying technology platform and will be a smaller version of the MVAD. Unlike the HVAD pump or the MVAD, the IV VAD is intended to be positioned within the body's vasculature network and implanted by minimally invasive catheter-based techniques. Once the IV VAD is fully developed, we expect the IV VAD to be about one-tenth the size of the HVAD pump.

We are headquartered in Sydney, Australia and have operations and manufacturing facilities in Miramar, Florida.

We are a development stage company that has generated significant losses since our inception, and we expect to continue to incur substantial losses for the foreseeable future. Our primary business activities relate to the research and development of the HVAD pump and the development of future products. As of December 31, 2006, we had an accumulated deficit of approximately $34.7 million (which includes approximately $2.8 million in share-based charges and other non-cash charges).

Development Stage

We have operated as a development stage enterprise since our inception by devoting substantially all of our efforts to raising capital, research and development of products noted above, and developing markets for our products. Accordingly, our financial statements have been prepared in accordance with the accounting and reporting principles prescribed by Statement of Financial Accounting Standard ("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 Food and Drug Administration (the "FDA") and other regulatory authorities. There can be no assurance that the Company will not encounter problems in clinical trials that will cause us or the FDA to delay or suspend clinical trials. The Company's success will depend in part on its ability to successfully complete clinical trials, obtain 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 or licensed by the Company will not be challenged, invalidated or circumvented, or that the rights granted thereunder will provide proprietary protection or competitive advantages to the Company. The Company will require substantial future capital in order to meet its objectives. The Company currently has no committed sources of capital. 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.

Note 2 Going Concern

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, 2006. In addition, as of December 31, 2006, the Company had a deficit accumulated during the development stage of $34.7 million.

Our continuation as a going concern is dependent on our ability to raise capital in order to continue to commercialize our technology and as such we are actively seeking to obtain additional capital and financing, though there is no assurance we will be successful in our efforts. Funds raised will be primarily applied for the purposes of meeting costs associated with expanding the Company's human clinical trials, product development (including in relation to the Company's transcutaneous energy transfer system and its next generation devices, the IV VAD and MVAD), regulatory and other compliance costs as well as for general working capital. The Company continually monitors its cash position.

The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

Note 3 Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of HeartWare Limited and its wholly- owned subsidiary, 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.

Plant and Equipment

The Company records plant, 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.

Share-based Payments

We elected to early adopt SFAS 123(R) "Share-Based Payments" 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 assumptions, including an estimated expected life of the option, share price volatility and a forfeiture rate. We have used the estimated life of the option in determining the fair value.

We estimate the volatility of our ordinary shares on the date of grant based on the volatility of our publicly-traded ordinary shares. We estimate the forfeiture rate based on our

historical experience of 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 use different assumptions, our share-based compensation expense could be materially different in the future.

Goodwill and Other Intangible Assets

The Company records goodwill and other intangible assets acquired in business combinations under the purchase method of accounting. Amounts paid for each acquisition are allocated to the assets acquired and liabilities assumed based on their fair values at the dates of acquisition. The Company then allocates the purchase price in excess of net tangible assets acquired to identifiable intangible assets. The fair value of identifiable intangible assets is based on detailed valuations that use information and assumptions provided by management. The Company allocates any excess purchase price over the fair value of the net tangible and intangible assets acquired to goodwill.

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.

Amortization and Impairment of Intangible Assets

The Company records intangible assets at historical cost. The Company amortizes its intangible assets using the straight-line method over their estimated useful lives from five to fifteen years. In accordance with SFAS No. 142, “Goodwill and Other Intangible Assets,” we do not amortize goodwill.

On an annual basis, the Company performs its annual fair value assessment of goodwill and other indefinite-lived intangible assets. The annual test date is December 31 of each year. In addition, the Company reviews its intangible assets subject to amortization quarterly to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment or a change in the remaining useful life. Conditions that would indicate impairment and trigger a more frequent impairment assessment include, but are not limited to, a significant adverse change in legal factors or business climate that could affect the value of an asset, or an adverse action or assessment by a regulator. If the carrying value of an asset exceeds its fair value, the Company writes-down the carrying value of the intangible asset to its fair value in the period identified. The Company generally calculates fair value of intangible assets as the

present value of estimated future cash flows to be generated by the asset using a risk-adjusted discount rate. If the estimate of an intangible asset's remaining useful life is changed, the Company amortizes the remaining carrying value of the intangible asset prospectively over the revised remaining useful life.

We completed an impairment test of long-lived assets, goodwill and other intangible assets subject to amortization as required by SFAS No. 142 and SFAS No. 144. Upon completion of our impairment tests as of the end of fiscal 2006 and 2005, we determined that neither goodwill nor intangible assets were impaired.

Income Taxes

The provision for income taxes is the tax payable or refundable for the period plus or minus the change during the period in deferred tax assets and liabilities and certain other adjustments. The Company provides for deferred taxes under the asset and liability method, in accordance with SFAS 109, "Accounting for Income Taxes." Under such method, deferred taxes are adjusted for tax rate changes as they occur. Deferred income tax assets and liabilities are computed annually for differences between the financial statements and tax basis of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates then applicable to the periods in which the differences are expected to affect taxable income. A valuation allowance is provided for deferred tax assets if it is more likely than not that these items will either expire before the Company is able to realize their benefit or the future deductibility is uncertain.

