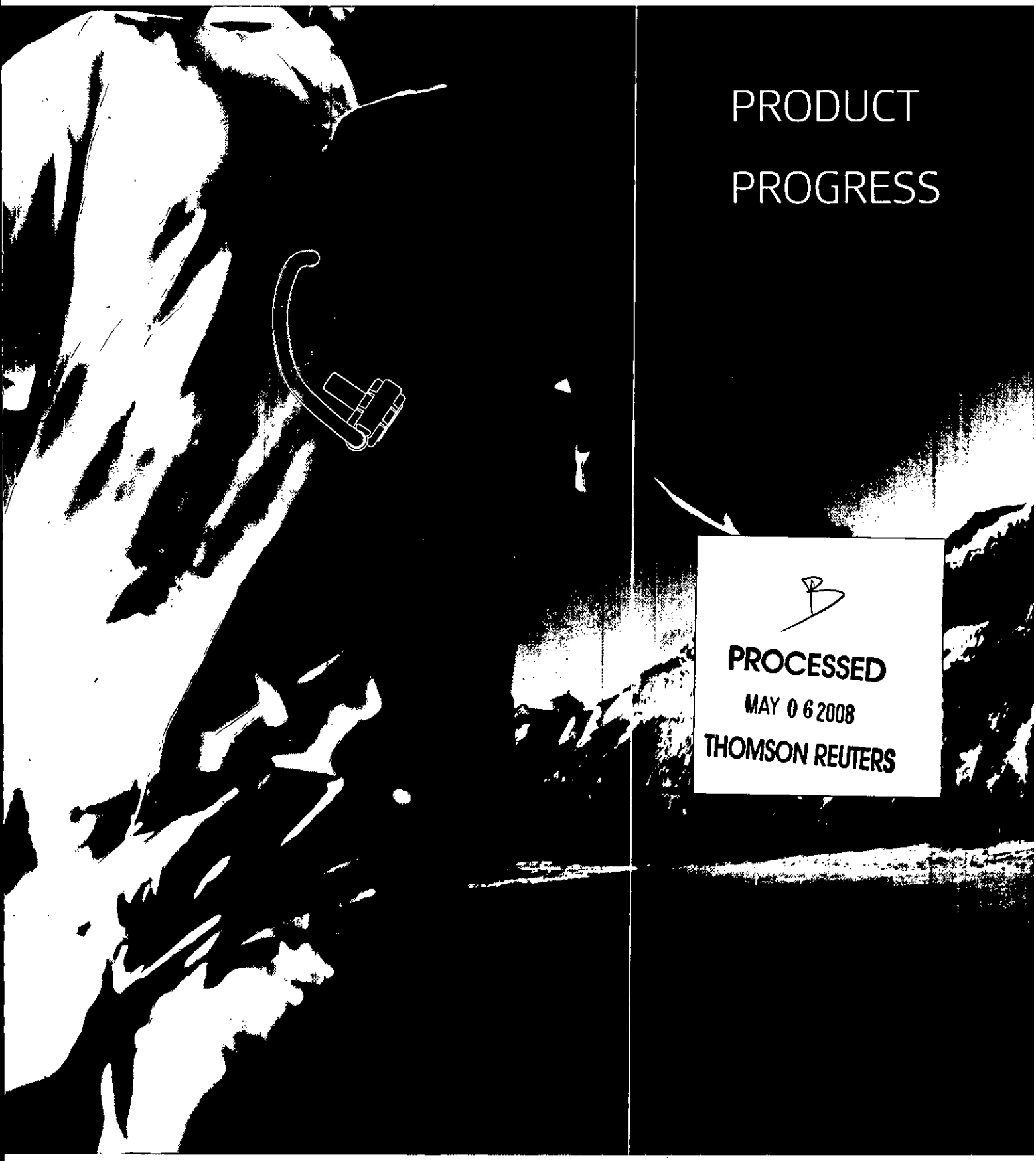
HeartWare



# PRODUCT PROGRESS



Annual Report 2007

# Corporate Profile

HeartWare is a medical device company developing a family of implantable mechanical circulatory support devices, or heart pumps, and the ancillary equipment required to run those devices. HeartWare's devices are aimed at treating patients suffering from advanced heart failure. The Company is listed on the Australian Stock Exchange with the symbol "HTW".

Heart failure is a degenerative, terminal disease affecting over ten million patients worldwide. Heart transplantation is considered the best available treatment for patients with advanced heart failure but fewer than 4,000 donor hearts become available worldwide each year. Mechanical circulatory support devices are gaining increasing acceptance, both as a bridge to transplantation and as an alternative long-term therapy.

An international clinical trial is underway for the HeartWare® Left Ventricular Assist System (LVAS). The HeartWare® LVAS comprises a fully implanted miniature pump, the HeartWare® Left Ventricular Assist Device (LVAD), and the peripheral components required to power, monitor and control the pump. The HeartWare® LVAD is the smallest full-output blood pump and the only such pump designed to be implanted above the diaphragm. The device's small size and novel configuration are expected to provide significant benefits for both the physician and the patient.

HeartWare is also developing a portfolio of further miniaturized devices, implantable by progressively less invasive surgery.

HeartWare's corporate head office is in Sydney, Australia. The Company's U.S. corporate office is in Framingham, Massachusetts. Operating and manufacturing activities are also based in the U.S. in Miramar, Florida.



> Dr Georg Wieselthaler (3rd from left), cardiothoracic surgeon at the Vienna General Hospital in Austria, pictured alongside three of his patients who have been implanted with the HeartWare® Left Ventricular Assist Device.

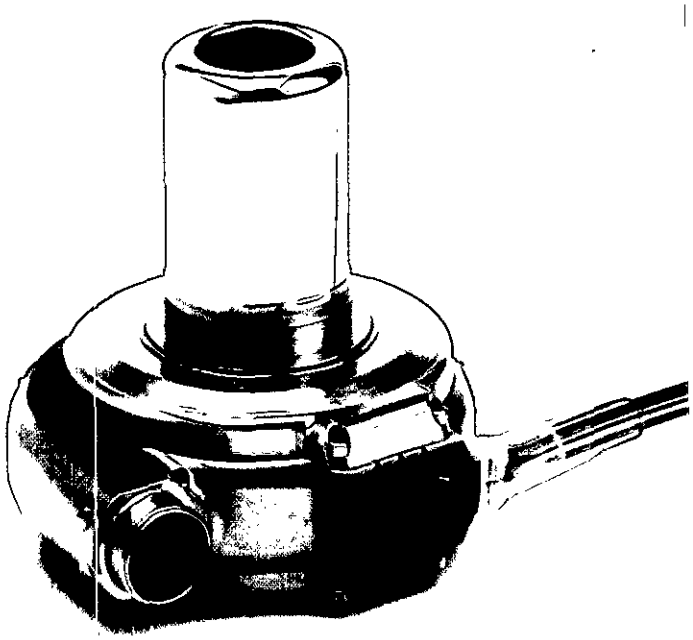
**The HeartWare® Left Ventricular Assist System**

The HeartWare® LVAS features a small, implantable, centrifugal blood pump, designed to help treat patients suffering advanced heart failure.

The HeartWare® pump, or Left Ventricular Assist Device (LVAD), is designed to draw blood from the left ventricle and to propel it through an outflow graft connected to the patient's ascending aorta. The device is capable of generating up to ten litres of blood flow per minute.

With a displaced volume of only 50cc, the HeartWare® device is the only full-output pump designed to be implanted in the pericardial space, directly adjacent to the heart. Implantation above the diaphragm is expected to lead to relatively short surgery time and relatively quick patient recovery.

The pump has only one moving part, the impeller, which spins at rates between 2,000 and 3,000 revolutions per minute. The impeller is suspended within the pump housing through a combination of passive magnets and a hydrodynamic thrust bearing. There are no mechanical bearings or any points of contact between the impeller and the pump housing. This wearless suspension mechanism is expected to provide excellent long-term device durability.



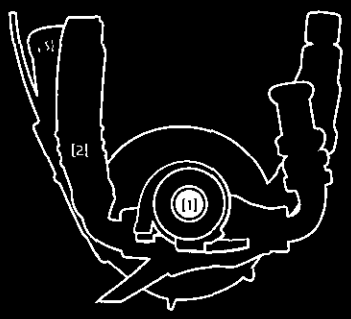
The HeartWare® Left Ventricular Assist Device

The pump's inflow cannula is integrated with the device itself, ensuring proximity between the heart and the pumping mechanism. This integrated design is expected to facilitate ease of implant and to help ensure optimal blood flow characteristics. The use of a wide-bladed impeller and the clear flow paths through the system are expected to help minimize any risk of pump induced hemolysis (damage to blood cells) or thrombus (blood clotting).

The device is powered via a percutaneous driveline which connects the pump to an external controller and battery pack, which are carried in a small pouch.

# PRODUCTS...

- The smallest full-output mechanical circulatory support device.




- The only full-output pump designed to be implanted above the diaphragm.
- Only one moving part.
- Designed for long-term reliability and optimal blood compatibility

> Relative device size: [1] The HeartWare® pump; [2] The Thoratec HeartMate XVE™, the only device currently approved in the U.S. for Destination Therapy; [3] The Thoratec HeartMate II™, the current market leader.

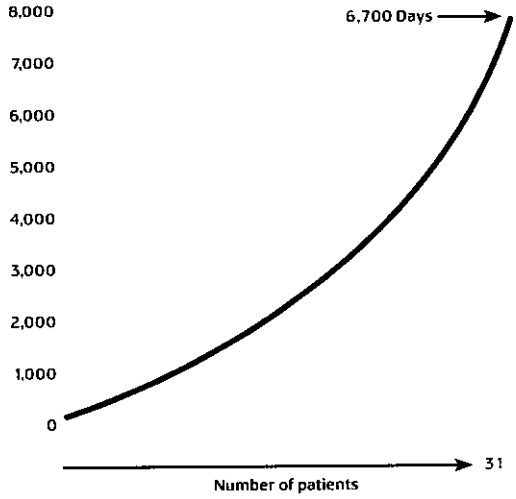
## The HeartWare Clinical Trial

The HeartWare® LVAS is the subject of an international clinical trial aimed at evaluating the safety and feasibility of the system as a bridge to cardiac transplantation in patients with end-stage heart failure. The trial is being conducted at five cardiac transplant centres in Europe and Australia.

As of 31 March 2008, 31 patients have been implanted with the HeartWare® device. The average duration of support on the pump is approximately 217 days. On a cumulative basis, these patients have been supported by the device for approximately 6,700 days, or 18 years.

HeartWare's initial clinical results will be presented in early April at the International Society for Heart and Lung Transplantation meeting in Boston. These results form the basis of HeartWare's submission for CE Mark for the system. Of the first 20 patients, 18 have passed the primary clinical endpoint of the trial, a success rate of 90%. These include 16 patients who survived on mechanical support for 180 days or more and two patients who successfully underwent cardiac transplantation within the first 180 days following their device implants.

**Cumulative Period of Support on the HeartWare® LVAS**




Among the entire patient group, a total of six patients have received heart transplants. On average, these transplants have occurred after 284 days of support on the pump. In addition, one patient recovered sufficiently to have his device explanted after 268 days of support.

In 2008, HeartWare will initiate a multi-institutional trial in the United States to evaluate the safety and efficacy of the system for FDA approval. During this time the system will be limited by federal law to investigational use in the United States.

# PATIENTS...

**31** patients enrolled in the HeartWare trial.

**18** years of cumulative support on the system.

**90%** success rate among initial 20 patient cohort.

During 2007 HeartWare made important progress across all key areas of the business.

- Increased patient enrolments under the international clinical trial from six (at December 2006) to 31 (at 31 March 2008).
- Made significant progress in resolving manufacturing issues that had restricted supply capability.
- Prepared and filed an application for an Investigational Device Exemption ("IDE") with the U.S. Food and Drug Administration ("FDA") in order to initiate a U.S. clinical trial for the HeartWare® LVAS.
- Advanced the Company's pipeline technologies, with our next generation miniaturized pump system progressing through preclinical trials and our Transcutaneous Energy Transfer ("TET") system and implantable electronics at working prototype stage.
- Commenced preparations to move to a new facility which, subject to finalizing present leasing discussions, will provide HeartWare approximately twice the square footage of our current facility and a significant upgrade to our manufacturing infrastructure.

These activities have positioned the Company well as we move towards our two key milestones for 2008:

- FDA approval of HeartWare's IDE submission and the subsequent start of our U.S. clinical trial; and
- Receipt of CE Mark and subsequent European commercial launch of the HeartWare® LVAS in Europe.

| Key Anticipated 2008 Milestones | |
|---|---|
| Q2 | Q3 |
| IDE Approval | CE Mark |
| First implants in the U.S. | Commercial launch in Europe |

# PROGRESS...

- International clinical trial demonstrating exceptional results.
- IDE approval to initiate U.S. clinical trial anticipated during the second quarter of 2008.
- CE Mark anticipated during the third quarter of 2008.
- First revenues anticipated within six months.

# Chairman's Review

DEAR SHAREHOLDERS

The past year has seen substantial progress across all areas of our business.

The international clinical trial for the HeartWare® Left Ventricular Assist System is nearing completion, with very promising results. We are now more confident than ever of the long-term commercial opportunity underpinned by this device.

We will soon be starting our U.S. clinical trial. Formal dialogue with the FDA has been ongoing since late last year. The team has worked exceedingly hard to prepare the enormous volumes of material required both for the initial IDE application and for subsequent submissions. Some 17,000 pages of materials have been lodged with the FDA, representing a synthesis of virtually everything the company has learnt about our device over the past ten years of development. We look forward to commencing our U.S. implant program and we share the enthusiasm of our prospective U.S. clinical investigators as to the potential of the device.

HeartWare will be entering the U.S. market with the HeartWare® LVAS at a particularly interesting time in the development of the mechanical circulatory support market. In November 2007 an independent panel convened by the FDA recommended unanimously that the Thoratec HeartMate II be approved for Bridge-to-Transplant in the United States. The HeartMate II will be the first continuous flow pump approved in the U.S., providing both patients and clinicians access for the first time to a relatively small, reliable device. We share the view of many clinicians that the HeartMate II will help drive a long-term shift in patient referral patterns and lead to a broad increase in the use of mechanical circulatory support devices. It is exciting that HeartWare will be entering this market as it begins a new phase of growth, with a device that we expect will demonstrate significant competitive advantages.

We also continue to make solid progress with our next-generation miniaturized devices. Our future miniature pump technology was first presented at the International Society of Rotary Blood Pumps (ISRBP) meeting in Sydney late last year and generated a great deal of interest. This novel and extremely small device will enable surgeons for the first time to implant a full-output pump through minimally invasive surgery, without the need for a sternotomy. This has the potential to significantly expand the market for our products. We hope to initiate Good Laboratory ("GLP") animal studies for the device in 2009.

As we move towards the start of our U.S. clinical trial, we are also in advanced discussions concerning a potential move to a new manufacturing facility. This facility, recently vacated by a major medical company, includes state of the art medical device manufacturing infrastructure and represents a significant upgrade for HeartWare. The facility, which occupies approximately double the manufacturing footprint of our current facility in Miramar, provides significant scope for expanding production over coming years.

Last year we sought to pursue in parallel both our IDE submission (to start our U.S. clinical trial) and our CE Mark submission (for European marketing approval). The Board determined that the U.S. IDE process had to take priority and, as a result, we are behind our previously discussed schedule for CE Mark. The decision to prioritize the IDE process proved fortuitous, given the Company's subsequent opportunity to relocate to a new, larger facility. Although the facility move remains subject to finalizing current lease negotiations, clearly it would not make sense to seek ISO certification of our Miramar facility – a prerequisite for CE Mark. Instead, we intend to hold off until the new facility has been commissioned. On this basis we anticipate receiving CE Mark in the second half of the year.

As you are aware the Board determined not to pursue an ADR listing on the NASDAQ Exchange as had been previously considered. This followed our successful equity capital raise of July 2007, during which the Company was able to generate substantial institutional interest from the United States directly into the ASX listed stock. We will continue to consider all financing options for the Company, including the possibility of a U.S. listing in 2009.

I would like, on behalf of the Board, to express my appreciation for the hard work and extraordinary dedication demonstrated by the HeartWare team over the past 12 months. The Company faced several challenges during 2007, calling for clear leadership and direction and, on occasion, testing the depth of the Company's manufacturing, engineering and clinical capabilities. Under the leadership of Doug Godshall, our Chief Executive Officer, the Company has emerged stronger than ever, with the product, capability and credibility to challenge the market leader within the next few years.

I wish to thank my fellow directors who continue to make very valuable contributions both in corporate governance and in helping to set strategic direction.

HeartWare is also very fortunate to have in place a world-class Medical Advisory Board, which comprises several pre-eminent cardiac surgeons and cardiologists. We continue to draw on their advice and counsel and appreciate their ongoing support. We also greatly appreciate the efforts and dedication of the surgeons, cardiologists and clinical staff at all our investigational centres.

> We are committed to establishing a world class medical device company with a leading technology position in a rapidly growing market.

Finally, a sincere thanks to all our shareholders. The year ahead promises to be yet another pivotal year for the company as we progress our U.S. trial, initiate commercial activities in Europe and begin to generate revenue. We are committed to establishing a world class medical device company, with a leading technology position in a rapidly growing market. With these objectives firmly in mind, we continue to strive to deliver substantial value for our shareholders. We thank you for your support and look forward to an exciting year ahead.

Yours sincerely

ROBERT B THOMAS
Chairman

# Chief Executive Officer's Report

DEAR SHAREHOLDERS

The past 12 months have seen an almost complete transformation of our business. Our core objective of advancing the HeartWare® Left Ventricular Assist System towards the market has not changed, however a comprehensive upgrade in the Company's systems, infrastructure, resources, personnel and overall capabilities has seen us evolve from an early stage technology developer into a full-fledged medical device enterprise. With each new implant of our device and with the exponential daily growth in our cumulative implant experience, we are making steady progress towards our long-term goal of achieving market leadership and revolutionizing the mechanical circulatory support sector.

## Our Clinical Results are Exceptional

In September 2007 we completed the enrolment of the initial 20 patients in the international clinical trial for the HeartWare® LVAS. We subsequently expanded the trial to 30 patients and completed our 30th implant in late February. At the encouragement of our investigators, we have further expanded enrolment under the trial to 50 patients so as to allow the continued use of our device as we work through the process of seeking CE Mark for the system.

As of 31 March the HeartWare® LVAS has been used to treat 31 patients. The sample size remains small but our early results are extremely promising. The simple goal of our company and technology is to keep patients with heart failure alive and every day we measure ourselves against this one objective. Virtually every patient enrolled in our trial would not be alive today if it were not for our system. This is both motivating and humbling.

> With each new implant we are making steady progress towards our long-term goal of achieving market leadership in the mechanical circulatory support sector.

The endpoint of our international study is patient survival to the earlier of 180 days or heart transplantation. Among our first 20 patients, we reported a 180 day survival rate of 90%. This was particularly encouraging given the high proportion of patients (16 out of 18) who were supported by our LVAS at 180 days and the relatively low number (2 out of 18) who met the study endpoint by virtue of having undergone heart transplantation. This tells us and our investigators a great deal about the promising reliability and durability of our system. Despite the clinical trial being for a Bridge-to-Transplant indication, the relatively long periods during which our patients, on average, remain on circulatory support bodes well for the potential future use of the device as a long-term treatment option.

On average our patients have been supported for 217 days each. Our cumulative clinical experience, which already exceeds 18 years, is building exponentially with each new implant. As this experience grows, so too does our confidence that the HeartWare® LVAS will command a meaningful market share and, over time, expand the overall market significantly.