Translation of Foreign Currency

The Company translates all assets and liabilities of non-US entities at the year-end exchange rate and translates sales and expenses at the average exchange rates in effect during the year. The net effect of these translation adjustments is shown in the accompanying financial statements as a component of shareholders' equity, titled "Accumulated Other Comprehensive Income (Loss)." Foreign currency transaction gains and losses are included in the consolidated statements of operations.

Research and Development

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

Net Loss Per Ordinary Share

Basic loss per share is computed by dividing net loss for the period by the weighted average number of ordinary shares outstanding during the period. Diluted loss per share is computed by dividing net loss for the period by the weighted average number of ordinary shares

outstanding during the period, plus the dilutive effect of ordinary share equivalents, such as options, using the treasury stock method.

New Accounting Standards

In June 2006, the FASB issued Interpretation Number 48, "Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109" ("FIN 48"). The interpretation contains a two-step approach to recognizing and measuring uncertain tax positions accounted for in accordance with SFAS No. 109. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement. The interpretation is effective for the first interim period beginning after December 15, 2006. We have not been able to complete our evaluation of the impact of adopting FIN 48 and as a result, are not able to estimate the effect the adoption will have on our financial position and results of operations

In September 2006, the SEC's Office of the Chief Accountant and Divisions of Corporation Finance and Investment Management released SAB No. 108, "Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements" ("SAB No. 108"), that provides interpretive guidance on how the effects of the carry-over or reversal of prior year misstatements should be considered in quantifying a current year misstatement. SAB No. 108 states that registrants should quantify errors using both a balance sheet and an income statement approach and evaluate whether either approach results in quantifying a misstatement that, when all relevant quantitative and qualitative factors are considered, is material. This guidance is effective for fiscal years ending after November 15, 2006. The adoption of SAB No. 108 did not have a material impact on our financial position, results of operations, or cash flows.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" ("SFAS No. 157"). This statement provides a single definition of fair value, a framework for measuring fair value, and expanded disclosures concerning fair value. Previously, different definitions of fair value were contained in various accounting pronouncements creating inconsistencies in measurement and disclosures. SFAS No. 157 applies under those previously issued pronouncements that prescribe fair value as the relevant measure of value, except SFAS No. 123(R) and related interpretations and pronouncements that require or permit measurement similar to fair value but are not intended to measure fair value. This pronouncement is effective for fiscal years beginning after November 15, 2007. We do not expect the adoption of SFAS No. 157 to have a material impact on our financial position, results of operations, or cash flows.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities" (SFAS 159). SFAS 159 allows an entity the irrevocable option to elect fair value for the initial and subsequent measurement for certain financial assets and liabilities on a contract-by-contract basis. Subsequent changes in fair value of these financial

assets and liabilities would by recognized in earnings when they occur. SFAS 159 is effective for the Company's financial statements for the year beginning January 1, 2008, with earlier adoption permitted. The Company does not expect adoption of this statement to have an impact on its consolidated financial position and results of operations.

A variety of proposed or otherwise potential accounting standards are currently under study by standard-setting organizations and various regulatory agencies. Because of the tentative and preliminary nature of these proposed standards, management has not determined whether implementation of such proposed standards would be material to our consolidated financial statements.

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, 2006	December 31, 2005
Property, Plant and Equipment			
Machinery and equipment	5 to 7 years	$2,811,800	$1,472,691
Leasehold improvements	3 to 5 years	209,116	161,912
Office equipment, furniture and fixtures	5 to 7 years	143,886	113,019
Software	5 to 7 years	276,092	—
		3,440,894	1,747,622
Less: accumulated depreciation		(730,024)	(375,223)
		$2,710,870	$1,372,399

Depreciation expense was $371,497 and $247,229 for the years ended December 31, 2006 and 2005, respectively.

	December 31, 2006	December 31, 2005
Accrued expenses and other current liabilities		
Accrued R&D materials	$ 504,528	$ —
Accrued payroll and other employee costs	409,441	121,331
Accrued professional fees	261,317	56,862
Other accrued expenses	111,856	17,075
	$1,287,142	$195,268

Note 5 Business Combination

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 paid approximately $35 million in conjunction with the acquisition of HeartWare, Inc. through the issuance of 88 million ordinary shares with a value of $34 million and a convertible note in the principal amount of $1.1 million less a write-off of amounts due to shareholder of approximately $140,000.

The acquisition was accounted for as a purchase in accordance with SFAS No. 141 and accordingly, the purchase price was allocated based on the estimated fair values of the assets and liabilities acquired. Goodwill of approximately $15.4 million is attributable to the collective experience of the management and employees. The results of operations of HeartWare, Inc. from January 25, 2005 through December 31, 2006 are included in the accompanying statements of operations. The unaudited pro forma results of operations for the year ended December 31, 2005 as if the business combination had occurred at the beginning of the period presented are not included as the pro forma results are not materially different from the actual results.

The following table summarizes the fair values of the assets acquired and liabilities assumed at the date of acquisition:

Fair value of identifiable net assets of HeartWare Inc.

Cash	$ 126,380
Receivable	75,000
Prepayments	220,000
Other non-current assets	20,771
Intangible assets — patents	15,497,043
Intangible assets — copyrights	1,408,423
Intangible assets — non-compete agreement	2,959,597
Trade creditors	(558,103)
Other current payables	(256,099)
Other non-current payables	(100,000)
Property, plant & equipment	205,453
Goodwill	15,371,221
Total purchase price	$34,969,686

Goodwill of $15.4 million is deductible for tax purposes.