## Our Operations are in Good Shape

Our shareholders will recall that in mid-2006 HeartWare was challenged in the early execution of its clinical trial. Our manufacturing capabilities and quality systems reflected the Company's R&D heritage and lacked the robustness required of a clinical stage medical device business. A key focus during 2007 was to upgrade our operational capabilities so as to improve manufacturing output, increase production yields and eliminate supply risk.

Our Quality and Manufacturing Engineering groups have done an outstanding job over the past 12 months to upgrade our systems and processes. We have vastly improved our manufacturing capabilities and greatly reduced the supply-side bottlenecks of the past. As we move towards the start of our U.S. clinical trial, we have product inventory awaiting shipment and a current monthly manufacturing output that will enable us to comfortably meet the demands of the trial.

# Developing a leading position in the mechanical circulatory support sector

- The smallest 3rd generation Left Ventricular Assist Device
- The only full-output circulatory support device designed to be implanted above the diaphragm
- 31 implants across five international investigational centres
- Exceptional early clinical results
  90% success rate among initial 20 patient cohort
- U.S. Bridge-to-Transplant clinical trial expected to begin in Q2 2008
- CE Mark expected in Q3 2008
- A pipeline of further miniaturized pumps in development, underpinning HeartWare's long-term competitive position

The HeartWare pump is implanted above the diaphragm. No abdominal surgery is required, leading to a less complex, less invasive and shorter procedure relative to that required to implant competing devices.

**Our Regulatory Program is Broadly on Track**

One of our key priorities last year was the preparation and submission of our application to the U.S. FDA for an Investigational Device Exemption (IDE) to enable the start of our U.S. clinical trial. We filed our submission in late October and received a series of follow-up questions from the FDA in late November. Formal dialogue has continued with the FDA over subsequent months as we have progressively addressed questions and refined elements of our application.

We hope to be granted an IDE in the short term and remain confident of a start to our U.S. trial by mid year. Certain elements of our trial design are novel and represent a departure from the historically conventional approach to LVAD trial protocols. This has perhaps necessitated a more extensive FDA process than might otherwise have been required but, subject to FDA approval, should allow HeartWare effectively to demonstrate the true clinical potential of our system. We look forward to sharing details of our trial design once approved.

Our second major upcoming regulatory milestone is our receipt of CE Mark, which is a requirement for commercializing the pump in Europe. The CE Mark process includes both a regulatory submission (the Technical Dossier) as well as the requirement for a manufacturing facility to pass an ISO audit. Subject to finalizing lease negotiations regarding our proposed new facility, we expect to be relocating our manufacturing activities in the short term. We have decided, therefore, not to go ahead with an audit of our Miramar facility but instead to wait until a decision concerning our proposed facility move has been finalized. Preparation of our Technical Dossier is well underway, so the timing of our CE Mark will be determined by the speed with which we are able to prepare our new facility for an audit. Where we previously anticipated CE Mark in the first or second quarter of 2008, a more realistic expectation now is that we gain approval during the third quarter.

> As we move towards the start of our U.S. clinical trial, we have product inventory awaiting shipment and current monthly manufacturing output that will enable us to comfortably meet the demands of the trial.

**Our Next Generation Programs are Progressing Well**

It is largely axiomatic in the world of medical devices that if a device decreases procedural invasiveness then, all else being equal, utilization of the device is likely to increase. This has been proven across virtually every device segment from coronary stents to pacemakers.

The small size of HeartWare's current device positions the pump uniquely amongst its mechanical circulatory support device peers. The HeartWare® LVAD is the only full-output pump designed to be implanted in the pericardial space, directly adjacent to the heart. This placement technique eliminates the abdominal surgery that is required to implant competing devices. Physicians believe that this will shorten their surgery time and reduce procedural complications for their patients. This is expected to lead to a more rapid patient recovery and, over time, preferential use of our device relative to competing systems.

With our next generation miniature pump, our objective is a further, even more dramatic reduction in the surgical invasiveness required to implant a full-output mechanical support device. This device is an axial flow pump approximately one third the size of the HeartWare® pump but still capable of generating up to ten litres of blood flow per minute. We have already confirmed that the pump has blood handling characteristics similar to those of our first pump. The focus of recent preclinical work has therefore been to refine a minimally invasive surgical implantation technique. We are excited by our early results and aim to begin a formal series of Good Laboratory Practice ("GLP") studies in 2009.

With our third pump platform we aim to develop a device that is one tenth the size of the HeartWare® LVAD so as to enable a catheter based delivery

approach. This program is at an early prototype stage, but holds tremendous promise.

Historically our primary focus has been on the pump technology itself, but of nearly equal importance is the external system which runs the device. We have received very positive feedback regarding our peripheral components, particularly the controller and batteries, which patients must have with them at all times.

We recognize that one of the limitations of all current mechanical circulatory support systems is the need for an externally worn battery and controller to power the implanted pump. Clearly, given the choice, all patients would prefer not to have a cable exiting their skin and tethering them to the controller. HeartWare has a major ongoing technology initiative aimed at eliminating this driveline by implanting the core electronics which run the pump. Over the year we have significantly advanced the development of our Transcutaneous Energy Transfer ("TET") system. An operational TET system will allow patients to recharge a fully implanted battery using an external, removable "paddle". Our objective is to enable our patients to be entirely free from any external charging system for a few hours per day and to eliminate the need for a cable altogether. Our TET system, which is currently at working prototype stage, is being developed to be compatible across all of our pump platforms.

## Our Team is Outstanding

I would like to express my gratitude to the entire HeartWare team, today numbering 82 personnel, all of whom have worked hard during the year to meet or exceed the ambitious objectives we always set.

Over the year we made several senior executive appointments, significantly bolstering our management depth. With a majority of our leadership team having previously held senior positions at large device companies such as Boston Scientific or Johnson & Johnson, I believe we have in place the operational, technical, clinical and management talent necessary to deliver on our plan.

## Looking Ahead

The coming year is set to be our busiest yet. In the short-term we expect to begin our U.S. trial. We will continue to support implants at our current five international centres and, following receipt of CE Mark, will expand our presence through Europe and Australia. We expect to generate revenues for the first time, both from reimbursement in the U.S. clinical trial and from commercial sales in Europe. All the while we will continue to advance our pipeline technologies, with a view to progressing towards GLP animal studies.

In anticipation of this increased level of activity, we have appropriately upgraded our internal capabilities, ensuring that we have in place the infrastructure, systems and personnel to execute effectively.

As we look forward to an exciting year ahead, I would like to join our Chairman in thanking you, our shareholders, for your support over the past year. We will continue to work diligently to build the value of your company.

DOUG GODSHALL
Chief Executive Officer

As of 31 March 2008, HeartWare has completed 31 implants of the HeartWare® Left Ventricular Assist Device across five centres in Europe and Australia. With some 18 years of cumulative implant experience across this patient group, the anticipated clinical advantages of the device are being strongly validated.

The market for mechanical circulatory support systems continues to develop rapidly. As HeartWare moves towards the start of its U.S. clinical trials and its first commercial sales in Europe, the Company is well positioned.

## Heart Failure

Heart failure results from the progressive deterioration of the pumping function of the heart, leading to its inability to meet the metabolic demands of the body. While certain symptoms associated with the disease can be treated, the underlying functional impairment of the heart generally cannot.

A commonly accepted method for categorizing chronic heart failure is the New York Heart Association Classification, which identifies four stages in the progression of the disease, as described below.

According to the American Heart Association, 4.9 million patients in the United States suffer from heart failure, with an additional 550,000 patients diagnosed each year. Worldwide, over ten million patients suffer the disease. Of these, approximately one million patients have reached Class IV, the most advanced stage of the condition.

Heart transplantation remains the "gold standard" of treatment for patients with advanced heart failure. However, with fewer than 4,000 donor hearts becoming available worldwide each year, transplantation is not an available option for the vast majority of patients.

While various drug based therapies are helpful in slowing the disease progression, drugs are generally ineffective in treating patients at an advanced stage of the condition. Therapies based on stem cell technology remain in their infancy but, in future, may be used effectively in combination with mechanical circulatory support.

## The Market Opportunity

For almost twenty years, Left Ventricular Assist Devices ("LVADs") have been used to "bridge" heart failure patients temporarily until a donor heart becomes available. This Bridge-to-Transplant ("BTT") market opportunity is, however, constrained by the relatively small number of donor hearts. Each year approximately 2,000 devices are implanted around the world to bridge patients to transplantation.

The more significant market opportunity is that of Destination Therapy ("DT") – the permanent or "lifelong" use of an LVAD to treat patients suffering from advanced heart failure. The National Institutes of Health (NIH) estimates that in the U.S. approximately 100,000 patients per year could benefit from an LVAD implant.

The DT market, however, remains in its infancy. The only device approved in the U.S. for DT is the HeartMate XVE™ from Thoratec Corporation, Inc. Market uptake has been constrained by the limitations of the device, specifically its large size and its relatively poor mechanical reliability over the long-term. The introduction and approval of smaller, improved second generation devices (such as Thoratec's HeartMate II™) and third generation products (such as the HeartWare® LVAD) are expected to drive a significant acceleration in implant numbers.

| **Class I** (least severe cases) | **Class II** (mild) | **Class III** (moderate) | **Class IV** (most severe) |
|---|---|---|---|
| > 40% of patients | > 25% of patients | > 25% of patients | > 10% of patients |
| > No limitation of physical activity | > Some limitation of physical activity | > Marked limitation of physical activity | > Symptoms at rest. Unable to carry out any physical activity without discomfort |
| > Little to no drug therapy | > Drug therapy | > Drug therapy, biventricular pacing, or surgery | > Candidates for transplant and LVADs |

A third opportunity for LVADs is their use as a Bridge-to-Recovery ("BTR"). In certain patients, the effect of an LVAD unloading the ventricle in combination with the use of a particular pharmaceutical regimen has been shown to lead to recovery of the heart muscle. This allows the physician to wean the patient from the pump and eventually to remove (or "explant") the device. This approach was detailed in a November 2006 *New England Journal of Medicine* article that described a recovery rate of approximately 75% in a study conducted at Harefield Hospital. Confirmatory studies are underway in the United States by Thoratec Corporation. Although BTR is only likely to apply to a small proportion of patients, this potential to "recover" the heart may also help drive overall implant numbers.

> The National Institutes of Health (NIH) estimates that in the U.S. approximately 100,000 patients per year could benefit from an LVAD implant.

In the U.S., the implantation of an approved LVAD, whether for BTT or DT, attracts reimbursement from the Centres for Medicare & Medicaid Services ("CMS") as well as from a number of private insurers. The procedure is currently reimbursed at approximately US$140,000. The devices themselves are priced at approximately US$70,000 each.

**The Competitive Landscape**

The schedule on page 12 shows the generational evolution of LVAD technologies.

The first generation devices are volume displacement pumps designed to replicate the heart's pulsatile flow. They are large and mechanically complex, with relatively poor long-term reliability profiles. They are implanted in the abdomen and require extensive surgery. Their size, weight and limited durability restrict their clinical application for Destination Therapy. The HeartMate XVE™, a first generation LVAD from Thoratec Corporation, remains the only device with FDA approval for Destination Therapy, however, as the LVAD market evolves, first generation devices are unlikely to remain competitive.

The second generation devices are continuous flow axial pumps. They have fewer moving parts, giving rise to greater expected long-term reliability than the volume displacement devices. They are, however, characterized by their use of internal mechanical bearings which may over time compromise reliability. The most important of the second generation pumps is the HeartMate II™ from Thoratec Corporation. The HeartMate II™ has completed its U.S. clinical trial for BTT. An independent panel convened by the FDA recommended unanimously on 30 November 2007 that the device should be approved for BTT in the U.S. FDA approval is anticipated early in 2008. Although still implanted in the abdomen, the HeartMate II™ has a lower rate of complication than the much larger HeartMate XVE™ and has demonstrated greatly improved long-term reliability. The approval of the HeartMate II™ is expected to be an important catalyst for the mechanical circulatory support industry and to help drive an overall increase in implant numbers over the medium term.

Third generation LVADs are continuous flow pumps which incorporate magnetic or hydrodynamic suspension systems to eliminate the need for internal mechanical bearings. This wearless suspension of the impeller reduces the risk of mechanical failure. As the smallest of the third generation devices, the HeartWare® LVAD is the only one to be implantable within the pericardial space, directly adjacent to the heart. This is expected both to improve blood flow characteristics and to facilitate a less complex and less invasive operating procedure.

### The HeartWare® Left Ventricular Assist Device

HeartWare's lead device, the HeartWare® LVAD, is a small, permanently implantable centrifugal blood pump capable of generating up to ten litres per minute of forward flow. The pump draws blood from the left ventricle and propels it through an outflow graft connected to the patient's ascending aorta.

With a displaced volume of only 50cc, the HeartWare® LVAD 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. This leads to a less complex, less invasive and shorter surgical procedure relative to that required to implant competing devices,

> The approval of the HeartMate II™ is expected to be an important catalyst for the mechanical circulatory support industry and to help drive an overall increase in implant numbers.

which are generally implanted in the abdomen, below the diaphragm.

The HeartWare® LVAD has only one moving part, the impeller, which is suspended within the pump housing through a combination of passive magnets and a hydrodynamic thrust bearing. The hydrodynamic thrust

## The LVAD Competitive Landscape

LVAD Technology

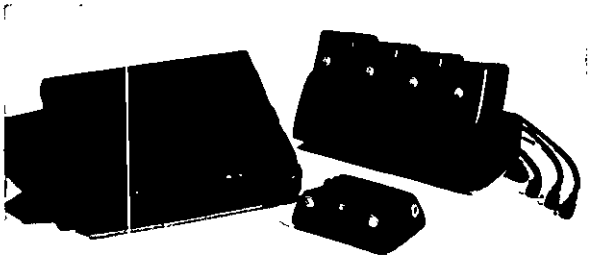
| | Volume | Mass | Pericardial Placement | Wearless | CE mark | U.S. Approved – BTT | U.S. Approved – DT |
|---|---|---|---|---|---|---|---|
| **FIRST GENERATION Volume Displacement** | | | | | | | |
| • Thoratec HeartMate XVE | These are large, heavy, mechanically complex devices. They are implanted in the abdomen and have limited long-term reliability. | | | | Y | Y | Y |
| • Worldheart Novacor | | | | | Y | Y | N |
| **CONTINUOUS FLOW** | | | | | | | |
| **SECOND GENERATION Mechanical Bearings** | | | | | | | |
| • Jarvik 2000 | 25cc | 85g | Y | N | Y | N | N |
| • Micromed DeBakey | 37cc | 95g | N | N | Y | N | N |
| • Thoratec Heartmate II | 63cc | 400g | N | N | Y | Y | N |
| **THIRD GENERATION (Wearless)** | | | | | | | |
| **Active Maglev** | | | | | | | |
| • WorldHeart Levacor | 155cc | 540g | N | N | N | N | N |
| • Terumo DuraHeart | 150cc | 420g | N | N | Y | N | N |
| • Berlin Incor | 60cc | 200g | N | Y | Y | N | N |
| **Passive Suspension** | | | | | | | |
| **Radial & Axial Hydronamic Support** | | | | | | | |
| Ventractor VentrAssist | 122cc | 298g | N | Y | Y | N | N |
| **Axial Hydrodynamic Support Plus Passive MagLev** | | | | | | | |
| **The smallest third generation pump in the clinic** | | | | | | | |
| HeartWare® LVAD | 50cc | 145g | Y | Y | N | N | N |
| **NEXT GENERATION** | | | | | | | |
| HeartWare's next generation miniaturized pump (in development) | <15cc | <50g | Y | Y | N | N | N |

bearing operates by establishing a "cushion" of blood between the impeller and the pump housing. Once power is applied to the system, there are no points of mechanical contact within the device. This wearless design significantly enhances the long-term durability of the pump, leading to an anticipated reliability profile in excess of ten years.

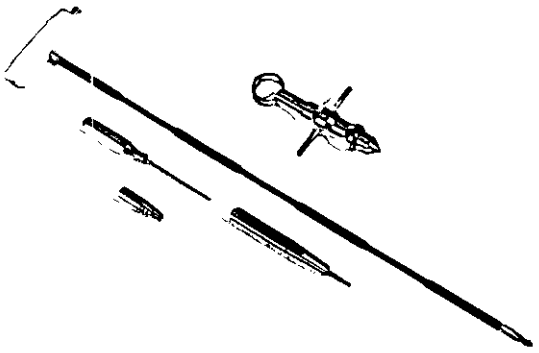
Device reliability is further enhanced through the use of dual motor stators with independent drive circuitry, allowing a seamless transition between dual and single stator mode if required. The pump's inflow cannula is integrated with the device itself, ensuring proximity between the heart and the pumping 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 system help minimize any risk of pump induced hemolysis (damage to blood cells) or thrombus (blood clotting).

The HeartWare® LVAD is powered via a percutaneous driveline which connects the pump to an external controller and battery pack, which are worn on the patient's belt or over the shoulder.

The HeartWare® pump is implanted using a set of customized surgical tools and accessories.

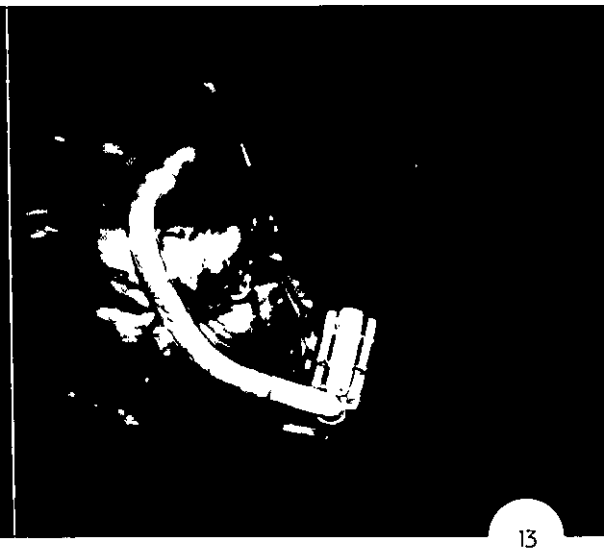


> The HeartWare® LVAS external components, including the controller, monitor, batteries and battery charger.



> The HeartWare® LVAS surgical tools, including the Driveline Tunneler, Coring Knife and Sewing Ring Torque Wrench.

> The HeartWare® LVAD – the smallest full-output circulatory support device.



> The HeartWare® LVAD is the only full-output blood pump designed to be implanted above the diaphragm. The pump is positioned in the pericardial space directly adjacent to the heart.

**HeartWare's International Clinical Trial**

Over the past two years, the HeartWare® Left Ventricular Assist System has been the subject of an international clinical trial. The purpose of the trial is to evaluate the safety and feasibility of the device as a bridge to transplantation in patients eligible for cardiac transplantation with refractory, end-stage heart failure at risk of death. The primary endpoint is survival to anesthetic induction for heart transplantation or survival to 180 days on the device.

The study is a multi-centre, prospective, non-randomized, single-arm study, enrolling patients across five participating centres. Initially the study involved 20 patients. Following the twentieth implant, an amendment to the protocol was sought to allow additional implants.

As at 31 March, 31 patients have been implanted with the HeartWare® LVAD as follows:

| Hospital | Principal Investigator | Implants at 31/3/08 |
|---|---|---|
| Vienna General Hospital, Austria | Dr Georg Wieselthaler | 8 |
| Royal Perth Hospital, Australia | Dr Gerry O'Driscoll | 4 |
| Hannover Medical Centre, Germany | Dr Martin Strüber | 11 |
| Harefield Hospital, UK | Dr Asghar Khaghani | 2 |
| St Vincents Hospital, Sydney, Australia | Dr Paul Jansz | 6 |

Summary results from the trial thus far are as follows:

| Total Patients Enrolled | 31 |
|---|---|
| Patient deaths within 180 days | 2 |
| Patient deaths beyond 180 days | 1 |
| Transplants within 180 days | 2 |
| Transplants beyond 180 days | 4 |
| Pump explant due to Recovery | 1 |
| Patients currently on left ventricular support | 21 |
| Cumulative support days | 6,723 |
| Average support days per patient | 217 |

- 28 patients remain alive out of 31 patients implanted with the HeartWare® LVAD
- Six patients have received heart transplants and 22 patients remain on circulatory support

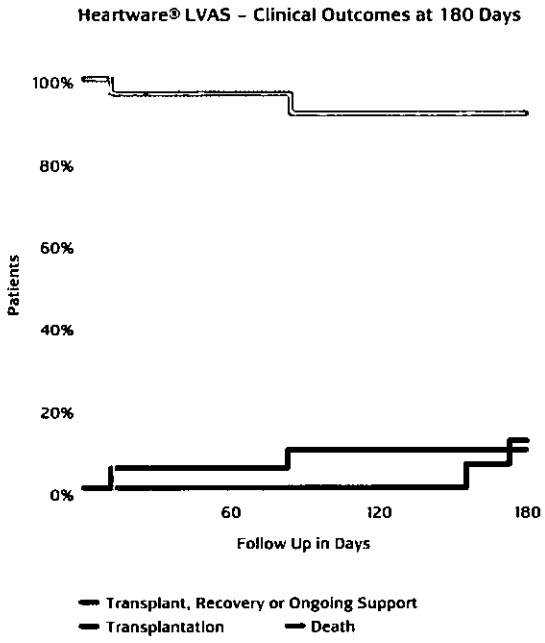
HeartWare's initial clinical trial results will be presented by Dr Georg Wieselthaler at the Annual Meeting of the International Society for Heart and Lung Transplantation ("ISHLT") in early April. The key results from the first 20 patients are as follows:

| Total Patients Enrolled | 20 |
|---|---|
| Patients successfully met endpoint | 18 |
| Patients supported >180 days | 16 |
| Transplants within 180 days | 2 |
| Patient deaths | 2 |
| Proportion of patients meeting endpoint | 90% |

As at 31 March 2008, of the 31 patients enrolled in the clinical trial, 28 are still alive today because of the HeartWare system. Of our first 20 patients, ten patients remain on left ventricular support, six patients have undergone successful heart transplants and one patient's heart function recovered sufficiently for the device to be removed. The average period of support among this patient group is 283 days. The six patients who received heart transplants underwent their procedures, on average, after 284 days of support.

The earliest transplant occurred on day 156. The latest transplant occurred on day 426. At 31 March 2008, the longest surviving patient still on left ventricular support has been supported by his HeartWare® LVAS for 497 days. The 21st through 31st patient all remain supported on our system.

The survival data at 180 days for HeartWare's first 23 patients are as follows:




> Clinical results reported for HeartWare's initial 23 patients. At 180 days, 21 out of 23 patients remained alive - a survival rate of 91%.

These results form the basis of HeartWare's application for CE Mark, which will enable the Company to begin commercial sales of the HeartWare® LVAS in Europe. HeartWare has largely completed the compilation of its Technical Dossier, the key submission required for the CE Mark. The key outstanding component of the application relates to the required audit and ISO certification of the HeartWare manufacturing facility. Subject to successfully completing present discussions concerning a facility move, HeartWare plans to initiate this certification process as soon as our new manufacturing facility is operational. On this basis, HeartWare expects to receive CE Mark for the device during the third quarter of 2008 and to begin commercial sales in Europe soon thereafter.

### HeartWare's U.S. Clinical Trial

In November 2007 HeartWare filed its submission for Investigational Device Exemption ("IDE") with the U.S. Food and Drug Administration ("FDA"). The submission relates to the proposed use of the HeartWare® LVAS in a Bridge-to-Transplant clinical trial aimed at evaluating the safety and effectiveness of the device in patients eligible for cardiac transplantation with refractory, advanced heart failure.

HeartWare received a response from the FDA seeking clarification of various elements of the submission. HeartWare filed its response in early February and received further questions from the FDA in early March. As of 31 March, dialogue with the FDA is ongoing. HeartWare hopes to start its U.S. clinical trial in the second quarter of this year.

Subject to approval by the FDA, HeartWare's U.S. BTT trial will involve 135 patients at up to 28 participating centres. Details of the clinical trial design will be disclosed following FDA approval of the Company's IDE application.

### HeartWare's Product Pipeline

HeartWare continues to make significant progress in the development of its next generation technologies, aimed at securing long-term technology leadership in the mechanical circulatory support sector. Over the past twelve months, HeartWare has made significant advances in its next generation miniaturized pumps as well as in the Company's Transcutaneous Energy Transfer ("TET") System.

### HeartWare's Miniaturized Pump Pipeline

HeartWare's next generation miniaturized device is a development-stage pump, approximately one third the size of the HeartWare® pump. This future device is based on the same impeller suspension technology used in the HeartWare® LVAD, with a single moving part held in place through a combination of passive-magnetic and hydrodynamic forces.

- HeartWare's next generation miniaturized device is a full-output pump approximately one third the size of the HeartWare pump
- The device will be implanted using a minimally invasive surgical procedure

> HeartWare's next generation device continues to show promising results in preclinical studies.

Over a series of preclinical studies, this next generation device has shown blood handling and flow characteristics comparable to those of the HeartWare® pump. The device is expected to support the human heart's full output.

Because of its small size, the device will be implanted by way of a minimally invasive procedure. The focus of ongoing pre-clinical work is to refine an innovative implant technique. These preclinical studies are being conducted in collaboration with several hospitals, both in Europe and the United States. HeartWare's objective is to advance this development program and to start formal Good Laboratory Practice (GLP) animal studies during 2009.

### HeartWare's Intravascular Device

HeartWare is also developing an axial flow pump which is approximately one-tenth the size of the HeartWare® pump. This device, which is currently at early prototype stage, is being designed to be delivered via a catheter and implanted within the patient's aorta. The initial prototype and design work suggests that this pump will have an output of approximately three litres per minute, making it appropriate for Class III heart failure patients who do not require the full output capability of the HeartWare® LVAD. We believe that the relatively low procedural invasiveness required to implant the intravascular device has the potential to vastly expand the number of heart failure patients for whom mechanical circulatory support therapy is considered appropriate.

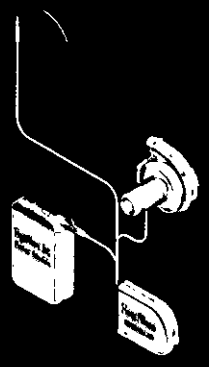
### Transcutaneous Energy Transfer

The objective of HeartWare's Transcutaneous Energy Transfer System development is to enable a fully implanted battery to be periodically recharged using induction across the skin. This will allow implantation of the complete pump system, including batteries and controllers, and the elimination of the current need for an externalized driveline. The aim of the development program is to enable patients implanted with a HeartWare device to be free of any external charging system for extended periods of time.

HeartWare's TET System is at a working prototype stage. Development work is ongoing to determine optimal configurations and to refine the specifications for the implantable battery and controller components.

The relatively high energy efficiency of the HeartWare devices makes them particularly conducive to operating with fully implanted battery and controller systems. The TET System is being developed to be compatible across all HeartWare pump platforms.

HeartWare's TET System will charge an implanted battery through the skin, eliminating the need for an externalized driveline.



# Board of Directors

## The HeartWare Team

HeartWare's executive team is comprised of an experienced group of industry professionals with extensive track records. The HeartWare team was bolstered during 2007 with several new executive appointments, including Mr James Schuermann as Vice President, Sales and Marketing.

Our management team is supported by a Board of Directors with a depth of relevant financial, commercial and industry experience.

HeartWare also draws substantially on the expertise of its Medical Advisory Board, which includes a number of pre-eminent cardiac surgeons and cardiologists.

**Mr Robert Thomas** Non-Executive Chairman

Rob has over 30 years experience in the securities industry. He is the immediate past Chairman, Citigroup Corporate and Investment Bank, Australia and New Zealand. He is currently also non-executive Chairman of Tower Australia Limited and a non-executive director of Virgin Blue Holdings Limited. He is also the Chairman of the Securities & Derivatives Industry Association and President of the Library Council of New South Wales.

**Mr Douglas Godshall**

Managing Director and Chief Executive Officer

Prior to joining HeartWare in September 2006, Doug spent over 16 years at Boston Scientific Corporation, most recently as President of the Vascular Surgery Division. He previously spent five years as Vice President, Business Development where he was instrumental in developing the acquisition strategies for the cardiology, electrophysiology and vascular surgery divisions. He led the negotiation and structuring of over 70 transactions and represented Boston Scientific on the Boards of 11 companies.

**Dr Seth Harrison** Non-Executive Director

Seth is Managing General Partner of Apple Tree Partners, an early stage healthcare venture capital firm based in Cambridge, Massachusetts. Apple Tree Partners s HeartWare's cornerstone investor. A qualified surgeon, Seth is an experienced life-sciences investor, with over 15 years experience at several leading venture capital firms, including Oak Investment Partners, Sevin Rosen Funds and Nazem & Company.

**Mr Robert (Bob) Stockman**

Bob joined HeartWare as a director in December 2006. He has over twenty years experience in managing and financing medical technology companies. Bob is 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 Chairman of REVA Medical, Inc, an interventional coronary medical device company which he helped co-found.

**Dr Denis Wade** Non-Executive Director

Denis has extensive experience in the development and commercialization of research based health care products. He was formerly Managing Director of Johnson & Johnson Research Pty Ltd. For ten years he was a member of J&J's U.S. based Corporate Office of Science & Technology. Denis previously had a distinguished academic career, holding the position of Foundation Professor of Clinical Pharmacology at the University of New South Wales.

**Dr Christine Bennett** Non-Executive Director

Christine is an experienced company director with a diverse background in clinical care, strategic planning and senior management. On 25 February 2008 Christine was appointed by the Prime Minister of Australia to Chair of the newly formed National Health and Hospitals Reform Commission. Christine also holds the position of Group Executive, Health and Financial Solutions and Chief Medical Officer of MBF Australia Limited, a leading health insurance provider. Christine's previous positions include Chief Executive Officer of Research Australia, Chief Executive Officer of Westmead Hospital and Community Health Service, Partner, Health and Life Sciences at KPMG and non-executive director of Symbion Health.



> Please refer to pages 36 to 39 for detailed biographies of Heartware's Board of Directors.

# Medical Advisory Board

**O. Howard 'Bud' Frazier, MD**

Chairman & Chief of Transplant Services,
Director Cardiovascular Research, Texas Heart Institute

For more than 25 years, Dr Frazier has been a pioneer in the surgical treatment of severe heart failure. He has been director of cardiopulmonary transplantation for 20 years. He serves on the editorial boards of several distinguished journals, including Circulation, the premier journal of the American Heart Association. He has authored or co-authored more than 1,000 scientific publications, presented over 1,200 lectures around the world, and written or edited numerous books in the field.

Dr Frazier is a former chairman of the Federal Affairs Committee for the American Society for Artificial Internal Organs and has served on other prominent committees, including the Education Committee of the American Society of Transplant Surgeons and the Advisory Board of the National Heart, Lung and Blood Institute. In 2001, he was elected president of the American Society for Artificial Internal Organs.

Dr Frazier's academic appointments include Professor of Surgery at the University of Texas Health Science Centre in Houston, Clinical Associate Professor of Surgery at the University of Texas M.D. Anderson Cancer Centre, and Clinical Professor at Baylor College of Medicine in Houston.

**Steven W Boyce, MD**

Director of Heart Transplantation and Cardiac Assist Device Programmes, Washington Hospital Centre

Dr Boyce has served as Director of the Cardiac Transplantation and Mechanical Circulatory Assist Device Programs for the Washington Hospital Centre, as well as Director of the Cardiac Surgery Research Program for over ten years. He is certified with the American Board of Thoracic Surgery, and performs approximately 500 adult cardiac surgeries per year.

Dr Boyce has served as principal investigator on a number of FDA pharmaceutical and device investigational protocols. He has worked with a variety of mechanical circulatory support devices, both investigational and commercially available.

Dr Boyce graduated from Johns Hopkins University's undergraduate program and the University of Maryland's medical school program. He completed his residency and chief residency in general surgery at the University of California, San Francisco and then trained at UCLA in cardiothoracic surgery. Dr Boyce has a number of professional affiliations, including the International Society of Heart and Lung Transplantation, the American College of Surgeons, the Society of Thoracic Surgeons, the American College of Cardiology, the Heart Failure Society of America, and the International Society for Minimally Invasive Cardiac Surgery. He has published and presented on a range of topics on the surgical management of end stage heart failure.

**Laman A Gray, Jr, MD**

Professor of Surgery and Director of the Division of Thoracic and Cardiovascular Surgery, University of Louisville School of Medicine

Dr Gray is highly experienced in the fields of cardiac surgery and development of artificial hearts and circulatory support systems. He was an original investigator for the Novacor Ventricular Assist System, he performed the first clinical use of Abiomed's SupraCor IABP and he implanted the first AbioCor Implantable Replacement Heart.

Dr Gray has been the Director of the University of Louisville School of Medicine's Division of Thoracic and Cardiovascular Surgery for more than 20 years, is a founding member of the Jewish Hospital Heart and Lung Institute and is currently the Director of the Cardiovascular Innovation Institute.

Dr Gray received his Bachelor of Arts degree with distinction in chemistry from Wesleyan University in Middletown. He then received his M.D. from Johns Hopkins University in Baltimore, and completed his training and residencies in general and thoracic surgery at the University of Michigan.

**Leslie Miller, MD**

Director of Cardiology, Washington Hospital Centre
Walters Chair of Cardiology, Georgetown School of Medicine

Dr Miller joined the Washington Hospital Centre in 2006. He was previously Professor and Director of the Cardiovascular Division and Director of the Heart Failure/Heart Transplant Program at the University of Minnesota in Minneapolis.

Dr Miller has been an investigator in over 80 clinical trials studying the safety and efficacy of therapies for heart failure, cardiac transplantation and ventricular assist devices. He is a Past President of the International Society for Heart & Lung Transplantation and the American Society of Transplant Physicians and is a Member of the Board of the American Heart Association. He is Founder and Chairman of the Working Group of Transplant Cardiologists and a member of the Cardiac Transplant Research Database Executive Committee. Dr Miller is also a current member on the U.S. Federal Agency Advisory Committees for national coverage policy for the use of left ventricular assist devices and the American Heart Association Committee on Heart Failure/ Transplantation. Dr Miller has contributed more than 285 medical papers and serves on the editorial boards and as a reviewer for major cardiovascular journals.

Dr Miller received his medical degree from the University of Missouri School of Medicine. His postgraduate training includes serving as Chief Resident in Medicine at Washington University and Barnes Hospital, Missouri, Cardiology Fellow at Peter Bent Brigham Hospital, and Senior Resident in Surgery at Boston University. He is a Fellow of the American College of Cardiology, the American College of Chest Physicians and the American Heart Association Council on Clinical Cardiology.

**Gerry O'Driscoll, MB, BCh, BAO, DMed, PhD**

Professor of Cardiology at University of Notre Dame, Western Australia Consultant Cardiologist at Royal Perth Hospital

Dr O'Driscoll is Consultant Cardiologist at Royal Perth Hospital and Medical Head of West Australian Advanced Heart Failure & Cardiac Transplant Services. He is also Head of the Cardiovascular Research Group at Royal Perth Hospital and a Board Member of the Heart & Lung Transplant Foundation of Western Australia.

Dr O'Driscoll has worked extensively with a wide range of mechanical circulatory support devices over the past decade. He has experience with the Thoratec, Heartmate, Novacor, Ventrassist, Biomedicus, Abiomed, Jarvik and HeartWare devices.

Dr O'Driscoll serves as a reviewer for several national funding bodies including the National Heart Foundation and National Health and Medical Research Council. He is a member of several national committees in clinical cardiology and a reviewer for a number of international scientific journals, including the American Journal of Cardiology, Lancet, Circulation and the Journal of the American College of Cardiology.

Dr O'Driscoll received his medical degree from the University College Cork in Ireland. He received his DMed from the National University of Ireland and his PhD from the University of Western Australia. He is a Fellow of the Royal Australasian College of Physicians, the Cardiac Society of Australia & New Zealand, the European Society of Cardiology and the American College of Cardiology.

**Georg M. Wieselthaler, MD**

Clinical Director of Mechanical Circulatory Support, University of Vienna, Dept of Cardiothoracic Surgery, Vienna General Hospital

Dr Wieselthaler has extensive experience with numerous ventricular assist device systems. He is the primary surgeon implanting VAD systems and supervising patient care at the University of Vienna and Vienna General Hospital.

Dr Wieselthaler has implanted a range of circulatory assist devices. He was the first to implant the MicroMed DeBakey rotary LVAD and has since supported more than 40 patients with this pump. Dr Wieselthaler conducted the first ever implant of the HeartWare® LVAD in March 2006.

Dr Wieselthaler has served as the Secretary General of the International Society of Rotary Blood Pumps.

# Executive Management Team

### Douglas Godshall

Managing Director, Chief Executive Officer

Doug joined HeartWare as Chief Executive Officer in September 2006.

For a detailed biography, please refer to page 18.

### David McIntyre

Chief Financial Officer, Company Secretary

David joined HeartWare soon after the IPO in January 2005.

Prior to joining HeartWare, David was the Chief Financial Officer and General Counsel to another ASX-listed medical device company. He has previously served as a corporate and commercial law specialist in major international law firms, advising some of the world's largest corporations in various areas including mergers and acquisitions, corporate fundraising and securities law. He has also held senior financial roles in multinational companies, among them Rio Tinto.

David holds a Bachelor of Economics, majoring in accounting from the University of Sydney and a Bachelor of Laws from the University of Technology, Sydney. He is admitted as a Solicitor of the Supreme Court of New South Wales and is a member of the Law Society of New South Wales and CPA Australia.

### Jeffrey A. LaRose

Chief Scientific Officer

Jeff has been the driving force behind the development of HeartWare's technology for almost ten years. He is responsible for all aspects of the design of the HeartWare® LVAD System and he leads the development of HeartWare's device miniaturisation program.

Jeff has over 20 years 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.

### Dozier Rowe

Chief Operating Officer

Dozier joined HeartWare as Chief Operating Officer in April 2006. He has primary responsibility for managing all internal operational functions of the business.

Dozier brings to HeartWare over 20 years of experience in the medical device industry, having held senior positions at Boston Scientific Corporation, St Jude Medical Inc. and Baxter Healthcare Corporation. He has worked with a variety of Class III implantable medical devices with responsibility across all elements of manufacturing, quality control, regulatory affairs, materials management, supply chain and operations. He previously held the position of Vice President and General Manager, Operations at Boston Scientific's Miami operations centre, where he had responsibility for over 1,000 staff and a budget in excess of US$100M per year.

# Executive Management Team (continued)

## Jennifer Foley

Vice President, Clinical and Regulatory Affairs

Jennifer joined HeartWare in January 2007. She is responsible for the design and execution of HeartWare's clinical trial program and regulatory plan.

Prior to joining HeartWare, she held the position of Vice-President, Clinical Sciences, Clinical Program Management and Operations at Boston Scientific Corporation. As one of the most senior executives within Boston Scientific's clinical affairs organization, she was responsible for overseeing the execution of clinical trials across nine of the company's divisions. Prior to joining Boston Scientific in 2002, Jennifer was responsible for managing major trials with The Medicines Company and Glaxo (now GlaxoSmithKline). She previously spent five years in leadership positions at Parexel International Corporation, one of the world's largest contract research organizations.