The amounts assigned to and the weighted average amortization period for amortizable intangible assets acquired are as follows:

(in millions)	Amount Assigned	Weighted Average Amortization Period
Amortizable Intangible Assets:		
Patents	$ 15.5	15 years
Copyrights	1.4	10 years
Non-Compete Agreements	3.0	5 years
	$ 19.9	

Note 6 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:

	2006		2005	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Amortizable Intangible Assets				
Patents	$15,741,230	$(2,013,089)	$15,706,285	$(957,504)
Copyrights	1,408,423	(269,948)	1,408,423	(129,105)
Non-Compete Agreements	2,959,597	(1,134,512)	2,959,597	(542,593)

Amortization expense for the years ended December 31, 2006 and 2005 was $1.8 million and $1.6 million, respectively.

Estimated amortization expense for each of the five succeeding fiscal years based upon the Company's intangible asset portfolio at December 31, 2006 is as follows:

	Estimated Amortization Expense
2007	$1,782,177
2008	1,782,177
2009	1,782,177
2010	1,239,584
2011	1,190,258

Note 7 Borrowings and Credit Facilities

Convertible Note – Related Party

The Company has a convertible note, denominated in Australian dollars, in the principal amount of AU$1.42 million outstanding at December 31, 2006 and 2005. At December 31, 2006, the principal amount of this note translated into US$1.1 million plus accrued interest that would convert into approximately 1.5 million ordinary shares at that time. At December 31, 2005, the principal amount of this note translated into US$1.1 million plus accrued interest that would convert into 1.4 million ordinary shares at that time.

The note accrues interest at 2.0% per annum. The conversion price is AU$1.00 per ordinary share. The principal and capitalized interest on the convertible note is repayable on demand as of January 31, 2007, and is therefore included as a current liability, but, as of December 31, 2006, the note has not been converted and the holder of the note, Apple Tree Partners I, L.P., the Company's majority shareholder, has given a written indication to the Company that it is its present intention to convert the note rather than demand repayment. Interest expense on this note was $22,062 and $19,227 for the years ended December 31, 2006 and 2005, respectively.

Note 8 Leases

Rent expense amounted to $484,226 in 2006 and $284,969 in 2005. Future minimum rental commitments at December 31, 2006 under non-cancelable operating lease agreements are as follows:

	Operating Leases
2007	$ 793,087
2008	395,725
2009	75,895
2010	75,895
2011	6,325
Total minimum lease payments	$1,346,927

Note 9 Income Taxes

At December 31, 2006 and 2005, the Company had deferred tax assets in excess of deferred tax liabilities of $13.2 million and $5.9 million, respectively. The Company determined that there is substantial doubt that such assets will be realized, and as such has taken a valuation allowance of $13.2 million and $5.9 million as of December 31, 2006 and 2005, respectively. The Company evaluates its ability to realize its deferred tax assets on a quarterly basis and adjusts the amount of its valuation allowance, if necessary. 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, 2006 and 2005.

The Company expects to continue to maintain a valuation allowance on certain future tax benefits until an appropriate level of profitability is reached or the Company is able to develop tax strategies which would enable it to conclude that it is more likely than not that a portion of its net deferred tax assets would be realized.

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

	For the Year Ended December 31,		
	2006	2005	2004
United States	$(15,239,069)	$(11,052,604)	$—
Foreign	(3,959,458)	(4,399,595)	
	$(19,198,527)	$(15,452,199)	$—

The effective tax rate of 0% differs from the statutory rate of 35% for all periods presented due primarily to the valuation allowance.

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

	At December 31,	
	2006	2005
Net operating loss and other carryforwards	$ 12,088,890	$ 5,131,772
Share based compensation	1,078,385	740,064
Total deferred tax assets	13,167,275	5,871,836
Valuation allowance	(13,167,275)	(5,871,836)
Net deferred tax assets	—	—

At December 31, 2006, the Company had net operating loss carryforwards of approximately $26.3 million for US federal income tax purposes and $5.5 million for non-US income tax purposes. Non-US losses have an unlimited carry over period and the US operating losses expire as follows:

Year of Expiration	US Operating Losses
2025	$11,052,604
2026	15,239,069
	$26,291,673

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 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;
- a milestone payment of $1,250,000 when the first circulatory assist device is approved for sale in the US, provided that the Company has at least $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.

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. 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 lump sum payments up to, but not exceeding, nine-months of their highest annual salary if their employment is terminated after a change in control of the Company, as defined in such agreements.

Note 11 Shareholders' Equity

Ordinary Shares

As of December 31, 2006, the Company has outstanding 186,262,097 ordinary shares. Under Australian law, the Company does not have authorized capital and the shares do not have a par value. Subject to the Corporations Act, the Company's Constitution and the Australian Stock Exchange Listing Rules, the Board of Directors may allot and issue ordinary shares to any person on such terms and with such rights as the Board determines. The Board may determine

that ordinary shares are to be issued with preferred, deferred or other special rights or restrictions, whether in regard to dividends, voting, return of share capital, payment of calls or otherwise.

Holders of ordinary shares are entitled to one vote per share at meetings of shareholders. Holders of ordinary shares are entitled to receive dividends if and when declared by the Board of Directors and to share ratably in the assets of the Company legally available for distribution to its shareholders in the event of liquidation. Holders of ordinary shares have no preemptive, subscription, anti-dilution, redemption or conversion rights. The holders of a majority of the ordinary shares can elect all of the directors and can control the management and affairs of the Company.