## James Schuermann

Vice President, Sales and Marketing

Jim joined HeartWare in September 2007. He has overall responsibility for HeartWare's sales and marketing activities.

Jim has over 15 years sales and marketing experience in the medical device arena. Prior to joining HeartWare, he spent nine years in sales and marketing at Boston Scientific Corporation. Over this time he progressed from sales through product management until being appointed Director of Marketing in 2005. With five direct reports and a broader team of over 150 product managers and salespeople, Jim led the marketing activities for a US$280M worldwide business which emerged as one of the strongest in the company. Before joining Boston Scientific, he spent five years in medical sales and sales management at Sherwood Davis & Geck. Jim received his undergraduate degree in marketing from Kelley School of Business, Indiana University, Bloomington, IN and his MBA from Ageno School of Business, Golden Gate University, San Francisco, CA.

## Barry M. Yomtov

Vice President, Product Development

Barry joined HeartWare in August 2006. He is responsible for the design and development of new products with a particular focus on HeartWare's electronics programs.

Barry has over 28 years experience in the medical device industry specializing in Class III implantable medical devices. Prior to joining HeartWare, Barry has held senior management positions at MicroCHIPS, Inc, Abiomed, Inc., and InControl, Inc. He also spent ten years at Cordis Corporation in the design and development of pacemakers, neurostimulators and defibrillators. Barry received a Masters of Engineering in Biomedical Engineering from Rensselaer Polytechnic Institute. He has nine patents issued, two patents pending, plus ten publications in the field of medical devices.

## Ramon Augusto Paz

Vice President, Quality Assurance

Ramon joined HeartWare in October 2004. He has primary responsibility for establishing and implementing the company's Quality Management System.

Ramon's has over 23 years of multifunctional experience in the medical device industry across Quality, Manufacturing, Engineering, Regulatory and Clinical organizations. He began his career with Cordis Corporation, where he spent 15 years in a range of positions across the Quality, Manufacturing and Product Development groups. In 1998 Ramon joined World Medical, a start-up company which was later acquired by Medtronic AVE, where Ramon was Head of Quality, with expanded responsibility for managing the regulatory and clinical groups responsible for the clinical study of the TALENT stent graft.

## Howard Leibman

Director, Corporate Development

Howard joined HeartWare in April 2005, soon after the Company's IPO. Based at HeartWare's corporate headquarters in Sydney, he is responsible for financing strategy, investor relations and corporate communications.

Prior to joining HeartWare, Howard was Associate Director at Emerging Growth Capital, a specialist life sciences investment house. He advised on a number of successful Initial Public Offerings, private capital raisings and other corporate transactions. While at Emerging Growth Capital, Howard played a key role in HeartWare's capital raising and listing on the Australian Stock Exchange.

Howard's previous roles include Executive Director at Aeris Technologies, a company listed on the ASX, and Design Engineer at General Electric Company. He holds a Bachelor of Engineering and a Bachelor of Arts from the University of New South Wales and an MBA from the Australian Graduate School of Management and London Business School.

# Directors' Report

The Board of Directors of HeartWare Limited ("the Company" or "HeartWare") is pleased to submit its Directors' Report for the Company and its controlled entities ("the HeartWare Group" or "the Consolidated Group") for the financial year ended 31 December 2007.

## Directors

The names of the directors in office at any time during or since the end of the financial year are as follows:

Mr Robert (Rob) B Thomas
(Appointed 26 November 2004)

Dr Seth L Harrison (Appointed 26 November 2004)

Mr Douglas E Godshall (Appointed 28 October 2006)

Dr Christine C Bennett (Appointed 15 December 2004)

Dr Denis N Wade AM (Appointed 15 December 2004)

Mr Robert (Bob) B Stockman
(Appointed 11 December 2006)

## Principal Activities

The principal activities of the HeartWare Group are the development and commercialisation of its circulatory assist device technology.

There were no significant changes in the nature of the principal activities of the HeartWare Group during the year ended 31 December 2007.

## Financial Results for the Year Ended 31 December 2007

During the year the HeartWare Group continued to commercialise the HeartWare® LVAD System, the first of its range of circulatory assist devices or "heart pumps", which are used for the treatment of congestive heart failure. 2007 was also a pivotal year for the Company as it completed enrolment of its 20-patient clinical trial, lodged an application with the United States Food & Drug Administration with a view to commencing its Bridge-to-Transplant clinical trials in the United States, conducted additional research and development on its future range of products including ongoing cannulation studies for its miniaturised ventricular assist device or "MVAD", as well as further development work on the intravascular pump or "IV VAD" and the fully implantable electronics system (i.e. transcutaneous energy transfer system ("TETS")).

The net loss of the HeartWare Group for the year ended 31 December 2007 after providing for income tax was $26,113,807 (2006: $23,250,653). The increase in the loss over the preceding year reflects the expansion of the Company's international clinical trials, progress towards the commencement of its US clinical trials and early-stage manufacturing development.

Total revenue for the year was $1,150,040 (2006: $1,143,912). Revenue comprises interest revenue only. The Company has no sales revenue as it has not received regulatory approval that permits sales of its heart pumps. Sales of the HeartWare® LVAD System are expected to commence during the first half of 2008.

## Dividends

As the Company has not made a profit for the year ended 31 December 2007 and has no accumulated retained earnings. For this reason no dividends have been, or were able to be, recommended, declared or paid during the year.

## Review of Operations

### Overview

The 2007 calendar year has seen HeartWare achieve some of its most important milestones to date, namely the completion of enrolment in its 20-patient international clinical trial and the lodgement of an investigational device exemption ("IDE") with the US Food and Drug Administration ("FDA") to commence a Bridge-to-Transplant clinical trial in the United States.

Undoubtedly, the key event for 2007 was the Company lodging a submission with the United States Food & Drug Administration seeking an IDE for the proposed use of the HeartWare® LVAD System in a Bridge-to-Transplant indication in the United States on 1 November 2007. The purpose of the proposed study is to evaluate the safety and effectiveness of the HeartWare® LVAD System in the United States in patients eligible for cardiac transplantation with refractory, advanced heart failure.

The proposed primary endpoint is survival to anaesthetic induction for heart transplantation or survival to 180 days on the device and listed for heart transplantation, whichever occurs first. The initial phase of the US clinical trial comprises thirty (30) patients implanted with the HeartWare® LVAD System at up to ten (10) clinical centres in the United States. The ultimate objective is for the Company to secure regulatory approval to sell its HeartWare® LVAD System in the United States of America. As at the date of this report, we have not yet received final approval from the FDA to commence our US clinical trial. Receipt of FDA approval in this regard is critical as it will mark the commencement of first revenues for the Company as the Company expects to be reimbursed during the course of its US clinical trial.

As at the date of this report, HeartWare has implanted thirty (30) patients across its five (5) international clinical centres, with more than 6,050 cumulative implant days, or approximately 14.25 years of patient data. Eighteen (18) of our first twenty (20) patients have reached successful completion of the 180-day primary endpoint, with sixteen (16) of these eighteen (18) patients also having been supported on the HeartWare® LVAD System for a period exceeding 180-days. Though early in the study, we have had encouraging clinical outcomes and very positive surgeon review.

The Company also further developed and stabilized its manufacturing processes, particularly towards the end of 2007 with the result that the Company is now in a position to easily meet the needs of the US clinical trial.

The Company has opened 2008 with sufficient quantities of its products, a stable manufacturing environment and with strong clinical results. These are excellent foundations for the Company as it looks forward to the commencement of US clinical trials and, importantly, "first revenue".

**Regulatory Approvals**

Our commercial focus at present is the rapid advancement of our lead product, the HeartWare® LVAD System, through clinical trials with a view to obtaining regulatory approval, particularly in the United States.

All our products will require regulatory approval prior to commercialization. Regulation by government authorities in the United States of America and foreign countries is a significant factor in the research and development, manufacturing, and marketing of our current and future products.

Medical device regulations are enforced in the United States of America by the US Food and Drug Administration ("FDA"), the Therapeutic Goods Administration ("TGA") in Australia and by the European Medical Device Directives in the European Union.

Regulatory requirements also include ISO-13485-2003 compliance for the manufacturing and assembly of medical devices. Various regulatory approvals will also be required as product development advances into commercialization. Following launch, there will be an ongoing requirement to file yearly reports with the FDA and to report any adverse events.

While it is difficult to predict the amount of time required for regulatory processes, we anticipate receiving an approval to commence our US trial in early 2008. Our plan is to file for a CE mark during the first part of 2008 and this would, subject to satisfaction of the relevant regulatory hurdles, lead to commercialization within the European Union in mid 2008.

**Financial Position**

HeartWare's cash reserves as at 31 December 2007 were $32.1 million (2006: $21.1 million).

Expenditure grew significantly during 2007 as the Company transformed itself from a focus on product development to one that is focused on both clinical trials and developing more substantive manufacturing processes. The Company expanded its clinical trials in both Europe and Australia, further advanced its product pipeline through additional research and development, and expects to shortly commence clinical trials in the United States for the HeartWare® LVAD System.

The growth of the Company is reflected in the increase in head count from 65 employees to 76 employees, with a parallel increase in annual employee entitlements costs to $10.4 million (2006: $10 million), noting that the 2006 cost was larger than expected due to the unanticipated one-off employee termination costs for two senior employees of approximately $650,000.

Other notable increases in costs include additional clinical and regulatory consulting costs totalling $2.2 million (2006: $1.6 million) incurred in consequence of the commencement of our international clinical trials. The Company also expenses all product used for its international clinical trials. Product costs have not been capitalized in the Balance Sheet because this is not permitted under applicable Australian accounting standards as we do not have regulatory approval and

therefore do not hold product "for sale". These costs are included in the Income Statement in the line item titled "Raw materials and consumables used". The Company expects to revisit this issue in early 2008 following the commencement of first revenue with the first US human implant and subject to satisfaction of relevant regulatory hurdles.

Other non-operating expenses included in this year's loss are the share-based payments expense of $2.8 million (2006: $1.2 million), together with amortization and depreciation expense of $0.8 million (2006: $0.8 million).

## Significant Changes in State of Affairs

The following significant changes in the state of affairs of the HeartWare Group occurred during the financial year:

(a) On 4 January 2007, Hannover Medical Centre in Germany became the third hospital to implant HeartWare's HeartWare® LVAD System when it implanted the Company's seventh patient.

(b) With effect from 31 January 2007, the Australian Securities Exchange released 87,003,221 ordinary shares from escrow, together with 2,264,204 options with various strike prices and one convertible note with a face value of $1.42 million.

(c) On 22 March 2007, the very first recipient of the HeartWare® LVAD System reached an important milestone, having been the first patient to be supported on the HeartWare® LVAD System device for a duration exceeding one year.

(d) On 28 March 2007, Harefield Hospital in the United Kingdom commenced implanting the HeartWare® LVAD System and thereby became the Company's 4th implanting centre in its international clinical trial.

(e) On 4 April 2007, St Vincent's Hospital became the Company's 5th implanting centre in the international clinical trial when it implanted a HeartWare® LVAD System in its first patient.

(f) On 14 June 2007, the Company announced that it had received commitments to raise in excess of $30 million pursuant to a private placement, with significant institutional participation. Shareholders subsequently approved the capital raising on 26 July 2007 with the Company receiving subscriptions for approximately $36 million.

(g) On 18 July 2007, the Company confirmed that it had successfully closed its Share Purchase Plan whereby it raised approximately $1.15 million.

(h) On 31 August 2007, the Company completed enrolment in its international clinical trial when Vienna General Hospital implanted the HeartWare® LVAD System in the Company's 20th patient.

(i) On 31 October 2007, the Company shipped its submission for an IDE to the FDA. The IDE submission is the key regulatory filing with the FDA and represents the most important regulatory milestone in the Company's history. As noted above, HeartWare's IDE submission relates to the proposed use of the HeartWare® LVAD System in a Bridge-to-Transplant indication in the United States.

(j) On 2 November 2007, the Company gave its first major presentation on its miniaturization capabilities at the International Society of Rotary Blood Pumps Conference in Sydney.

(k) On 20 November 2007, the Company announced its annual employee incentive allotment, pursuant to which the Company issued 2.9 million options under its Employee Share Option Plan and a further 2.05 million performance rights under the Performance Rights Plan.

Except as stated above there were no material changes to the Consolidated Group during the financial year.

## After Balance Date Events

There have been no matters or circumstances that have arisen since the end of the financial year which have or may significantly affect the operations of the Consolidated Group, the results of those operations or the state of affairs of the Consolidated Group in future financial years.

## Further Developments, Prospects and Business Strategies

The likely developments in the operations of the Consolidated Group and the expected results of those operations in future financial years are as follows:

(a) Notwithstanding the commencement of human clinical trials in both Europe and Australia, the Company has not, as at the date of this report, received an IDE to commence human clinical trials in the United States of America, the world's largest medical device market. In this regard, the Company envisages commencing its US human clinical trials shortly (with the prior approval of the FDA). The Company anticipates that it will receive reimbursement (i.e. revenue) during the course of its US human clinical trials.

(b) HeartWare is hopeful of receiving CE marking for the HeartWare® LVAD System during mid 2008 and this will enable commercialisation to commence in the European Union. Receipt of CE mark will allow equivalent regulatory filings to be made in other countries, including Australia, and this will further expand the Company's commercialisation activities.

(c) HeartWare must raise capital in order to continue to commercialise its technology. As at 31 December 2007, the Company has $32.1 million in cash and cash equivalents. Notwithstanding this cash holding and the impending commencement of revenue, the Company will need to raise additional capital in the future. These funds will be primarily applied for the purposes of meeting costs associated with expanding the Company's human clinical trials into the United States, commercialisation costs in the European Union and Australia, product development (including in relation to the Company's transcutaneous energy transfer system and its next generation devices, the IV VAD and MVADTM), regulatory and other compliance costs as well as for general working capital. The Company continually monitors its cash position and, based on prior successful capital raisings and the continued success of the Company's progress towards commercialisation of the HeartWare® LVAD System, is confident that a capital raising as contemplated above is achievable (and for this reason the Financial Statements are prepared on a going concern basis).

The expected results of the above have not been included in this Directors' Report because the directors believe, on reasonable grounds, that disclosure of such information would be likely to result in unreasonable prejudice to the Consolidated Group.

Notwithstanding the above, it is the Board's view that the above events are achievable.

## Environmental Regulation

The HeartWare Group is not subject to significant environmental regulation.

## Information on Directors and Company Secretary

Information regarding the qualifications and experience of each of the directors and the company secretary, together with details concerning the responsibilities of directors and the directorships held by each director in the three years to 31 December 2007 are set out in the Corporate Governance Statement and those details form part of this Directors' Report and are incorporated by reference.

## Directors' Interest

The direct and indirect interests of the directors in the shares of the Company (including interests in options) are set out in the Remuneration Report on pages 43 to 56 (inclusive).

## Meetings of Directors

During the financial year 15 meetings of directors (including committees of directors) were held. The number of meetings attended by each of the directors during the financial year is as follows:

| | Directors' meeting | | Non-executive Directors' meeting | | Comittee meetings: Audit & compliance committee | | Comittee meetings: Nomination & remuneration committee | |
|---|---|---|---|---|---|---|---|---|
| | A | B | A | B | A | B | A | B |
| Rob Thomas | 9# | 8 | - | - | 5 | 5 | 1# | 1 |
| Seth Harrison | 9 | 8 | - | - | * | * | 1 | 1 |
| Denis Wade | 9 | 9 | - | - | 5 | 5 | 1 | 1 |
| Christine Bennett | 9 | 8 | - | - | 5# | 5 | 1 | 1 |
| Doug Godshall | 9 | 9 | * | * | * | * | * | * |
| Bob Stockman | 9 | 8 | - | - | * | * | * | * |

*A – Number of meetings held during the time the director held office during the year.*
*B – Number of meetings attended.*
** – Not a member of the relevant committee.*
*# – Designates the Chair of the relevant committee.*

In relation to the above please note that significant Company announcements are reviewed by either the full Board of Directors or by the Continuous Disclosure Committee ("CDC"). The members of the Continuous Disclosure Committee are Mr Rob Thomas, Dr Seth Harrison and Mr Doug Godshall. In all instances, the Continuous Disclosure Committee reviews and approves recommendations on ASX announcements from senior management, prior to their release to the ASX. Formal meetings of the CDC are held infrequently and on an "as needed" basis. No formal meetings of the CDC were held during the financial year.

## Indemnification & Insurance

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

The Company has 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 wilful breach of duty in relation to the Company.

The directors have not included details of the nature of the liabilities covered or the amount of the premium paid in respect of the directors' and officers' liability insurance contract because disclosure is prohibited under the terms of the contract.

## Options issued to directors and other key management personnel during or since the end of the financial year

On 26 July 2007 and following shareholder approval, the Company granted 200,000 options under the Company's HeartWare Limited Employee Share Option Plan to Mr Bob Stockman, Non-Executive Director. The exercise price of these options is $0.75 per option and the options vest in three equal annual tranches commencing on the first anniversary of the grant date (i.e. 26 July 2008).

Except as stated above, no options were granted during or since the end of the financial year to any director of the HeartWare Group.

Details of options that were granted during or since the end of the financial year to any of the other key management personnel (including the five most highly remunerated officers) as part of remuneration is set out in Note 29 in the Notes to the Financial Statements.

**Shares under Option**

At the date of this report, the unissued ordinary shares of HeartWare under option are as follows:

| Grant date | Expiry date | Exercise price | Category | Number under option |
|---|---|---|---|---|
| 24 January 2005 | 24 January 2010 | $0.20 | ESOP* | 4,273,804 |
| 24 January 2005 | 24 January 2010 | $0.60 | ESOP | 191,051 |
| 24 January 2005 | 24 January 2010 | $0.75 | ESOP | 191,051 |
| 24 January 2005 | 24 January 2010 | $1.00 | ESOP | 191,051 |
| 24 January 2005 | 24 January 2010 | $1.50 | ESOP | 191,051 |
| 24 January 2005 | 24 January 2010 | $0.60 | Incentive | 600,000 |
| 24 January 2005 | 24 January 2010 | $1.00 | Incentive | 600,000 |
| 24 January 2005 | 24 January 2010 | $1.50 | Incentive | 300,000 |
| 27 April 2005 | 27 April 2010 | $0.60 | ESOP | 191,051 |
| 27 April 2005 | 27 April 2010 | $0.75 | ESOP | 191,051 |
| 27 April 2005 | 27 April 2010 | $1.00 | ESOP | 191,051 |
| 27 April 2005 | 27 April 2010 | $1.50 | ESOP | 191,051 |
| 27 April 2005 | 27 April 2015 | $0.50 | ESOP | 2,190,510 |
| 15 December 2006 | 15 December 2012 | $0.75 | ESOP | 764,204 |
| 20 April 2006 | 20 April 2016 | $1.41 | ESOP | 1,000,000 |
| 25 July 2006 | 25 July 2016 | $1.10 | ESOP | 2,444,580 |
| 27 September 2006 | 27 September 2016 | $1.10 | ESOP | 5,581,264 |
| 28 October 2006 | 28 October 2016 | $1.10 | ESOP | 900,000 |
| 2 January 2007 | 2 January 2017 | $1.10 | ESOP | 1,150,000 |
| 26 July 2007 | 26 July 2017 | $0.75 | ESOP | 200,000 |
| 16 November 2007 | 16 November 2017 | $0.75 | Incentive | 350,000 |
| 16 November 2007 | 16 November 2017 | $0.75# | ESOP | 2,900,000 |
| 16 November 2007 | 16 November 2017 | $0.00# | PRP^ | 2,050,000 |
| | | | | **26,832,770** |

# The exercise of these options is subject to satisfaction of various performance hurdles as set out in the terms of issue.

* Options issued under the Company's Employee Share Option Plan ("ESOP").

^ Performance rights issued under the Company's Performance Rights Plan ("PRP").

No person entitled to exercise their respective option had or has any right by virtue of the option to participate in any share issue of any other body corporate.

### Shares issued on exercise of options

During and since the year ended 31 December 2007, the following ordinary shares of the Company have been issued on the exercise of options granted under the ESOP:

| Grant date | Exercise date | Exercise price | Amount paid | Number of shares issued |
|---|---|---|---|---|
| 24 January 2005 | 17 January 2007 | $0.20 | $8,000 | 40,000 |
| 24 January 2005 | 12 December 2007 | $0.20 | $17,600 | 88,000 |

No amounts are unpaid on any of the above shares.

## Corporate Governance

In recognising the need for the highest standards of corporate behaviour and accountability the directors support and have endeavoured to adhere to and promote the principles of good corporate governance.

The Company's Corporate Governance Statement is set out immediately after this Directors' Report and all matters set out therein are incorporated into this Directors' Report by reference.

## Remuneration Report

The Company's Remuneration Report is set out immediately after the Corporate Governance Statement and all matters set out therein are incorporated into this Directors' Report by reference.

## Life Sciences Code of Best Practice for Reporting

### Patents

The Code of Best Practice for Reporting by Life Sciences Companies (published by the ASX and AusBiotech) recommends that the Company make a variety of disclosures across a range of areas of interest. In accordance with those recommendations, the Company provides the following information concerning the Consolidated Group's patents (as at 31 December 2007):

| Title | Country | Status | Patent or application number |
|---|---|---|---|
| Sealless Rotary Blood Pump with Passive Magnetic Radial Bearings and Blood Immersed Axial Bearings | Australia | Granted | 708476 |
| Sealless Rotary Blood Pump with Passive Magnetic Radial Bearings and Blood Immersed Axial Bearings | Australia | Granted | 734310 |
| Rotary Blood Pump | Canada | Granted | 2218342 |
| Sealless Rotary Blood Pump with Passive Magnetic Radial Bearings and Blood Immersed Axial Bearings | Europe | Pending | 4014527.8 |
| Sealless Rotary Blood Pump with Passive Magnetic Radial Bearings and Blood Immersed Axial Bearings | Israel | Granted | 121834 |
| Sealless Rotary Blood Pump with Passive Magnetic Radial Bearings and Blood Immersed Axial Bearings | Korea | Granted | 351336 |
| Sealless Rotary Blood Pump with Passive Magnetic Radial Bearings and Blood Immersed Axial Bearings | United States | Granted | 5695471 |
| Sealless Rotary Blood Pump | Australia | Granted | 730235 |
| Sealless Rotary Blood Pump | Australia | Granted | 742536 |
| Sealless Rotary Blood Pump | Germany | Granted | 69828926.9-8 |
| Sealless Rotary Blood Pump | Europe | Granted | 901797 |
| Sealless Rotary Blood Pump | France | Granted | 901797 |
| Sealless Rotary Blood Pump | Great Britain | Granted | 901797 |

| Title | Country | Status | Patent or application number |
|---|---|---|---|
| Sealless Rotary Blood Pump | Japan | Pending | 205985/98 |
| Sealless Rotary Blood Pump | Netherlands | Granted | 901797 |
| Sealless Rotary Blood Pump | United States | Granted | 5840070 |
| Sealless Blood Pump with Means for Avoiding Thrombus Formation | Australia | Granted | 768864 |
| Sealless Blood Pump with Means for Avoiding Thrombus Formation | Japan | Pending | 19027/99 |
| Sealless Blood Pump with Means for Avoiding Thrombus Formation | United States | Granted | 6120537 |
| Sealless Rotary Blood Pump | United States | Granted | 6080133 |
| Power System for an Implantable Heart Pump | United States | Granted | 6149683 |
| Active Magnetic Bearing System for Blood Pump | Australia | Granted | 765716 |
| Active Magnetic Bearing System for Blood Pump | Europe | Granted | 1135181 |
| Active Magnetic Bearing System for Blood Pump | France | Granted | 1135181 |
| Active Magnetic Bearing System for Blood Pump | Germany | Granted | 1135181 |
| Active Magnetic Bearing System for Blood Pump | Italy | Granted | 1135181 |
| Active Magnetic Bearing System for Blood Pump | Spain | Granted | 1135181 |
| Active Magnetic Bearing System for Blood Pump | Great Britain | Granted | 1135181 |
| Active Magnetic Bearing System for Blood Pump | Japan | Pending | 2000-584946 |
| Active Magnetic Bearing System for Blood Pump | United States | Granted | 6264635 |
| Rotary Blood Pump with Ceramic Members | Australia | Granted | 765033 |
| Rotary Blood Pump with Ceramic Members | Europe | Pending | 957558.2 |
| Rotary Blood Pump with Ceramic Members | Japan | Pending | 2000-590707 |
| Rotary Blood Pump with Ceramic Members | United States | Granted | 6158984 |
| Blood Pump Using Cross-Flow Principles | Australia | Granted | 760773 |
| Blood Pump Using Cross-Flow Principles | Germany | Granted | 69931960 |
| Blood Pump Using Cross-Flow Principles | Europe | Granted | 1146920 |
| Blood Pump Using Cross-Flow Principles | France | Granted | 1146920 |
| Blood Pump Using Cross-Flow Principles | Great Britain | Granted | 1146920 |
| Blood Pump Using Cross-Flow Principles | Netherlands | Granted | 1146920 |
| Blood Pump Using Cross-Flow Principles | Japan | Pending | 2000-594506 |
| Blood pump using Cross-Flow Principles | United States | Granted | 6217541 |
| Rotary Blood Pump | Australia | Granted | 773136 |
| Rotary Blood Pump | Europe | Pending | 923125.9 |
| Rotary Blood Pump | Japan | Pending | 2000-613497 |
| Rotary Blood Pump | United States | Granted | 6234772 |
| Method and Apparatus for Controlling Brushless DC Motors in Implantable Medical Devices | Australia | Granted | 771931 |
| Method and Apparatus for Controlling Brushless DC Motors in Implantable Medical Devices | Japan | Pending | 2001-509146 |
| Method and Apparatus for Controlling Brushless DC Motors in Implantable Medical Devices | United States | Granted | 7138776 |

| Title | Country | Status | Patent or application number |
|---|---|---|---|
| Sealless Rotary Blood Pump | United States | Granted | 6234998 |
| Power System for an Implantable Heart Pump | United States | Granted | 6592620 |
| Sealless Rotary Blood Pump | United States | Granted | 6368083 |
| Sealless Rotary Blood Pump | United States | Granted | 6688861 |
| Ventricular Connector | United States | Granted | 6732501 |
| Sealless Rotary Blood Pump | United States | Pending | 10/887116 |
| Ventricular Connector | United States | Pending | 10/799534 |
| Sensorless Flow Estimation For Implanted Ventricle Assist Device | Australia | Pending | 2005247478 |
| Sensorless Flow Estimation For Implanted Ventricle Assist Device | Europe | Pending | 05755086.5 |
| Sensorless Flow Estimation for Implanted Ventricle Assist Device | United States | Pending | 10/853302 |
| Wide Blade, Axial Flow Pump | PCT | Pending | PCT/US05/042495 |
| Wide Blade, Axial Flow Pump | United States | Pending | 11/003810 |
| Multiple Rotor, Wide Blade, Axial Flow Pump | PCT | Pending | PCT/US05/35964 |
| Multiple Rotor, Wide Blade, Axial Flow Pump | United States | Pending | 11/118551 |
| Impeller for a Rotary Ventricle Assist Device | United States | Pending | 11/243722 |
| Implantation Procedure for Blood Pumps | United States | Pending | 11/280030 |
| Implant Connector | PCT | Pending | |
| Implant Connector | United States | Pending | 11/298410 |
| Surgical Cutting Tool for Making Precise and Accurate Incisions | United States | Pending | 11/332455 |
| Surgical Tool for Coring Precise Holes and Providing for Retrieval of Tissue | United States | Pending | 11/332016 |
| Surgical Tool for Coring Precise Holes and Providing for Retrieval of Tissue | PCT | Pending | PCT/US07/000764 |
| Hydrodynamic Thrust Bearings for Rotary Blood Pumps | United States | Pending | 11/337708 |
| Shrouded Thrust Bearings | United States | Pending | 11/654217 |
| Stabilizing Drive for Contactless Rotary Blood Pump Impeller | United States | Pending | 11/654226 |
| Surgical Tool | PCT | Pending | PCT/US07/001743 |
| Surgical Tool | United States | Pending | 11/337708 |
| Axial Flow Pump with Multi-Grooved Rotor | PCT | Pending | PCT/US06/21 |
| Axial Flow Pump with Multi-Grooved Rotor | United States | Pending | 11/445963 |
| Control Panel | United States | Pending | 29/273244 |
| Controller | United States | Pending | 29/273238 |
| Rotary Blood Pump | PCT | Pending | PCT/US07/000763 |
| Hydrodynamic Thrust Bearings for a Rotary Blood Pump | United States | Pending | 11/243722 |
| Method and Apparatus for Controlling Brushless DC Motors in Implantable Medical Devices | United States | Pending | 11/603933 |

## Escrow

As at the date of this report, none of the Company's securities were subject to escrow under the ASX Listing Rules.

## Intangible Assets

Note 14 of the Company's Financial Statements provide details of the Consolidated Group's intangible assets.

## Proceedings on Behalf of Company

The Company has not received written notice that any person has applied for leave of Court to bring proceedings on behalf of the Company or intervene in any proceedings to which the Company is a party for the purpose of taking responsibility on behalf of the Company for all or any part of those proceedings.

The Company was not a party to any such proceedings during the financial year.

## Denomination

All amounts set out in Company's Annual Report & Directors' Report are denominated in Australian dollars.

## Filing Requirements in the United States of America

With effect from 1 January 2007, the Company is no longer able to rely on the "foreign private issuer exemption" as set out under the Securities Exchange Act of 1934 and is therefore subject to the same registration and reporting requirements that are required of domestic U.S. companies. These requirements generally call for the filing of annual, quarterly and current reports with the U.S. Securities and Exchange Commission. The Company is now "registered" with the U.S. Securities and Exchange Commission ("SEC") and all US filings can be obtained from the SEC website (www.sec.gov).

## Non-audit Services

The directors are satisfied that the provision of non-audit services during the year is compatible with the general standard of independence for auditors imposed by the Corporations Act 2001. The directors are satisfied that the services disclosed below did not compromise the external auditor's independence as the scope of services rendered during the year was minor in nature.

The directors, in accordance with advice from the Audit & Compliance Committee, are satisfied that the services disclosed below did not compromise the general principles relating to auditor independence as set out in APES 110: Code of Ethics for Professional Accountants, issued by the Accounting Ethical Professional Standards Board.

The following non-audit services were paid/payable to the external auditors during the financial year ended 31 December 2007:

| | 2007 $ | 2006 $ |
|---|---|---|
| Auditors of the parent entity – Grant Thornton NSW | | |
| - Tax services | 20,350 | 9,190 |
| - Advisory fees in connection with Company's US GAAP and Australian GAAP filings | 14,857 | 2,650 |
| Auditors of HeartWare, Inc. – Grant Thornton LLP | | |
| - Tax services | - | 7,768 |
| - Advisory fees in connection with Company's obligations to lodge US GAAP compliant financial statements with the Securities Exchange Commission | - | 2,328 |
| | **35,207** | **21,936** |

## Auditor's Independence Declaration

The lead auditor's independence declaration for the financial year ended 31 December 2007 has been received and can be found immediately following this Directors' Report (including the Corporate Governance Statement and the Remuneration Report) and forms part of this report.

## Auditor

Grant Thornton NSW continues in office in accordance with section 327 of the Corporations Act 2001.

This report (and the attaching Corporate Governance Statement, Remuneration Report and the Auditor's Independence Declaration) is made in accordance with a resolution of the Board of Directors.

ROB THOMAS
Chairman
Date 29 February 2008

# Corporate Governance Statement

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

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

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

## Principle 1 – Lay solid foundations for management and oversight

### Obligation – Recognise and publish the respective roles and responsibilities of both the Board of Directors and Management

The primary responsibility of:

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

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

The Board's responsibilities are recognized and documented on an aggregated basis via the Charter of the Board of Directors and via Letters of Appointment for each individual director. Copies of the Charter of the Board of Directors as well as the Delegation of Authority may be downloaded from the Company's website.

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

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

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

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

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

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

### Reporting Requirement

The Company fully complied with Best Practice Recommendation 1.1 during the year ended 31 December 2007.

## Principle 2 – Structure the Board to add value

### Obligation – Have a Board of an effective composition, size and commitment to adequately discharge its responsibilities and duties

### Composition

The Board of Directors presently comprises six (6) directors. The six (6) directors encompass four (4) independent non-executive directors (including the Chairman of the Board), one (1) executive director (being the Chief Executive Officer) and one (1) non-independent, non-executive director (being the Deputy Chairman).

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

| Name | Position | Date appointed | Tenure* | Inde-pendent |
|---|---|---|---|---|
| **Rob Thomas** | Non-executive Chairman | 26 Nov 2004 | 3.1 years | Yes |
| **Seth Harrison** | Non-executive Deputy Chairman | 26 Nov 2004 | 3.1 years | No |
| **Denis Wade** | Non-executive director | 15 Dec 2004 | 3.0 years | Yes |
| **Christine Bennett** | Non-executive director | 15 Dec 2004 | 3.0 years | Yes |
| **Bob Stockman** | Non-executive director | 11 Dec 2006 | 1.1 years | Yes |
| **Doug Godshall** | Chief Executive Officer/ President/ Executive Director | 28 Oct 2006 | 1.2 years | No |

* Calculated as at 31 December 2007.

### Expertise

The Board has a diverse range of skills and experience, details of which are set out below:

#### Robert Bain Thomas

Position Non-executive Chairman
Age 62
Independent Yes

Rob is the immediate past Chairman, Global Corporate & Investment Bank, Australia and New Zealand of Citigroup Global Markets Australia Pty Limited, one of Australia's leading investment banks.

Rob has in excess of 30 years experience in the investment and securities industry. In 1986, Rob joined County NatWest Securities Australia Limited to establish its stockbroking operations and was appointed Managing Director.

In April 1998, County NatWest Securities was taken over by Salomon Smith Barney and Rob was subsequently appointed Chief Executive Officer of Australia and New Zealand, Corporate and Investment Bank and ultimately, Chairman.

In the last three years, Rob has been a non-executive director of Virgin Blue Holdings Limited (Appointed 8 September 2007 – Present), non-executive Chairman of Tower Australia Limited (ASX:TAL) (Appointed 27 September 2007 – Present), non-executive Chairman of Australian Wealth Management Limited (ASX:AUW) (Appointed 15 February 2006 – Resigned 27 September 2007) and Deputy Chairman of Benitec Limited (ASX: BLT) (Appointed 7 May 2004 – Resigned 30 November 2006). In addition, Rob is also the Chairman of the Securities & Derivatives Association, and President of the Library Council of New South Wales.

Rob holds a Bachelor of Economics from Monash University. 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.

Rob is the Chairman of the Nomination & Remuneration Committee and a member of each of the Audit & Compliance Committee and the Continuous Disclosure Committee.

#### Dr Seth Loring Harrison

Position Non-executive Deputy Chairman
Age 47
Independent No

Seth has been involved in life sciences venture capital since 1991.

Seth is presently Managing General Partner of HeartWare's major shareholder, Apple Tree Partners. Apple Tree Partners is an early stage life sciences venture capital firm, based in Cambridge, Massachusetts, managing US$105 million. Prior to this, Seth held senior executive positions with U.S. based Oak Investment Partners, Sevin Rosen Funds and Nazem & Company.

Seth has significant experience in the successful establishment and sale of start-up entities. Seth also has a long term and intimate understanding of HeartWare's technology, having previously acted as HeartWare's Chief Executive Officer.

Seth received a Bachelor of Arts from Princeton University, a Bachelor of Medicine and Masters of Business Administration both from Columbia University and completed a surgery internship at the 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 partnerships engaged in the development of anti-HIV microbicides. Seth is also on the Board of the New York Studio School for Drawing, Painting and Sculpture.

In the last three years, Seth has not held any directorships of Australian listed companies.

Seth is a member of the Nomination & Remuneration Committee as well as the Continuous Disclosure Committee.

**Robert (Bob) Bernard Stockman**

Position Non-executive director
Age 54
Independent Yes

Bob is the President and CEO of Group Outcome LLC, a US 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 Chairman of REVA Medical, Inc, an interventional coronary medical device company he helped co-found.

Bob has played a critical role in a number of significant US-based buyout transactions, recapitalizations, turnarounds and subsequent sales of various medical companies, which included two divestitures from Johnson & Johnson. Bob also co-founded and provided the start-up financing for CentriMed, which thrives today as the Global HealthCare Exchange, the world's leading electronic exchange for hospital supplies.

Prior to establishing Group Outcome LLC, Bob spent 18 years with Johnston Associates and Narragansett Capital Corporation, where he focused on venture capital investments in healthcare. He previously was an auditor with Price Waterhouse in New York.

Bob holds a Bachelors Degree from Harvard College and a Master in Business Administration from The Tuck School at Dartmouth College.

Bob is not a member of any committee having only recent been appointed to the Board of Directors.

**Dr Denis Newell Wade AM**

Position Non-executive director
Age 70
Independent Yes

Denis has extensive experience in international health care markets, with a particular emphasis on the development of research based health care products in Australia and their commercialisation in the global market.

He regularly engages, often informally, with senior industry executives both in Australia and internationally.

Denis is the immediate past Managing Director and Chairman of Johnson & Johnson Research Pty Ltd ("J&J"). In his 15 years with J&J, he held various roles including as a member of J&J's US-based Corporate Office of Science & Technology and it's Business Development Council.

In addition, Denis was the former Foundation Professor of Clinical Pharmacology at the University of New South Wales and the former President of the Australian Society of Clinical and Experimental Pharmacology. Denis has also held senior positions in the International Union of Pharmacology, serving as Chairman of the Clinical Pharmacology Section.

In the last 18 years, Denis has acted as a non-executive director of a number of developing health-care companies including Gene Shears Pty Limited, Chemgenex Limited (ASX:CXS) (Appointed 5 December 2007 – Resigned 8 February 2007) and Cryptome Pharmaceuticals Limited (ASX:CRP) (Appointed January 2003 – Resigned 10 February 2007). He currently chairs the Industry Advisory Committee of the Australian Synchrotron and is a former member of the Pharmaceuticals Committee of the Australian Industry Research and Development Board. He is the former Chairman of the Innovation Council of New South Wales.

Denis holds a Bachelor degree in Medicine and Surgery from the University of New South Wales and a doctorate in Philosophy from Oxford. 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.

Denis is a member of the Nomination & Remuneration Committee and the Audit & Compliance Committee.

**Dr Christine Constance Bennett**

Position Non-executive director
Age 52
Independent Yes

Christine has recently been appointed as Group Executive, Health and Financial Solutions and Chief Medical Officer of MBF Australia Limited having previously held the position of Chief Executive Officer of Research Australia, a highly regarded national body of Australian organisations and companies that are committed to making health and medical research a higher national priority in Australia and globally.