Since November 26, 2004, our inception, we have issued the following securities:

- In connection with our initial public offering in Australia, on January 27, 2005, we issued 55,838,000 ordinary shares. The aggregate offering price for this issuance was $21.6 million (AU$27.9 million), and we incurred underwriting commissions of $1.6 million (AU$2.1 million).
- Also on January 27, 2005, we issued 9,000,876 ordinary shares, for an aggregate consideration of approximately $3.5 million (AU$4.5 million), in a private placement exempt from registration pursuant to Regulation D promulgated under the Securities Act and Section 4(2) of the Securities Act.
- Also on January 27, 2005, in connection with our acquisition of all of the common stock of HeartWare, Inc., we issued 88,000,000 ordinary shares.
- On April 20, 2005, we issued 2,859,998 ordinary shares to Dr. Robert Fine, former CEO of Kriton Medical, Inc., upon the cashless exercise by Dr. Fine of three warrants to purchase 5,259,076 ordinary shares at an exercise price of AU$0.20 per share. These warrants had originally been issued to him by Kriton Medical's subsidiary, HeartWare, Inc., on October 3, 2003
- On May 23, 2006, we issued 29,679,220 ordinary shares in a private placement. The aggregate proceeds to us in connection with this offering were US$23.4 million.
- On June 15, 2006, we issued 75,452 ordinary shares to our Australian shareholders pursuant to our Shareholder Purchase Plan for aggregate proceeds to us of $61,254 (AU$82,997).
- From June 2005 to August 2006, we issued an aggregate of 806,551 ordinary shares pursuant to the exercise of options under our ESOP at exercise prices ranging from $0.16 to $0.36 (AU$0.20 to AU$0.50) for aggregate proceeds of

$162,712 (AU$218,656) to five individuals. The issuance of these ordinary shares was exempt from registration pursuant to Rule 701 under the Securities Act.

Note 12 Share Option Plan

Employee Share Option Plan

On December 15, 2004, the Company adopted the HeartWare Limited Employee Share Option Plan ("ESOP"). The ESOP allows the Company to grant options for ordinary shares in the Company to employees and directors. The ESOP provides for the issuance of up to 11% of the ordinary shares at any time outstanding.

Each option issued under the ESOP allows the holder to subscribe for and be issued with one ordinary share in the capital of the Company. In accordance with the ESOP Rules, all ESOP options issued after the Company became listed on the ASX must have an exercise price which is not less than the weighted average sale price of ordinary shares sold during the five days (or such other period as the Board determines) prior to the grant of the ESOP option.

Options may generally be exercised after they have vested and prior to the specified expiry date if applicable exercise conditions are met. The expiry date can be for periods of up to ten years from the date of grant of the option.

Non-Plan Options

The Company has also granted an aggregate of 1,500,000 options outside of our ESOP or any formal plan. Of these options, 1,000,000 were granted to three non-executive directors and 500,000 were granted to a third party for services rendered to the Company. The options granted to the third party service provider have exercise prices per share ranging from AU$0.60 to AU$1.50 per share and were immediately exercisable upon granting. The options granted to the non-executive directors were granted for no consideration and are subject to a vesting schedule whereby, as of December 31, 2006, 800,000 of the 1,000,000 options have vested and the remaining 200,000 options will vest on December 31, 2007. The exercise prices per share with respect to the options granted to non-executive directors range from AU$0.60 to AU$1.50. Information related to options, including non-plan options, at December 31 is as follows:

	2006		2005		2004	
(option amounts in thousands)	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding at January 1	16,145,410	$0.51	1,000,000	$0.74	0	
Granted	10,116,324	0.89	15,808,462	0.48	1,000,000	$0.74
Exercised	(411,051)	0.27	(395,400)	0.16	0	—
Forfeited	(5,349,433)	0.71	(267,652)	0.33	0	—
Outstanding at December 31	20,501,250	0.65	16,145,410	0.51	1,000,000	0.74
Exercisable at December 31	5,524,880	0.32	3,855,600	0.25	—	—

We generally recognize compensation expense for our share awards using a straight-line method over the substantive vesting period. The Company allocates expense to general and administrative expense and research and development expense based on the option holders' employment function. For the years ended December 31, 2006 and 2005, the Company recorded general and administrative share-based expense of approximately $598,000 and $693,000, respectively and research and development share-based expense of approximately $293,000 and $1,255,000, respectively.

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 option. We have applied an annual forfeiture rate of approximately 12% to all unvested share awards as of December 31, 2006, 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.

Under the provisions of Statement No. 123(R), we expect to recognize approximately $3.4 million, net of estimated forfeitures, of future expense for awards granted as of December 31, 2006. These awards have a weighted average remaining vesting period of 2.15 years.

There was no aggregate intrinsic value of outstanding options at December 31, 2006. At December 31, 2005, the aggregate intrinsic value of outstanding options was $683,000. The aggregate intrinsic value of options which were exercisable at December 31, 2006 and 2005 was $1.1 million and $1.2 million, respectively. The intrinsic value of exercised options was $135,000 at December 31, 2006 as compared to $97,000 at December 31, 2005.

The weighted average grant date fair value per share of options granted, calculated using the Black-Scholes option pricing model, was $0.46 for the year ended December 31, 2006, $0.21 for the year ended December 31, 2005 and $0.15 for the year ended December 31, 2004.