In her role as a Group Executive of MBF, Christine is charged with the responsibility of developing and manufacturing products for the health insurance and various financial services businesses operating as part of the MBF Group. Christine is also responsible for provider contracts and health benefits management. As Chief Medical Officer, Christine is the health spokesperson for MBF and is responsible for building strategic alliances within the health industry both in Australia and overseas.

Christine has 30 years experience in the health sector in senior executive, strategic and clinical roles. Specifically, Christine brings substantial experience as a specialist clinician, strategist and planner and chief executive in both the public and private sectors.

Previous roles have included Chief Executive Officer of Westmead Hospital and Community Health Services, a partner at KPMG in Health and Life Sciences and senior positions in the New South Wales Department of Health in services planning and policy.

In the last three years, Christine has acted as a non-executive director of Resonance Health Limited (ASX:RHT) (Appointed 12 July 2004 – 20 April 2006) and Symbion Health (ASX:SYB) (Appointed 1 February 2007 – Present).

Christine is the Chair of the Audit & Compliance Committee and a member of the Nomination & Remuneration Committee.

Christine holds a Bachelor of Medicine and Surgery (University of Sydney), Master of Paediatrics (University of NSW) and is a Fellow of the Royal Australasian College of Physicians.

**Douglas (Doug) Evan Godshall**

Position Chief Executive Officer/President/ Executive Director
Age 43
Independent No

Doug has almost two decades of senior managerial and executive experience with Boston Scientific Corporation (Boston Scientific).

Prior to accepting appointments as Chief Executive Officer and Executive Director of HeartWare, Doug served on the Operating Committee at Boston Scientific, one of the world's largest medical device companies.

From January 2006 until his departure to join HeartWare, Doug was President, Vascular Surgery at Boston Scientific, with overall responsibility for a business division employing some 600 personnel and generating revenues of approximately US$100 million. Doug previously spent five years as Vice President, Business Development at Boston Scientific, where he was instrumental in developing the acquisition strategies for the cardiology, electrophysiology, neuroradiology and vascular surgery divisions. During this period, he led the negotiation and structuring of over seventy (70) transactions and represented Boston Scientific on the Boards of eleven (11) companies. Prior to assuming the Business Development position, he was Director of Marketing for Boston Scientific's Urology Division where he helped build global sales to over US$150 million. Doug joined Boston Scientific in 1990.

Doug is well known and highly regarded within the US medical device community and his wealth of knowledge and experience will play, and indeed has already played, an invaluable role as HeartWare matures into a leading medical device manufacturer.

Doug is a member of the Continuous Disclosure Committee.

In the last three years, Doug has not held any directorships of Australian listed companies.

**David John McIntyre (Chief Financial Officer & Company Secretary)**

As HeartWare's Chief Financial Officer and Company Secretary, David has broad financial and legal skills and experience.

David has held senior financial and reporting roles in multinational companies, among them Rio Tinto. He has also previously served as a corporate and commercial law specialist in major international law firms, advising some of the world's largest corporations in various areas including mergers and acquisitions, corporate fundraising and securities law.

David holds a Bachelor of Economics (Accounting) from the University of Sydney as well as a Bachelor of Law from the University of Technology, Sydney. He is a Certified Practising Accountant (CPA) and is admitted as a Legal Practitioner of the Supreme Court of New South Wales (and is a member of the Law Society of New South Wales).

In the last three years, David has not held any directorships of Australian listed companies.

**Independent advice**

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

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

**Reporting requirement**

For the year ended 31 December 2007, the Company is pleased to confirm that it has fully complied with the requirements of Best Practice Recommendations 2.1 to 2.5 (inclusive).

**Principle 3 – Promote ethical and responsible decision-making**

**Obligation – Actively promote ethical and responsible decision-making**

The Company has adopted a Code of Conduct that is designed to convey the obligations and standards of behaviour expected of the Chief Executive Officer, the Chief Financial Officer and other employees. It is also designed to help staff resolve any ethical issues that may arise during the course of their duties.

The Company also adopted a "Complaint Procedures for Accounting and Audit Matters". This policy established procedures that operate in addition to the Code of Conduct and which are primarily focused on dealing with employee complaints concerning any questionable accounting or auditing matters. These policies operate in addition to the Company's Operational Policies, Employee Handbook and other corporate policies such as the Risk Management Policy, Securities Trading Policy and Continuous Disclosure Policy.

The Board acknowledges that ethical conduct, together with responsible decision-making, is a matter of concerted diligence and effective promotion of the relevant principles by all employees, particularly senior executives. The establishment of the above policies reflect the Company's commitment in this regard and are, in simple terms, designed to ensure that a suitable framework is established whereby employees are promoted to observe the letter and spirit of the law, adhere to high standards of business conduct and comply with best practice.

A copy of the Code of Conduct and the Securities Trading Policy is available on the corporate governance page of the Company's website.

**Reporting requirement**

The Company fully complied with Best Practice Recommendations 3.1 to 3.3 (inclusive) during the year ended 31 December 2007.

## Principle 4 – Safeguard integrity in financial reporting

### Obligation – Have a structure to independently verify and safeguard the integrity of the Company's financial reporting

The Company is committed to exhibiting the highest standard of integrity in its financial reporting. The Company is also equally committed to safeguarding the interests of its shareholders, employees, creditors and the general investing public and believes that, at its simplest, this is achieved via open and appropriate financial reporting.

The Company is, however, a growing organization and is therefore limited in terms of the resources available to it to protect the integrity of its financial reporting mechanism (as compared to larger, more mature organizations). For example, separation of duties, responsibilities and controls in key accounting functions, are intrinsically difficult to preserve when the finance function comprises relatively few employees with diverse responsibilities.

As the associated costs of, for example, an internal audit function are not presently within the Company's available resources, the Company seeks to reduce its financial reporting risk via detailed and frequent financial reporting to the Board, together with various policies and procedures (e.g. Complaint Procedures for Accounting and Audit Matters).

As the Company continues to grow and mature, it is expected that greater resources will be brought to bear on preserving and safeguarding the integrity of the Company's financial reporting function.

### Reporting requirement

The Company fully complied with Best Practice Recommendations 4.1 to 4.5 (inclusive) during the year ended 31 December 2007.

## Principle 5 – Make timely and balanced disclosure

### Obligation – Promote timely and balanced disclosure of all material matters concerning the Company

Heartware is committed to providing timely and balanced disclosure to the market and, in consequence, to meeting its continuous disclosure requirements.

In accordance with its commitment to fully comply with its continuous disclosure requirements, the Company has adopted a Continuous Disclosure Policy, together with a Continuous Disclosure Committee. The Continuous Disclosure Committee comprises the Chairman of the Board, the Deputy Chairman of the Board and the Chief Executive Officer. The Chief Financial Officer acts as convenor for the Continuous Disclosure Committee.

The Continuous Disclosure Committee has been established by the Board as a committee to be responsible for ensuring full compliance with the Company's policy in this regard, particularly in relation to the continuous disclosure obligations set out in the ASX Listing Rules and the Corporations Act 2001.

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

### Reporting Requirement

The Company fully complied with Best Practice Recommendations 5.1 to 5.2 (inclusive) during the year ended 31 December 2007.

**Principle 6 – Respect the rights of shareholders**

**Obligation – Respect the rights of shareholders and facilitate the effective exercise of those rights**

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

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

**Reporting requirement**

The Company complies with Best Practice Recommendations 6.1 to 6.2 (inclusive) for the year ended 31 December 2007.

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**Principle 7 – Recognise and manage risk**

**Obligation – Establish a sound system of risk oversight and management and internal control**

The risks that the Company faces are continually changing in line with the development of the Company. The primary risks faced by the Company during 2007 include liquidity or funding risk, operational risks associated with the manufacture of an implantable medical device, and the ongoing risks of the Company's human clinical trials.

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

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

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

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

**Reporting requirement**

The Company complies with Best Practice Recommendation 7.1 and 7.2 for the year ended 31 December 2007 and the Chief Executive Officer and the Chief Financial Officer have provided the requisite written sign-offs.

**Principle 8 – Encourage enhanced performance**

**Obligation – Fairly review and actively encourage enhanced Board and management effectiveness**

The attached Remuneration Report provides detailed information in relation to the manner in which the Company reviewed the effectiveness of the Company's management, including details of a benchmark exercise.

The Board has not undertaken any other type of Board review, including a performance evaluation of the Board, its committees or of individual directors.

A copy of the Company's charter for the Nomination & Remuneration Committee is available on the corporate governance page of the Company's website.

**Reporting requirement**

The Company has not fully complied with the requirements of Best Practice Recommendation 8.1 as it has not undertaken a review of, and is therefore unable to disclose the details of, the performance of the Board, its committee or individual directors.

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**Principle 9 – Remunerate fairly and responsibly**

**Obligation – Ensure that the level and composition of remuneration is sufficient and reasonable and that its relationship to corporate and individual performance is defined**

As noted above in the discussion regarding Principle 8, the Remuneration Report includes detailed information in relation to the Company's remuneration practices and policies, including its annual performance review process, its external benchmarking review and its meritorious approach to employee performance. Shareholders should read the Remuneration Report for further information in this regard.

**Reporting requirement**

The Company full complied with Best Practice Recommendations 9.1 to 9.5 (inclusive) during the year ended 31 December 2007.

**Principle 10 – Recognise the legitimate interests of stakeholders**

**Obligation – Recognise legal and other obligations to all legitimate stakeholders**

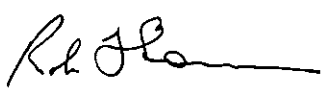
As noted elsewhere in this Corporate Governance Statement, the Company has adopted a variety of practices, policies and procedures, including a Code of Conduct and a "Complaint Procedures for Accounting and Audit Matters". These "mechanisms" are some of the main drivers for achieving compliance with legal and other obligations.

A copy of the Company's Code of Conduct is available on the corporate governance page of the Company's website.

**Reporting requirement**

The Company complied with Best Practice Recommendation 10.1 during the year ended 31 December 2007.

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



Rob Thomas
Chairman
Date 29 February 2008

# Remuneration Report

This report and the information referenced in this report detail the remuneration policy for directors, executives and employees of HeartWare Limited ("HeartWare" or "the Company") and its controlled entities (collectively, "the HeartWare Group" or the "Consolidated Group").

This report also endeavours to provide details of the links between the performance of the HeartWare Group and individual remuneration outcomes. Remuneration arrangements, including details of equity holdings, are also disclosed in this report and the Notes to the Financial Statements.

## Nomination & Remuneration Committee

The HeartWare Group's remuneration arrangements are overseen by the Nomination & Remuneration Committee ("Remuneration Committee"). The Remuneration Committee presently consists of four non-executive directors, being Mr Rob Thomas (Chairman), Dr Seth Harrison, Dr Denis Wade and Dr Christine Bennett.

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

Details, including experience and qualifications, of the members of the Remuneration Committee are set out in the Directors' Report.

## Remuneration Policy

We believe that our compensation policies and practices are central to our ability to attract and retain our executives, and that this will be especially critical 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 and applicable medical device experience, and competition for executives with relevant experience is intense. We also recognize that because the bulk of our facilities are located in the southeastern United States, many potential new executives are forced to consider the additional burden of both travel and relocation into their decision-making process.

During this period of growth and development, we acknowledge that 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 importance and directly impact our ability to achieve our corporate objectives in a timely manner.

Our compensation policies are therefore designed to attract, retain and motivate executives officers as well as the entire staff of the organization and to align compensation and related financial incentives with the interests of shareholders.

The key principles of our compensation policies are as follows:

(a) offer sufficient rewards to attract and retain executives in light of current employment market conditions in our industry;

(b) link rewards for executives to the achievement of corporate goals thereby aligning the interest of our executives and our shareholders;

(c) ensure parity in terms of compensation among executives; and

(d) assess and reward executives using a variety of measures of performance.

**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. It is also well-recognized that companies like HeartWare who are early-stage, pre-revenue, have limited clinical experience and which are largely dependant on their ability to raise capital in order to remain viable, are perceived by employees to have a significantly higher risk profile than other more established medical device companies.

We believe that we need to take account of a number of factors when negotiating and determining compensation levels for our executives. For example, we consider the relevant executive's compensation level prior to joining HeartWare as well as wider medical device industry compensation practices, especially those compensation practices adopted by other development-stage companies. We also consider each executive's current or anticipated future contribution, responsibilities, previous experience, perceived importance to the Company, work ethic and seniority following commencement with the Company.

In order to confirm the appropriateness of the Company's compensation practices the Company retained an external consultant in 2007 to assist in reviewing our executives' compensation. This review, which is discussed below under the heading "Benchmark Exercise", was undertaken to enable the Company to compare our executives' compensation with compensation practices of other medical device companies who are at a similar development stage. Using the benchmark exercise as a guide, we then considered each individual on a case-by-case basis and took into account the factors referred to above as well as years of experience, actual performance, the executives' role and importance and each individual executives' compensation and employment history.

While we believe that equity-based compensation is an important financial motivator for our executives, the Board of Directors recognizes that the Company's risk profile is such that the salary component of each executive's compensation will continue to constitute a critical component of an executive's total compensation from an executive's perspective. Above all, we believe that that a combination of cash and equity compensation is currently appropriate to ensure that we are able to attract and retain talented executives to manage the business and affairs of the Company, to become a significant player in the growing circulatory assist market and to increase shareholder value. We continue to monitor both our cash and equity compensation approaches to ensure that they are competitive and motivating.

**Benchmark Exercise**

During 2007, the Company retained Frederick W. Cook & Co., Inc. ("F W Cook") to examine the compensation practices of a peer group of companies and to compare that data to our senior executives' compensation. F W Cook is an independent, third party, specialist in United States-based compensation norms.

The exercise included representatives of F W Cook:

(a) Meeting with management and selected members of the Board of Directors for the purposes of learning about the Company, its background, historical compensation practices and perceived shareholder views.

(b) Collecting and analyzing company-specific background data from management for the purposes of independent analysis.

(c) Identifying and examining the compensation practices of a peer group of 16 comparable, publicly traded, development stage, biotechnology and medical device companies located in the United States, and comparing that data to HeartWare's data.

The analysis undertaken by F W Cook focused on base salaries, annual bonuses, long-term incentives and total "carried-interest ownership", which is a form of measurement of the equity awards received by each executive during the course of their employment. Carried-interest measures the amount of future increase in value captured by each executive arising through their equity awards and is calculated as the aggregate holding of options and shares plus recent share sales of an executive, divided by the number of Company shares outstanding.

**Components of Remuneration**

Remuneration packages are set at levels that are intended to attract and retain executives capable of managing HeartWare's diverse operations and achieving the Company's strategic objectives in a timely manner.

For the short term, the base salary component is the most significant component 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 goals. Other relevant considerations include perceived long-term value to HeartWare, succession planning and retention and the executives' compensation prior to joining the Company.

Performance-based bonuses are an important element of our compensation strategy. These bonuses are used 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.

In rare instances, HeartWare also uses sign-on bonuses. If the Company does use a sign-on bonus then this is because management believes that an upfront payment to an executive significantly influences that individual's decision to join the Company. The decision to offer such bonuses generally evolves as part of the employment negotiation process and is dependent on the importance of the relevant appointment, the availability of candidates and the individual qualities and experience of the candidate. A sign-on bonus is also beneficial where a potential employee becomes ineligible to receive a bonus at their existing employee if the employee decides to join HeartWare.

The Remuneration Committee and the Board of Directors also determined to pay a discretionary bonus on October 31, 2007 in recognition of the Company completing enrolment in its international clinical trial, the filing of its submission with the US Food & Drug Administration for an investigational device exemption for the commencement of human clinical trials in the United States and in consideration of the overall progress made by the Company since June 2006. These accomplishments were achieved through an enormous contribution by the Company's executives and the Company determined that the payment of this bonus was appropriate in the circumstances. As the above bonus was both discretionary and retrospective in nature, there were no objectives established in relation to this bonus.

The Board notes that the above operates in tandem with the Company's Employee Share Option Plan ("ESOP") and its Performance Rights Plan ("PRP") which are primarily utilised for the purposes of employee retention and long-term incentives. Further details of the ESOP and the PRP are set out at the bottom of this Remuneration Report.

All benefits received by key management personnel (including the 5 most highly remunerated executives) are set out in Appendix A to this Remuneration Report (and the contents of Appendix A are incorporated into this Remuneration Report by reference). The information is as follows:

(a) Director and Other Key Management Personnel – Section 1 to Appendix A to this Remuneration Report

(b) Compensation options – Section 2 to Appendix A to this Remuneration Report.

(c) Option holdings – Section 3 to Appendix A to this Remuneration Report.

(d) Compensation, including salary and retirement benefits – Section 4 to Appendix A to this Remuneration Report.

(e) Shareholdings – Section 5 to Appendix A to this Remuneration Report.

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**Employment Arrangements**

The executives set out below include direct reports to the Chief Executive Officer.

**Doug Godshall MBA – Chief Executive Officer, President and Executive Director**

**Overview**

Mr Godshall is responsible for the day-to-day management of HeartWare, as well as for planning and directing all of HeartWare's policies, objectives and initiatives. Mr Godshall was appointed Chief Executive Officer with effect from 18 September 2006 and became a director of the Company on 28 October 2007.

Details of Mr Godshall's background and experience are set out in the attached Corporate Governance Statement. Mr Godshall resides in the United States of America and his employee arrangements are denominated in US dollars.

**Employment Arrangements**

Mr Godshall has a service agreement with HeartWare Limited and HeartWare, Inc. Set out below is an overview of the ongoing key elements of this agreement:

(a) Annual salary of approximately $417,000 being equivalent to US$350,000.

(b) An annual performance bonus of up to approximately $89,000 (being equivalent to US$75,000) subject to satisfaction of agreed annual performance hurdles.

The above agreement does not include a fixed term and is terminable by either party on notice (in certain circumstances). Mr Godshall does not receive any additional compensation, except as provided above, for his role as an executive director of the Company.

**David McIntyre BEc LLB CPA– Chief Financial Officer and Company Secretary**

**Overview**

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

Mr McIntyre holds a Bachelor of Economics (Accounting) from the University of Sydney as well as a Bachelor of Law from the University of Technology, Sydney. He is an Australian Certified Practising Accountant ("CPA") and is admitted as a Legal Practitioner of the Supreme Court of New South Wales.

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.

**Employment Arrangements**

Mr McIntyre has a service agreement with HeartWare Limited that has been temporarily suspended with effect from 30 April 2006 (i.e. prior to his temporary relocation to the United States of America). Set out below is an overview of the key ongoing elements of this agreement:

(a) Annual salary of $220,000 per annum.

(b) Superannuation calculated at the statutory rate of 9% per annum.

(c) Provision of one car parking space and a maintained motor vehicle.

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:

(a) Annual salary of approximately $268,000 per annum (being equivalent to US$225,000).

(b) A monthly after-tax payment 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 of America.

The above agreement does not contain a fixed term and may be terminated by either party at will.

**Dozier Rowe MGT Sci – Chief Operating Officer**

**Overview**

As Chief Operating Officer, Mr Rowe is responsible for HeartWare's manufacturing and operational processes including final product development, assembly methods, plant layout, workflow and workforce utilisation.

Mr Rowe holds a Bachelor of Science degree in Management Science from Georgia Institute of Technology. Mr Rowe resides in the United States of America and is employed by HeartWare's US subsidiary, HeartWare, Inc. Mr Rowe's employee arrangements are denominated in US dollars.

**Employment Agreement**

Mr Rowe has a service agreement with HeartWare, Inc. Set out below is an overview of the key ongoing elements of the terms of his employment:

(a) Annual salary of approximately $268,000 per annum (being equivalent to US$225,000).

(b) In certain circumstances the termination of Mr Rowe's employment within twelve months of a "Change of Control" (e.g. a merger or takeover) will permit Mr Rowe to exercise those options which would vest within twelve months of the date of termination.

The above agreement does not contain a fixed term and may be terminated by either party at will.

### Jeff LaRose MSME – Chief Scientific Officer

**Overview**

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

Mr LaRose holds a Masters of Science in Mechanical Engineering and is a member of American Society of Mechanical Engineers, American Society for Artificial Internal Organs, and International Society of Rotary Blood Pumps.

Mr LaRose resides in the United States of America and is employed by HeartWare's US subsidiary, HeartWare, Inc. Mr LaRose's employee arrangements are denominated in US dollars.

**Employment Agreement**

Mr LaRose has a service agreement with HeartWare, Inc. with an annual salary of approximately $268,000 per annum (being equivalent to US$225,000).

The above agreement does not contain a fixed term and may be terminated by either party at will.

### Jennifer Foley BS MBA – Vice-President, Clinical & Regulatory Affairs

**Overview**

As Vice-President, Clinical & Regulatory Affairs, Ms Foley is primarily responsible for the conduct of the Company's clinical trials.

Ms Foley holds a Bachelor of Science in Microbiology from the University of Maryland and a Masters of Business Administration from Boston University.

Ms Foley resides in the United States of America and is employed by HeartWare's US subsidiary, HeartWare, Inc. Ms Foley's employee arrangements are denominated in US dollars.

**Employment Agreement**

Ms Foley has a service agreement with HeartWare, Inc. with an annual salary of approximately $252,000 per annum (being equivalent to US$220,000).

Ms Foley was paid US$30,000 as a sign-on bonus immediately following the commencement of her employment. Ms Foley is a highly experienced and well-regarded clinical specialist who, prior to joining the Company, was one of the most senior executives within Boston Scientific Corporation's clinical affairs organization where Ms Foley was responsible for overseeing the execution of clinical trials across nine of that company's divisions.

Ms Foley was also eligible to receive a US$30,000 bonus provided the Company filed its IDE with the FDA within 90 days of the Company implanting its 20th patient.

The above agreement does not contain a fixed term and may be terminated by either party at will.

### James (Jim) Schuermann BS MBA – Vice President Sales and Marketing

**Overview**

Mr Schuermann is responsible for global sales and marketing and for managing reimbursement strategy in domestic and international markets.

Mr Schuermann holds an undergraduate degree in marketing from the Kelley School of Business at Indiana University, Bloomington, Indiana, together with a Masters in Business Administration from Ageno School of Business at Golden Gate University, San Francisco, California.

Mr Schuermann resides in the United States of America and is employed by HeartWare's US subsidiary, HeartWare, Inc.. Mr Schuermann's employee arrangements are denominated in US dollars.

**Employment Agreement**

Mr Schuermann has a service agreement with HeartWare, Inc. with an annual salary of approximately $252,000 per annum (being equivalent to US$220,000).

The above agreement does not contain a fixed term and may be terminated by either party at will.

**Jane Reedy RN MSN– Vice President Sales and Marketing (Former)**

**Overview**

Ms Reedy, former Vice President Sales and Marketing, was previously responsible for global marketing, managing reimbursement systems in domestic and international markets, and directing clinical trials to support product registration.

Ms Reedy holds a Bachelor of Science (Nursing) from the University of Missouri-Columbia as well as a Master of Science (Nursing) from St. Louis University. Ms Reedy is a member of the International Society for Heart and Lung Transplantation and American Society for Artificial Internal Organs.

Ms Reedy resides in the United States of America and is employed by HeartWare's US subsidiary, HeartWare, Inc. Ms Reedy's employee arrangements are denominated in US dollars.

Ms Reedy ceased her role as Vice-President, Sales & Marketing in October 2007 but remained employed by the Company through 31 December 2007.

The Company and Ms Reedy entered into an agreement on 12 September 2007 under which Ms Reedy will continue to be employed by the Company until 31 December 2007 at which time Ms Reedy will resign all positions with the Company. Under this agreement, the Company agreed to pay Ms Reedy a severance payment equal to twelve months salary, being approximately $252,000 (or US$220,000) and this amount has been accrued at 31 December 2007.

**Employment Agreement**

Ms Reedy had a service agreement with HeartWare, Inc. with an annual salary of approximately $252,000 per annum (being equivalent to US$220,000).

The above agreement did not contain a fixed term and may be terminated by either party at will.

This report includes the 11 pages in Appendix A to the Remuneration Report (and is incorporated by reference) and is made in accordance with a resolution of the Board of Directors.



ROB THOMAS
Chairman
Date 29 February 2008

## SECTION 1 – APPENDIX A TO THE REMUNERATION REPORT

### DIRECTORS AND OTHER KEY MANAGEMENT PERSONNEL

Names and positions held of directors and other key management personnel in office at anytime during the financial year are as follows:

| Name | Position | Entity | Tenure |
|---|---|---|---|
| **Directors** | | | |
| Mr R B Thomas | Non-executive Chairman | (i) | 26 November 2004 – Current |
| Dr S L Harrison | Non-executive Deputy Chairman | (i) | 26 November 2004 – Current |
| Dr D N Wade | Non-executive Director | (i) | 15 December 2004 – Current |
| Dr C C Bennett | Non-executive Director | (i) | 15 December 2004 – Current |
| Mr D E Godshall | Chief Executive Officer<br>Executive Director | (i), (ii) | 18 September 2006 – Current<br>28 October – Current |
| Mr R B Stockman | Non-executive Director | (i) | 11 December 2006 – Current |
| **Other Key Management Personnel** | | | |
| Mr D J McIntyre | Chief Financial Officer<br>Company Secretary | (i), (ii) | 28 February 2005 – Current<br>28 February 2005 – Current |
| Mr D A Rowe | Chief Operating Officer | (ii) | 17 April 2006 – Current |
| Mr J A LaRose | Chief Scientific Officer | (ii) | 10 July 2003 – Current |
| Ms J H Foley | Vice President, Clinical & Regulatory Affairs | (ii) | 2 January 2007 – Current |
| Ms J E Reedy | Vice President, Sales & Marketing (Former) | (ii) | 16 May 2005 – 31 December 2007 |
| Mr J F Schuermann | Vice President, Sales & Marketing | (ii) | 4 September 2007 – Current |

Notes:
(i) HeartWare Limited
(ii) HeartWare, Inc.

## COMPENSATION OPTIONS FOR DIRECTORS AND OTHER KEY MANAGEMENT PERSONNEL

| | | | TERMS & CONDITIONS FOR EACH GRANT | | | | |
|---|---|---|---|---|---|---|---|
| **Parent Entity Directors** | **Vested number** | **Granted number** | **Grant date** | **Value per option at grant date ($)** | **Exercise price ($)** | **First exercise date** | **Last exercise date** |
| Thomas, R | 382,102 | 764,204 | 24 January 2005 | $0.36 | $0.20 | *24 January 2006 | 24 January 2010 |
| | 200,000 | 200,000 | 24 January 2005 | $0.23 | $0.60 | *24 January 2006 | 24 January 2010 |
| | 200,000 | 200,000 | 24 January 2005 | $0.17 | $1.00 | *24 January 2007 | 24 January 2010 |
| | – | 100,000 | 24 January 2005 | $0.12 | $1.50 | 24 January 2008 | 24 January 2010 |
| Harrison, S | – | – | – | – | – | – | – |
| Stockman, R | – | 200,000 | 26 July 2007 | $0.40 | $0.75 | 26 July 2008 | 26 July 2017 |
| Wade, D | 100,000 | 100,000 | 24 January 2005 | $0.23 | $0.60 | *24 January 2006 | 24 January 2010 |
| | 100,000 | 100,000 | 24 January 2005 | $0.17 | $1.00 | *24 January 2007 | 24 January 2010 |
| | – | 50,000 | 24 January 2005 | $0.12 | $1.50 | 24 January 2008 | 24 January 2010 |
| Bennett, C | 100,000 | 100,000 | 24 January 2005 | $0.23 | $0.60 | *24 January 2006 | 24 January 2010 |
| | 100,000 | 100,000 | 24 January 2005 | $0.17 | $1.00 | *24 January 2007 | 24 January 2010 |
| | – | 50,000 | 24 January 2005 | $0.12 | $1.50 | 24 January 2008 | 24 January 2010 |
| Godshall, D | 1,395,316 | 5,581,264 | 27 September 2006 | $0.50 | $1.10 | 27 September 2007 | 27 September 2016 |
| **Total** | **2,577,418** | **7,545,468** | | | | | |

No options were exercised by directors during the year ended 31 December 2007. On 20 November 2007, the Company announced its intention to seek shareholder approval in 2008 to grant 1.1 million performance rights to Mr Godshall with a zero strike price. No such approval has been obtained, and therefore no performance rights have been issued (or recorded above), at the date of this report.

## COMPENSATION OPTIONS FOR DIRECTORS AND OTHER KEY MANAGEMENT PERSONNEL (continued)

| | | | TERMS & CONDITIONS FOR EACH GRANT | | | | |
|---|---|---|---|---|---|---|---|
| **Other Key Management Personnel** | **Vested number** | **Granted number** | **Grant date** | **Value per option at grant date ($)** | **Exercise price ($)** | **First exercise date** | **Last exercise date** |
| Rowe, D | 250,000 | 1,000,000 | 20 April 2006 | $0.87 | $1.41 | 20 April 2007 | 20 April 2016 |
| | 50,000 | 200,000 | 28 October 2006 | $0.50 | $1.10 | 28 October 2007 | 28 October 2016 |
| | – | 200,000 | 16 November 2007 | $0.75 | $0.00 | (A) 16 November 2008 | (B) 16 November 2017 |
| LaRose, J | 382,102 | 764,204 | 27 April 2005 | $0.26 | $0.50 | 27 April 2006 | 27 April 2015 |
| | 1,540,000 | 1,540,000 | 24 January 2005 | $0.36 | $0.20 | 31 January 2005 | 24 January 2010 |
| | 50,000 | 200,000 | 28 October 2006 | $0.50 | $1.10 | 28 October 2007 | 28 October 2016 |
| | – | 300,000 | 16 November 2007 | $0.75 | $0.00 | (A) 16 November 2008 | (B) 16 November 2017 |
| McIntyre, D | 191,051 | 191,051 | 24 January 2005 | $0.23 | $0.60 | 24 January 2006 | 24 January 2010 |
| | 191,051 | 191,051 | 24 January 2005 | $0.20 | $0.75 | 24 January 2007 | 24 January 2010 |
| | – | 191,051 | 24 January 2005 | $0.17 | $1.00 | 24 January 2008 | 24 January 2010 |
| | – | 191,051 | 24 January 2005 | $0.12 | $1.50 | 24 January 2009 | 24 January 2010 |
| | 382,102 | 764,204 | 15 December 2005 | $0.38 | $0.75 | 31 January 2007 | 15 December 2013 |
| | 50,000 | 200,000 | 28 October 2006 | $0.50 | $1.10 | 28 October 2007 | 28 October 2016 |
| | – | 400,000 | 16 November 2007 | $0.75 | $0.00 | (A) 16 November 2008 | (B) 16 November 2017 |
| Foley, J | – | 1,000,000 | 2 January 2007 | $0.43 | $1.10 | 2 January 2008 | 2 January 2017 |
| | – | 200,000 | 16 November 2007 | $0.75 | $0.00 | (A) 16 November 2008 | (B) 16 November 2017 |
| Reedy, J | 573,153 | 1,146,306 | 27 April 2005 | $0.26 | $0.50 | 27 April 2005 | 27 April 2015 |
| | 50,000 | 200,000 | 28 October 2006 | $0.50 | $1.10 | 28 October 2007 | 28 October 2016 |
| Schuermann, J | – | 900,000 | 16 November 2007 | $0.42 | $0.75 | (A) 16 November 2008 | (B) 16 November 2017 |
| | – | 100,000 | 16 November 2007 | $0.75 | $0.00 | (A) 16 November 2008 | (B) 16 November 2017 |
| **Total** | **3,709,459** | **9,878,918** | | | | | |

Notes:

(A) 16 November 2008 is the earliest exercise date for the first tranche of this grant of equity. However, vesting does not occur until certain performance conditions are satisfied. The performance hurdles are as follows:

(i) Vesting for the first tranche, representing 25% of the total allotment, occurs on the last to occur of the first anniversary of the grant date, the Company receiving CE marking in Europe, the Company filing its application for Therapeutic Goods Administration approval and the commencement of the Company's Bridge-to-Transplant clinical trial in the United States.

(ii) Vesting for the second tranche, representing 25% of the total allotment, occurs on the last to occur of the second anniversary of the grant date and the completion of enrolment under the Company's Bridge-to-Transplant trial in the United States.

(iii) Vesting for the third tranche, representing 25% of the total allotment, occurs on the last to occur of the third anniversary of the grant date, the Company filing an application for Pre-Market Approval with the United States Food and Drug Administration as a Bridge-to-Transplant therapy and the completion of enrolment under the Company's Destination Therapy clinical trial in the United States.

(iv) Vesting for the fourth tranche, representing 25% of the total allotment, occurs on the last to occur of the fourth anniversary of the grant date and the Company completing a human feasibility study for its next generation device, the MVAD.

(B) Unvested equity lapses on the fifth anniversary of the grant date. Unexercised, vested equity expires on the tenth anniversary of the grant date.

## SECTION 3 – APPENDIX A TO THE REMUNERATION REPORT

### OPTION HOLDINGS OF DIRECTORS AND OTHER KEY MANAGEMENT PERSONNEL

| | | | | | | | Vested 31 December 2007 | | |
|---|---|---|---|---|---|---|---|---|---|
| **Parent Entity Directors** | **Note** | **Balance 1 January 2007** | **Granted as compen-sation** | **Net change** | **Options exercised** | **Balance 31 December 2007** | **Total** | **Not exercisable** | **Exercisable** |
| Thomas, R | (a), (b) | 1,264,204 | – | – | – | 1,264,204 | 782,102 | – | 782,102 |
| Harrison, S | | – | – | – | – | – | – | – | – |
| Stockman, R | (b) | – | 200,000 | – | – | 200,000 | – | – | – |
| Wade, D | (a) | 250,000 | – | – | – | 250,000 | 200,000 | – | 200,000 |
| Bennett, C | (a) | 250,000 | – | – | – | 250,000 | 200,000 | – | 200,000 |
| Godshall, D* | (b) | 5,581,264 | – | – | – | 5,581,264 | 1,395,316 | – | 1,395,316 |
| **Total** | | **7,345,468** | **200,000** | **–** | **–** | **7,545,468** | **2,577,418** | **–** | **2,577,418** |

* On 20 November 2007, the Company announced its intention to seek shareholder approval in 2008 to grant 1.1 million performance rights to Mr Godshall with a zero strike price. No such approval has been obtained, and therefore no performance rights have been issued (or recorded above), at the date of this report.

| | | | | | | | Vested 31 December 2007 | | |
|---|---|---|---|---|---|---|---|---|---|
| **Other Key Management Personnel** | **Note** | **Balance 1 January 2007** | **Granted as compen-sation** | **Net change** | **Options exercised** | **Balance 31 December 2007** | **Total** | **Not exercisable** | **Exercisable** |
| Rowe, D | (b), (c) | 1,200,000 | 200,000 | – | – | 1,400,000 | 300,000 | – | 300,000 |
| LaRose, J | (b), (c) | 2,504,204 | 300,000 | – | – | 2,804,204 | 1,972,102 | – | 1,972,102 |
| McIntyre, D | (b), (c) | 1,728,408 | 400,000 | – | – | 2,128,408 | 814,204 | – | 814,204 |
| Foley, J | (b), (c) | – | 1,200,000 | – | – | 1,200,000 | – | – | – |
| Reedy, J | (b), (c) | 1,346,306 | – | – | – | 1,346,306 | 623,153 | – | 623,153 |
| Schuermann, J | (b), (c) | – | 1,000,000 | – | – | 1,000,000 | – | – | – |
| **Total** | | **6,778,918** | **3,100,000** | **–** | **–** | **9,878,918** | **3,709,459** | **–** | **3,709,459** |

Notes:

(a) The options refer to Incentive Options, further details of which are set out below under the heading "Options". In relation to Mr Thomas, 764,204 of his options were granted under the Company's ESOP with the balance comprising Incentive Options.

(b) The options refer to performance rights granted under the Company's Performance Rights Plan ("PRP"). Ms Foley's equity includes 1,000,000 options granted under the Company's ESOP with the remainder constituting performance rights. Mr Schuermann's equity includes 900,000 options granted under the Company's ESOP with the remainder constituting performance rights.

(c) In accordance with the terms of the Company's ESOP Rules and the PRP Rules, each option/performance right entitles the holder to purchase one ordinary share at the relevant exercise price (with the strike price under the PRP being zero) and subject to satisfaction of performance hurdles, if any.

Net Change refers to those options that have been forfeited or cancelled in accordance with the terms of the Company's ESOP Rules.

## SECTION 4 – APPENDIX A TO THE REMUNERATION REPORT

### COMPENSATION FOR DIRECTORS AND OTHER KEY MANAGEMENT PERSONNEL

| | | Short-term benefits | | | Other benefits | Notes | Post employment | | Share-based payments | | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Parent Entity Directors** | | Salary & fees | Cash bonus | Non-monetary | | | Super-annuation | Retire-ment benefits | Options* | % of total remun. | |
| Thomas, R | 2007 | 120,000 | – | – | – | | 10,800 | – | – | – | 130,800 |
| | 2006 | 120,000 | – | – | – | | 10,800 | – | – | – | 130,800 |
| Harrison, S | 2007 | 100,000 | – | – | – | | 9,000 | – | – | – | 109,000 |
| | 2006 | 100,000 | – | – | – | | 9,000 | – | – | – | 109,000 |
| Stockman, R | 2007 | – | – | – | – | (a) | – | – | 64,667 | – | 64,667 |
| | 2006 | – | – | – | – | | – | – | – | – | – |
| Wade, D | 2007 | 35,000 | – | – | – | | 30,400 | – | – | – | 65,400 |
| | 2006 | 35,000 | – | – | – | | 30,400 | – | – | – | 65,400 |
| Bennett, C | 2007 | 60,000 | – | – | – | | 5,400 | – | – | – | 65,400 |
| | 2006 | 60,000 | – | – | – | | 5,400 | – | – | – | 65,400 |
| Godshall, D | 2007 | 417,462 | 84,983 | – | 15,952 | | – | – | – | – | 518,397 |
| | 2006 | 115,441 | 98,949 | – | 3,524 | (b) | – | – | 2,802,962 | 93% | 3,020,876 |
| **Total Remun-eration** | **2007** | **732,462** | **84,983** | **–** | **15,952** | | **55,600** | **–** | **64,667** | **7%** | **953,664** |
| **Total Remun-eration** | **2006** | **430,441** | **98,949** | **–** | **3,524** | | **55,600** | **–** | **2,802,962** | **83%** | **3,391,476** |

* Black-Scholes option valuation incorporating an annualised standard deviation of return of 51.10% (2006: 55.14%) for European style options.