Shares reserved for future issuance under the Company's ESOP totaled approximately 1,487,581 at December 31, 2006.

Information related to options, both plan and non-plan, outstanding and exercisable at December 31, 2006 is as follows:

	Stock Options Outstanding			Stock Options Exercisable	
	Options	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price ($)	Options	Weighted Average Exercise Price ($)
$0.00-$ 0.50	7,574,416	4.60	0.27	4,824,880	0.25
$0.50-$ 1.00	11,244,732	8.62	0.84	600,000	0.79
$1.00-$ 1.50	1,682,102	6.80	1.14	100,000	1.19
	20,501,250	6.90	0.65	5,524,880	0.32

The Company recognizes share-based compensation on fixed awards with pro rata vesting on a straight-line basis over the award's vesting period. The fair value of the options used to calculate net loss and net loss per share was estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

	2006	2005
Dividend yield	0%	0%
Estimated annual volatility	54.82%	55.33%
Risk-free interest rate	5.67%	5.47%
Estimated forfeiture rate	12.12%	7.69%
Estimated holding period (years)	10	6.15

Dividend Yield

Since inception, we have not paid any dividends to our shareholders. We currently do not intend to pay dividends, and presently intend to retain all of our earnings for the purposes of investing in the continued growth of our business. Therefore, we have assumed an expected dividend yield of 0% in our grant date fair value assessment.

Estimated Annual Volatility

We used our historical share price volatility as a basis to estimate expected volatility in our valuation of share options.

Risk-Free Interest Rate

We use yield rates government bonds as prescribed by the Australian government for a period approximating the expected term of the award to estimate the risk-free interest rate in our grant date fair value assessment.

Estimated Forfeiture Rate

We estimate forfeiture rate based on historical employee retention rate data.

Expected Term

We estimate the expected term to equal the outstanding contractual term at the time of grant.

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.

Note 14 Net Loss Per Share

Basic earnings (loss) per share is computed by dividing net income (loss) applicable to ordinary shares by the weighted-average of ordinary 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.

Ordinary shares issuable upon:	2006	2005
Exercise of stock options	20,501,250	16,145,410
Conversion of convertible note	1,475,396	1,446,205

Note 15 Quarterly Results of Operations (Unaudited)

The following is a summary of our unaudited quarterly results of operations for the years ended December 31, 2006 and 2005:

(In thousands, except per share data)	First	Second	Third	Fourth
Fiscal Year 2006				
Revenue	$ —	$ —	$ —	$ —
Net loss	(3,593)	(4,267)	(4,878)	(6,461)
Basic and diluted net loss per share	(0.02)	(0.03)	(0.03)	(0.03)
Fiscal Year 2005				
Revenue	$ —	$ —	$ —	$ —
Net loss	(4,348)	(3,887)	(3,524)	(3,693)
Basic and diluted net loss per share	(0.04)	(0.03)	(0.02)	(0.02)

Note 16 Subsequent Events

The matters or circumstances that have arisen since December 31, 2006 which have or may significantly affect our operations, the results of those operations or our state of affairs in future financial years are as follows:

- On January 2, 2007, we granted 1,150,000 options to new senior appointments under the Company's ESOP, at an exercise price of AU$1.10 per share.

Except as stated above, no other matters or circumstances have arisen since December 31, 2006 that have significantly affected or are expected to significantly affect our future results of our operations or our financial condition.

REPORT OF INDEPENDENT CERTIFIED
PUBLIC ACCOUNTANTS

Board of Directors
HeartWare, Inc.

We have audited the accompanying balance sheets of HeartWare, Inc. (a Development Stage Company) (the "Company") as of December 31, 2004 and 2003, and the related statements of operations, shareholders' deficit, and cash flows for the year ended December 31, 2004, the period from April 8, 2003 (date of inception) through December 31, 2003 and the period from April 8, 2003 (date of inception) through December 31, 2004. 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 auditing standards generally accepted in the United States of America as established by the American Institute of Certified Public Accountants. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes 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 financial statements referred to above present fairly, in all material respects, the financial position of HeartWare, Inc. (a Development Stage Company) as of December 31, 2004 and 2003, and the results of its operations and its cash flows for the year ended December 31, 2004, the period from April 8, 2003 (date of inception) through December 31, 2003 and the period from April 8, 2003 (date of inception) through December 31, 2004 in conformity with accounting principles generally accepted in the United States of America.

/s/ Grant Thornton LLP

Fort Lauderdale, Florida
April 23, 2007

HeartWare, Inc.
(A Development Stage Company)
BALANCE SHEETS

	December 31, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 139,242	$ 197,039
Total current assets	139,242	197,039
Property, plant and equipment, net	212,377	186,954
Other non-current assets	20,771	35,071
Total Assets	$ 372,390	$ 419,064
LIABILITIES AND SHAREHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 425,753	$ 177,292
Accrued expenses and other current liabilities	1,354,559	311,251
Debt agreement, short-term portion	180,000	180,000
Notes payable, convertible — related party	9,951,509	5,106,535
Total current liabilities	11,911,821	5,775,078
Debt agreement	115,000	295,000
Total liabilities	12,026,821	6,070,078
Shareholders' deficit:		
Common stock, $0.001 par value; 2,000,000 shares authorized, none issued or outstanding	—	—
Preferred stock, $0.001 par value; 2,000,000 shares authorized Series A-1, 626,700 shares issued and outstanding; liquidation preference of $10.00 per share	627	627
Series A-2, 436,500 shares issued and outstanding; liquidation preference of $21.00 per share	436	436
Series B, 603,150 shares issued and outstanding; participating; convertible; liquidation preference of $10.00 per share	603	603
Additional paid-in capital	51,158	51,158
Deficit accumulated during the development stage	(11,707,255)	(5,703,838)
Total shareholders' deficit	(11,654,431)	(5,651,014)
Total Liabilities and Shareholders' Deficit	$ 372,390	$ 419,064

The accompanying notes are an integral part of these financial statements

HeartWare, Inc.
(A Development Stage Company)
STATEMENTS OF OPERATIONS

	Year Ended December 31, 2004	Period from April 8, 2003 (Inception) through December 31, 2003	Cumulative Period from April 8, 2003 (Inception) Through December 31, 2004
Revenue	$ —	$ —	$ —
Costs and expenses			
Research and development	4,795,012	1,270,995	6,066,007
Depreciation	87,825	35,446	123,271
General and administrative	137,860	166,493	304,353
In process research and development expensed when acquired	—	3,984,388	3,984,388
	5,020,697	5,457,322	10,478,019
Loss from operations	(5,020,697)	(5,457,322)	(10,478,019)
Other expenses			
Interest — related party	982,720	246,516	1,229,236
Loss before provision for income taxes	(6,003,417)	(5,703,838)	(11,707,255)
Provision for income taxes	—	—	—
Net loss	$(6,003,417)	$ (5,703,838)	$(11,707,255)

The accompanying notes are an integral part of these financial statements

HeartWare, Inc.
(A Development Stage Company)
STATEMENT OF CHANGES IN SHAREHOLDERS' DEFICIT

	Preferred Stock						Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Total
	Series A-1		Series A-2		Series B				
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at April 8, 2003 (inception)	—	$ —	—	$ —	582,610	$583	$49,417	$ —	$ 50,000
Issuance of stock in conjunction with July 10, 2003 acquisition	626,700	627	436,500	436	20,540	20	1,741	—	2,824
Net loss	—	—	—	—	—	—	—	(5,703,838)	(5,703,838)
Balance at December 31, 2003	626,700	627	436,500	436	603,150	603	51,158	(5,703,838)	(5,651,014)
Net loss								(6,003,417)	(6,003,417)
Balance at December 31, 2004	626,700	$627	436,500	$436	603,150	$603	$51,158	$(11,707,255)	$(11,654,431)

The accompanying notes are an integral part of these financial statements

HeartWare, Inc.
(A Development Stage Company)
STATEMENT OF CASH FLOWS

	For the Year Ended December 31, 2004	For the period from April 8, 2003 (Inception) through December 31, 2003	Cumulative Period from April 8, 2003 (Inception) Through December 31, 2004
Cash flows from operating activities			
Net loss	$ (6,003,417)	$ (5,703,838)	$ (11,707,255)
Adjustments to reconcile net loss to net cash used in operating activities (net of effects of acquisition):			
In process research and development acquired	—	3,984,388	3,984,388
Depreciation	87,825	35,446	123,271
Changes in assets and liabilities Decrease in other non-current assets	14,300	—	14,300
Increase in accounts payable	248,461	177,292	425,753
Increase in accrued expenses	1,043,308	311,251	1,354,559
Net cash used in operating activities	(4,609,523)	(1,195,461)	(5,804,984)
Cash flows from investing activities			
Additions to property, plant and equipment	(113,248)	—	(113,248)
Net cash used in investing activities	(113,248)	—	(113,248)
Cash flows from financing activities			
Proceeds from issuance of convertible debt — related party	4,844,974	1,417,500	6,262,474
Proceeds from issuance of preferred stock, net	—	50,000	50,000
Payments on debt agreement	(180,000)	(75,000)	(255,000)
Net cash provided by financing activities	4,664,974	1,392,500	6,057,474
Net (decrease) increase in cash and cash equivalents	(57,797)	197,039	139,242
Cash and cash equivalents, beginning of period	197,039	—	197,039
Cash and cash equivalents, end of period	$ 139,242	$ 197,039	$ 336,281
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ —	$ —	$ —
Cash paid for taxes	$ —	$ —	$ —
Noncash investing and financing activities:			
On July 10, 2003, the Company issued preferred stock in connection with the acquisition of certain assets and certain liabilities of Kriton Medical, Inc.			
The following assets and liabilities were transferred:			
Property and equipment		$ 222,400	$ 222,400
In process research and development		3,984,388	3,984,388
Other non current assets		35,071	35,071
Debt agreement		(550,000)	(550,000)
Notes payable, convertible		(3,689,035)	(3,689,035)
Net		2,824	2,824
Net cash paid		—	—
Preferred stock issued		(2,824)	(2,824)
Total price consideration		(2,824)	(2,824)
		$ —	$ —

The accompanying notes are an integral part of these financial statements

NOTE A — NATURE OF THE BUSINESS

HeartWare, Inc. f/k/a Perpetual Medical, Inc. (the "Company") was incorporated in the State of Delaware on April 8, 2003 and operates as a biotechnology company 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.

We have operated as a development stage enterprise since our inception by devoting substantially all of our efforts to raising capital, research and development of products noted above, and developing markets for our products. Accordingly, our financial statements have been prepared in accordance with the accounting and reporting principles prescribed by Statement of Financial Accounting Standard ("SFAS") No. 7, "Accounting and Reporting by Development Stage Enterprises," issued by the Financial Accounting Standards Board ("FASB").

NOTE B — KRITON MEDICAL, INC. ACQUISITION

On July 10, 2003, the Company purchased substantially all of the assets and certain intellectual property related to the business of Kriton Medical, Inc. ("Kriton"), a privately held company engaged in the business of developing a ventricular assist device ("VAD"). The asset purchase agreement was executed on April 8, 2003 contemporaneous with a petition filed pursuant to Chapter 11 of Title 11 of the United States Code with the Untied States Bankruptcy Court. Kriton continued to operate with debtor-in-possession financing provided by Apple Tree Partners I, L.P., one of Kriton's debtors and a shareholder of the Company. However, the transaction could not be consummated until the order was approved by the Bankruptcy Court. Such approval was received June 20, 2003, and the Assignment, Assumption and Bill of Sale was executed on July 10, 2003. With the exception of the Apple Tree Partners I, L.P. financing, by virtue of the Court Order, the Company took the Kriton assets free and clear of any and all liens, security interests, encumbrances and claims. In addition, there are certain restrictions placed on the minority shareholders on transferring their shares and voting.

The acquisition was accounted for as a purchase in accordance with Statement of Financial Accounting Standard No. 141 ("SFAS No. 141"). Under this method of accounting, the Company allocated the purchase price to the fair value of the assets acquired, including identifiable intangible assets. The allocation was based on management's estimates, which included an independent third party valuation on the intangible assets.

The purchase price totaled $4,241,859 and was paid through a combination of cash, debt, issuance of preferred stock, and assumption of liabilities. Certain of the cash paid was paid by Apple Tree Partners I, L.P. on behalf of the Company and is included in the notes payable amount in the following table. The following table summarizes the estimated fair values of the assets acquired, liabilities assumed and shares issued as of the acquisition date:

Property and equipment	$ 222,400
In-process research and development	3,984,388
Other assets	35,071
Debt agreement	(550,000)
Notes payable	(3,689,035)
Preferred stock	(2,824)
Net assets	$ —

Of the purchase price, $3,984,388 represents the estimated fair value of projects that, as of the acquisition date, had not reached technological feasibility and had no alternative future use. Accordingly, this amount was immediately expensed as in-process research and development costs as of the acquisition date.

NOTE C — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Property and Equipment

Property and equipment is stated at cost. The costs of additions and betterments are capitalized and expenditures for repairs and maintenance are expensed in the period incurred. When items of property and equipment are sold or retired, the related cost and accumulated depreciation are removed from the accounts and any gain or loss is included in income. The Company generally provides for depreciation using the straight line method at rates that approximate the estimated useful lives of the assets ranging from 3 to 5 years.

Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and 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. The estimates are based on historical experience and various other assumptions that the Company believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates under different assumptions or conditions.

Income Taxes

The provision for income taxes and corresponding balance sheet accounts are determined in accordance with Statement of Financial Accounting Standards No. 109, “Accounting for Income Taxes” (“SFAS No. 109”). Under SFAS 109, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect for the years in which the differences are expected to reverse. A valuation allowance is provided for that portion of deferred tax assets, which the Company cannot determine is more likely that not to be

recognized due to the Company's cumulative losses and uncertainty as to future recoverability.

Cash and Cash Equivalents

The Company considers all investments purchased with an original maturity of three months or less to be cash or cash equivalents.

Fair Value of Financial Instruments

The carrying amounts reported in the accompanying consolidated balance sheets for cash and cash equivalents, accounts receivable and accounts payable approximate fair value due to the short-term nature of these accounts.

Research and Development Expenses

Research and development expenses are comprised of the following types of costs incurred in performing research and development activities: salaries and benefits, overhead and occupancy costs, clinical trial and related clinical manufacturing costs, contract services, and other outside costs. Research and development costs are expensed as incurred.

NOTE D — PROPERTY AND EQUIPMENT

Property and equipment at December 31 consists of the following:

	2004	2003
Furniture, fixtures and equipment	$335,649	$222,400
Less: Accumulated depreciation	123,272	35,446
	$212,377	$186,954

Depreciation expense for the year ended December 31, 2004 and the period ended December 31, 2003 totaled $87,825 and $35,446 respectively.

NOTE E — INCOME TAXES

The Company has not recorded an income tax expense or benefit due to the operating losses incurred.

As of December 31, 2004 and December 31, 2003, the Company had Federal and State net operating loss carryforwards, which may be applied to future taxable income, approximating $11.7 million and $5.7 million, respectively. This net operating loss carryforward expires in 2023 and 2024. The Company believes it is more likely than not the deferred tax assets resulting from the net operating loss carryforwards will not be realized. Accordingly, a full valuation has been recorded against the deferred tax assets as of December 31 2004 and December 31, 2003.

The effective tax rate of 0% differs from the statutory rate of 35% for all periods presented due primarily to the valuation allowance.

NOTE F — NOTES PAYABLE, CONVERTIBLE — RELATED PARTY

As of December 31, 2004 and December 31, 2003, the Company has issued convertible notes payable in the amount of $9,951,509 and $5,106,535, respectively. Under certain conditions, these notes can be converted into the Company's next series of preferred stock to be issued, if any, at the face value of these notes, including accrued interest not yet paid.

On November 19, 2004 the Company entered into a revised promissory note that superseded a series of prior loan agreements. The revised promissory note bears interest at eighteen percent (18%) per annum and is repayable to the Company's majority stockholder, Apple Tree Partners I, L.P. The note is secured by all of the Company's assets.

The revised promissory note replaces prior loan agreements with Apple Tree Partners I, L.P. which bore interest at ten percent (10%) per annum and if not repaid within a defined time period, would go into default, whereby the interest rate would increase to twelve percent (12%). At December 31, 2003 these loan agreements were in technical default.

There was no interest paid on these convertible notes for the period ending December 31, 2004 or December 31, 2003. Interest expense relating to these convertible notes payable was $982,720 for the year ended December 31, 2004 and $246,516 for the period ended December 31, 2003. Accrued interest payable on these notes was $1,229,236 at December 31, 2004 and $246,516 at December 31, 2003.

NOTE G — DEBT AGREEMENT

As part of the purchase consideration for the Kriton acquisition, the Company agreed to assume a 2003 agreement between Apple Tree Partners I, L.P., the Company's majority stockholder, and the former CEO of Kriton, which called for the Company to pay to the

former CEO of Kriton $550,000 in monthly payments of $15,000 per month for a period of three years. This agreement was included as part of the Kriton purchase consideration. The balance due on this agreement as of December 31, 2004 and December 31, 2003 was $295,000 and $475,000, respectively. The current portion of this agreement as of December 31, 2004 and December 31, 2003 was $180,000.

NOTE H — SHAREHOLDERS' DEFICIT

Common Stock

At December 31, 2004 and December 31, 2003, the Company has authorized 2,000,000 shares of $0.001 par value common stock none of which has been issued nor is outstanding.

Preferred Stock

At December 31, 2004 and December 31, 2003, the Company has authorized 2,000,000 shares of preferred stock of which 626,700 are designated as Series A-1, non-voting preferred stock, par value $0.001, 436,500 shares are designated as Series A-2, non-voting preferred stock, par value $0.001, collectively known as "Series A Preferred Stock", 603,150 shares are designated as Series B convertible participating preferred stock, par value $0.001 and 333,650 shares are undesignated preferred stock, par value $0.001.

Series A-1

At December 31, 2004 and December 31, 2003, the Company has 626,700 shares of Series A-1 non-voting, non-cumulative, preferred stock outstanding. The preferred shares rank senior to the common stock and have liquidation preference of $10 per share.

Series A-2

At December 31, 2004 and December 31, 2003, the Company has 436,500 shares of Series A-2 non-voting, non-cumulative, preferred stock outstanding. The preferred shares rank senior to the common stock and have liquidation preference of $21 per share.

Series B

At December 31, 2004 and December 31, 2003, the Company has 603,150 shares of Series B, voting, non-cumulative, convertible preferred stock outstanding. Currently each preferred stock is convertible, at the option of the holders, into shares of common stock on a one for one basis.

The preferred shares rank senior to the common stock and have a liquidation preference of $10 per share plus any declared unpaid dividends on each share. The Series B preferred stock ranks *pari passu* with any dividends paid on any other class of capital stock and also with other series of preferred stock with respect to rights to dividends and rights upon liquidation

of dissolution. The common stock and Series B stock are the only voting stock and the Series B stock is the only stock entitled to receive dividends. At December 31, 2004 and December 31, 2003 the company had not declared any dividends and there were no dividends in arrears.

NOTE I — COMMITMENTS AND CONTINGENCIES

Leases

The Company has an operating lease for office space. The future minimum lease payments as required under this agreement as of December 31, 2004 are as follows:

	Amount
2005	$191,121
2006	196,856
2007	66,262
	$454,239

Rent expense for the year ended December 31, 2004 and the period ended December 31, 2003 was $213,794 and $101,708, respectively.

Agreement with former Chief Executive Officer (CEO)

Apple Tree Partners I, L.P. entered into an agreement with the former CEO of Kriton on behalf of the Company. The details of this arrangement are as follows:

1. $550,000 to be paid by the Company in monthly installments of $15,000. See Note H. In addition to this debt agreement, the agreement included certain milestone based accelerations. These milestones are as follows:
    a. Payment of $750,000 by the Company 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;
    b. Payment of $1,250,000 by the Company 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;
    c. A special payment of up to $500,000 by the Company upon the sale of the Company if such sale generates proceeds in excess of the aggregate liquidation preferences of all the Company's then outstanding preferred stock, see Note I; and
    d. A warrant for three percent (3%) of the Company on a fully diluted basis ("3% warrant"). The warrants have a strike price based upon future funding. In a separate

Agreement, Apple Tree has paid $300,000 to the former CEO of Kriton for the option to acquire 66.67% of the 3% warrant.

Significant Contract

In January 2004, the Company entered into a system development proposal with Minnetronix, Inc. This proposal provides that Minnetronix, Inc. will serve as the Company's design partner focusing on the control software to accompany the ventricular assist device ("VAD") and will assist with commercialization of the Company's products. The term of this agreement shall continue until the completion of phase II of the VAD. The Company may terminate this agreement at any time with a thirty (30) day notice. The Company incurred approximately $780,000 of research and development expense as a result of this contract in 2004.

NOTE J — SUBSEQUENT EVENT

On January 24, 2005 the stockholders of the Company sold all outstanding voting stock to HeartWare Limited, an unrelated company, headquartered in Sydney, Australia and listed on the Australian Stock Exchange. Prior to the transaction, all of the Company's outstanding convertible notes were converted into equity. The transaction was a share for share exchange valued at approximately $35 million.