## COMPENSATION FOR DIRECTORS AND OTHER KEY MANAGEMENT PERSONNEL (continued)

| | | Short-term benefits | | | Other benefits | Notes | Post employment | | Share-based payments | | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Other Key Management Personnel** | | Salary & fees | Cash bonus | Non-monetary | | | Super-annuation | Retire-ment benefits | Options* | % of total remun. | |
| Rowe, D | 2007 | 268,368 | 32,204 | – | 15,952 | (c), (d) | – | – | 149,000 | 33% | 465,524 |
| | 2006 | 194,220 | – | – | 8,946 | (c) | – | – | 970,071 | 81% | 1,173,237 |
| LaRose, J | 2007 | 268,368 | 53,674 | – | 15,952 | (c) (e) | – | – | 223,500 | 41% | 561,494 |
| | 2006 | 279,088 | 59,370 | – | 13,154 | (c) | – | – | 100,300 | 22% | 451,912 |
| McIntyre, D | 2007 | 268,368 | 53,674 | – | 144,769 | (c), (f), (g) | – | – | 298,000 | 40% | 764,811 |
| | 2006 | 246,494 | 46,176 | 4,497 | 151,205 | (c), (g) | 6,600 | – | 100,300 | 18% | 544,175 |
| Foley, J | 2007 | 252,313 | 71,565 | – | 15,952 | (c), (h) | – | – | 576,333 | 64% | 916,163 |
| | 2006 | – | – | – | – | (c), (h) | – | – | – | – | – |
| Reedy, J | 2007 | 261,487 | – | – | 277,439 | (c), (i) | – | – | – | – | 538,926 |
| | 2006 | 263,865 | 32,983 | – | 14,850 | (c) | – | – | 100,300 | 24% | 411,998 |
| Schuermann, J | 2007 | 77,414 | – | – | 4,310 | (c) | – | – | 480,740 | 86% | 562,464 |
| | 2006 | – | – | – | – | | – | – | – | – | – |
| **Total Remun-eration** | **2007** | 1,396,318 | 211,117 | – | 212,887 | | – | – | 1,727,573 | 49% | 3,547,895 |
| **Total Remun-eration** | **2006** | 983,667 | 138,529 | 4,497 | 188,155 | | 6,600 | – | 1,270,971 | 49% | 2,581,332 |

* Black-Scholes option valuation incorporating an annualised standard deviation of 55.14% (2006: 55.14%). This figure also includes performance rights granted under the Performance Rights Plan that have a strike price of zero and a fair value at the grant date of $0.75.

## COMPENSATION FOR DIRECTORS AND OTHER KEY MANAGEMENT PERSONNEL (continued)

**Notes:**

(a) Pursuant to shareholder approval Mr Stockman was granted 200,000 options under the Company's ESOP with a strike price of $0.75 each. Mr Stockman did not draw a salary or other fees during the financial year.

(b) In accordance with the terms of his employment, Mr Godshall was paid a one-off sign-on bonus on commencement of employment of $98,949 in September 2006 (being US$75,000).

(c) Unless otherwise stated, the Other Benefit refers to the cost of the relevant employee's participation in the Company's medical and insurance scheme (which is available to all employees).

(d) Mr Rowe was paid a cash bonus of $32,204 (being US$27,000) on 31 October 2007 as part of a Company-wide bonus in recognition of the Company's progress.

(e) Mr LaRose was paid a cash bonus of $53,674 (being US$45,000) on 31 October 2007 as part of a Company-wide bonus in recognition of the Company's progress.

(f) Mr McIntyre was paid a cash bonus of $53,674 (being US$45,000) on 31 October 2007 as part of a Company-wide bonus in recognition of the Company's progress.

(g) At the Company's request, Mr McIntyre has relocated to the United States of America. Following an independent assessment undertaken by Ernst & Young, the following payments were made to Mr McIntyre under his relocation arrangements:

  (i) In April 2006, a one-off payment of $36,611 as a relocation allowance, being US$27,750. This payment is subject to personal income tax in the United States at the normal statutory rate and was provided to assist with meeting out-of-pocket expenses that were incurred on relocation to the United States, such as installation and purchase of electrical appliances, house cleaning, establishment of utilities, telephone installation etc, together with associated costs of leaving Australia (termination of existing services and utilities etc).

  (ii) A monthly after-tax payment 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 the United States of America. In 2006, a pre-tax amount of US$80,077 ($105,647) has been paid to Mr McIntyre in this regard while in 2007 an amount of US$108,000 ($128,817) has been paid.

(h) In accordance with Ms Foley's employment agreement, Ms Foley was paid US$30,000 ($35,782) on commencement of employment on 2 January 2007 and this amount is included in the disclosed salary amount. Ms Foley was also paid a cash bonus of $35,782 (being US$30,000) on 31 October 2007 as part of a Company-wide bonus in recognition of the Company's progress.

(i) Ms Reedy has entered into a Separation Agreement with the Company pursuant to which Ms Reedy resigns her positions with the Company with effect from 31 December 2007. Pursuant to this agreement, Ms Reedy is entitled to receive twelve months salary, being US$220,000 ($261,487), over the course of 2008 and otherwise in accordance with normal pay periods. This amount, which constitutes a termination benefit, is included in Other Benefits and has been accrued at 31 December 2007.

(j) Ms Schuermann commenced his position with the Company on 4 September 2007.

In addition to the above, all of the above employees are provided with a mobile telephone or Blackberry at no cost to the employee.

## SECTION 5 – APPENDIX A TO THE REMUNERATION REPORT

## SHAREHOLDINGS OF DIRECTORS AND OTHER KEY MANAGEMENT PERSONNEL

| | Note | Balance 1 January 2007 | Granted as remuneration | Options exercised | Net change* other | Balance 31 December 2007 |
|---|---|---|---|---|---|---|
| **Parent Entity Directors** | | | | | | |
| Thomas, R | (a) | 1,758,000 | – | – | 600,000 | 2,358,000 |
| Harrison, S | (b) | 91,588,782 | – | – | – | 91,588,782 |
| Stockman, R | | – | – | – | 500,000 | 500,000 |
| Wade, D | (c) | 1,000,000 | – | – | 8,333 | 1,008,333 |
| Bennett, C | | – | – | – | – | – |
| Godshall, D | | 37,305 | – | – | 63,000 | 100,305 |
| **Other Key Management Personnel** | | | | | | |
| Rowe, D | | 10,000 | – | – | – | 10,000 |
| LaRose, J | | – | – | – | – | – |
| McIntyre, D | | 28,000 | – | – | – | 28,000 |
| Foley, J | | – | – | – | – | – |
| Reedy, J | | – | – | – | – | – |
| Schuermann, J | | – | – | – | – | – |
| Total | | 94,422,087 | – | – | 1,071,333 | 95,593,420 |

* Net Change Other refers to shares purchased or sold during the year.

**Notes:**

(a) Mr Thomas owns shares in the Company through a variety of direct and indirect holdings. The bulk of Mr Thomas' indirect shareholding is held by himself and his wife (Mrs Kyrenia Thomas) as trustee of the Robert Thomas Superannuation Fund.

(b) As noted elsewhere in this Directors' Report, Dr Harrison is the Managing General Partner of Apple Tree Partners I LP ("Apple Tree Partners"), the Company's largest shareholder. To this end, the shares set out in the table above refer to shares owned by Apple Tree Partners.

Under Dr Harrison's employment arrangement with Apple Tree Partners, he is prohibited from having an interest, directly or indirectly, in any entity in which Apple Tree Partners has invested. For this reason, Dr Harrison has no share or option holding in HeartWare (other than indirectly via Apple Tree Partners).

It should also be noted that, in connection with the acquisition of HeartWare, Inc. by HeartWare Limited, the Company issued a convertible note in favour of Apple Tree Partners in the amount of $1,420,000 which will accrue interest at 2.0% per annum (capitalised monthly in arrears). The conversion price is $1.00 per ordinary share. The principal and capitalised interest on the convertible note is repayable on the secondary anniversary of the date of issue of the convertible note (being 24 January 2007). As Managing General Partner of Apple Tree Partners and for the purposes of the *Corporations Act 2001*, Dr Harrison is deemed to have an indirect interest in this convertible note.

(c) The shares are held by Nickeli Holdings Pty Limited as trustee of the Wade Family Superannuation Fund. The options refer to Incentive Options, further details of which are set out below under the heading "Options".

### Remuneration Benefits

Apart from the details disclosed in this note, no Director has entered into a material contract with the Company or the Consolidated Group during the year and there were no material contracts involving Directors' interests subsisting at anytime.

At 31 December 2007, there were no amounts receivable from or payable to directors and their director-related entities.

Grant Thornton

**Grant Thornton NSW**
**ABN 25 034 787 757**

**Level 17, 383 Kent Street**
**Sydney NSW 2000**
**PO Locked Bag Q800**
**QVB Post Office**
**Sydney NSW 1230**

**T** +61 2 8297 2400
**F** +61 2 9299 4445
**E** info@gtnsw.com.au
**W** www.grantthornton.com.au

## INDEPENDENT AUDITOR'S REPORT
## TO THE MEMBERS OF HEARTWARE LIMITED

We have audited the accompanying financial report of HeartWare Limited (the company), which comprises the balance sheet as at 31 December 2007, and the income statement, statement of changes in equity and cash flow statement for the year ended on that date, a summary of significant accounting policies and other explanatory notes of the company and the consolidated entity, comprising the company and the entities it controlled at the year's end or from time to time during the financial year.

### Directors' responsibility for the financial report

The directors of the company are responsible for the preparation and fair presentation of the financial report in accordance with Australian Accounting Standards (including the Australian Accounting Interpretations) and the Corporations Act 2001. This responsibility includes establishing and maintaining internal controls relevant to the preparation and fair presentation of the financial report that is free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting policies; and making accounting estimates that are reasonable in the circumstances. In Note 1 the directors also state, in accordance with Accounting Standard AASB 101: Presentation of Financial Statements, that compliance with the Australian equivalents to International Financial Reporting Standards ensures that the financial report, comprising the financial statements and notes, complies with International Financial Reporting Standards.

As permitted by the Corporations Regulations 2001, the company has disclosed information about the remuneration of directors and executives (remuneration disclosures), required by Accounting Standards AASB 124: Related Party Disclosures, under the heading "remuneration report" on pages 26 to 44 of the directors' report and not in the financial report.

The directors are also responsible for preparation and presentation of the remuneration disclosures contained in the directors' report in accordance with the Corporations Regulations 2001.

### Auditor's responsibility

Our responsibility is to express an opinion on the financial report based on our audit. We conducted our audit in accordance with Australian Auditing Standards, which require us to comply with relevant ethical requirements relating to audit engagements and plan and perform the audit to obtain reasonable assurance as to whether the financial report is free of material misstatement.

Grant Thornton

**INDEPENDENT AUDITOR'S REPORT**
**TO THE MEMBERS OF HEARTWARE LIMITED (cont)**

**Auditor's responsibility (cont)**
An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial report. The procedures selected depend on the auditor's judgement, including the assessment of the risks of material misstatement of the financial report, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial report in order to design audit procedures that are appropriate in the circumstance, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the financial report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

**Independence**
In conducting our audit, we complied with the independence requirements of the Corporations Act 2001.

**Auditor's opinion**
In our opinion:

a the financial report of HeartWare Limited is in accordance with the Corporations Act 2001, including:

  i giving a true and fair view of the company's and consolidated entity's financial position as at 31 December 2007 and of their performance for the year ended on that date; and

  ii complying with Australian Accounting Standards (including the Australian Accounting Interpretations) and the Corporations Regulations 2001; and

b the financial report also complies with International Financial Reporting Standards as disclosed in Note 1.

c the remuneration disclosures that are contained on pages 26 to 44 of the directors' report comply with Accounting Standard AASB 124.

Grant Thornton NSW

GRANT THORNTON NSW
Chartered Accountants

M A ADAM-SMITH
Partner

Sydney, 29 February 2008

# Auditor's Independence Declaration

Grant Thornton

**Grant Thornton NSW**
ABN 25 034 787 757

Level 17, 383 Kent Street
Sydney NSW 2000
PO Locked Bag Q800
QVB Post Office
Sydney NSW 1230

T +61 2 8297 2400
F +61 2 9299 4445
E info@gtnsw.com.au
W www.grantthornton.com.au

**AUDITOR'S INDEPENDENCE DECLARATION**
**TO THE DIRECTORS OF HEARTWARE LIMITED**

In accordance with the requirements of section 307C of the Corporations Act 2001, as lead auditor for the audit of HeartWare Limited for the year ended 31 December 2007, I declare that, to the best of my knowledge and belief, there have been:

a no contraventions of the auditor independence requirements of the Corporations Act 2001 in relation to the audit; and

b no contraventions of any applicable code of professional conduct in relation to the audit.

Grant Thornton NSW

GRANT THORNTON NSW
Chartered Accountants

M A ADAM-SMITH
Partner

Sydney, 29 February 2008

# Directors' Declaration

The directors of HeartWare Limited declare that:

(a) the financial statements and notes, set out on pages 61 to 90, are in accordance with the Corporations Act 2001 and:

  (i) give a true and fair view of the financial position as at 31 December 2007 and of the performance for the year ended on that date of the Company and Consolidated Group; and

  (ii) comply with Accounting Standards and the Corporations Regulations 2001; and

(b) the Chief Executive Officer and Chief Financial Officer have each declared that:

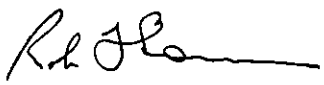
  (i) the financial records of the Company and the Consolidated Group for the financial year have been properly maintained in accordance with section 286 of the Corporations Act 2001;

  (ii) the financial statements and notes for the financial year comply with Australian Accounting Standards; and

  (iii) the financial statements and notes for the financial year give a true and fair view; and

(c) in the Directors' opinion there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

Signed in accordance with a resolution of the Directors:



ROB THOMAS
Chairman
Date 29 February 2008

# Income Statement

**For the year ended 31 December 2007**

| | Note | Consolidated group | | Parent entity | |
|---|---|---|---|---|---|
| | | 2007 $ | 2006 $ | 2007 $ | 2006 $ |
| Revenue | 2 | 1,150,040 | 1,143,912 | 1,089,199 | 1,100,864 |
| Administrative and facilities expenses | | (616,162) | (516,717) | (309,765) | (112,014) |
| Advertising and marketing expenses | | (166,983) | (106,790) | (91,296) | (82,209) |
| Audit, financial and taxation services | | (233,231) | (186,468) | (189,423) | (174,622) |
| Consultants – clinical, regulatory and medical | | (2,240,969) | (1,624,884) | – | – |
| Consultants – corporate advisory and investor relations | | (159,269) | (283,567) | (129,929) | (283,567) |
| Contractor expenses | | (1,152,546) | (201,952) | (36,154) | – |
| Depreciation and amortization expenses | 3 | (810,881) | (746,821) | (60,624) | (100,259) |
| Share-based payments to employees and directors | 25 | (2,762,319) | (1,174,620) | (2,762,319) | (1,174,620) |
| Other employee and director benefits expenses | | (10,677,938) | (10,043,836) | (802,658) | (2,421,829) |
| Net loss on foreign exchange transactions | | (1,042,508) | (770,227) | (1,042,507) | (770,227) |
| Information technology expense | | (372,026) | (278,385) | (31,271) | (46,654) |
| Insurance expenses | | (206,524) | (269,700) | (49,411) | (54,322) |
| Legal expense – intellectual property protection, litigation costs and related expenditure | | (191,425) | (584,397) | – | (4,405) |
| Legal expense – corporate, compliance and commercial advisory | | (1,038,896) | (529,163) | (822,314) | (276,003) |
| Raw materials and consumables used | | (1,043,583) | (2,223,821) | – | – |
| Rental expense and outgoings | | (953,042) | (699,350) | (122,153) | (199,735) |
| Research and development expenses | | (550,306) | (1,695,837) | – | – |
| Sterilisation and testing expenses | | (174,241) | (133,899) | – | – |
| Tax and duties expenses, other than income tax | | (236,407) | (131,178) | – | – |
| Travel, accommodation and related expenses | | (1,645,113) | (1,357,808) | (177,615) | (467,143) |
| Trials expenses – animal and human | | (587,837) | (435,839) | – | (12,649) |
| Validation and verification expense | | (18,575) | (228,178) | – | – |
| Other expenses | | (645,906) | (171,128) | (55,089) | (144,410) |
| **(Loss) before income tax** | | **(26,376,647)** | **(23,250,653)** | **(5,592,329)** | **(5,223,804)** |
| Income tax expense | 5 | – | – | – | – |
| **(Loss) attributable to members of HeartWare Limited** | | **(26,376,647)** | **(23,250,653)** | **(5,592,329)** | **(5,223,804)** |
| | | **Cents** | **Cents** | | |
| Basic and diluted (loss) per share (cents per share) | 6 | (12.4) | (13.3) | | |

*The Financial Statements should be read in conjunction with the accompanying notes.*

# Balance Sheet

**As at 31 December 2007**

| | Note | Consolidated group 2007 $ | Consolidated group 2006 $ | Parent entity 2007 $ | Parent entity 2006 $ |
|---|---|---|---|---|---|
| Current Assets | | | | | |
| Cash and cash equivalents | 8 | 32,073,942 | 21,101,693 | 31,225,265 | 20,267,573 |
| Trade and other receivables | 9 | 180,035 | 153,905 | 191,062 | 166,658 |
| Other current assets | 10 | 705,785 | 609,916 | 244,676 | 236,350 |
| **Total Current Assets** | | 32,959,762 | 21,865,514 | 31,661,003 | 20,670,581 |
| Non-Current Assets | | | | | |
| Financial assets | 11 | - | - | 100,094,335 | 78,897,414 |
| Property, plant and equipment | 13 | 3,072,874 | 3,140,329 | 28,185 | 193,409 |
| Intangible assets | 14 | 2,592,089 | 2,881,771 | 3,561 | 4,390 |
| Other non-current assets | 10 | - | 2,527 | - | - |
| **Total Non-Current Assets** | | 5,664,963 | 6,024,627 | 100,126,081 | 79,095,213 |
| **Total Assets** | | 38,624,725 | 27,890,141 | 131,787,084 | 99,765,794 |
| Current Liabilities | | | | | |
| Trade and other payables | 15 | 1,665,561 | 1,782,239 | 102,684 | 236,776 |
| Financial liabilities | 17 | 1,517,689 | 1,495,676 | 1,517,689 | 1,495,676 |
| Short-term provisions | 16 | 311,870 | 200,608 | 28,849 | 19,328 |
| **Total Current Liabilities** | | 3,495,120 | 3,478,523 | 1,649,222 | 1,751,780 |
| Non-Current Liabilities | | | | | |
| Financial liabilities | 17 | - | 20,139 | - | 20,139 |
| **Total Non-Current Liabilities** | | - | 20,139 | - | 20,139 |
| **Total Liabilities** | | 3,495,120 | 3,498,662 | 1,649,222 | 1,771,919 |
| **Net Assets** | | **35,129,605** | **24,391,479** | **130,137,862** | **97,993,875** |
| Equity | | | | | |
| Issued capital | 18 | 94,647,107 | 59,673,110 | 140,230,916 | 105,256,919 |
| Reserves | 19 | 5,647,770 | 3,506,994 | 6,489,531 | 3,727,212 |
| Retained earnings | | (65,165,272) | (38,788,625) | (16,582,585) | (10,990,256) |
| **Total Equity** | | **35,129,605** | **24,391,479** | **130,137,862** | **97,993,875** |

*The Financial Statements should be read in conjunction with the accompanying notes.*

# Statement of Changes in Equity

**For the year ended 31 December 2007**

| | Consolidated group | | | | | |
|---|---|---|---|---|---|---|
| | Share capital $ | Foreign currency translation reserve $ | Share option reserve $ | Exercised options reserve $ | Retained earnings $ | Total $ |
| **Balance at 1 January 2006** | 28,824,205 | 112,210 | 2,408,356 | 144,236 | (15,537,972) | 15,951,035 |
| Currency translation | – | (332,428) | – | – | – | (332,428) |
| Net income recognized directly in equity | – | (332,428) | – | – | – | (332,428) |
| Loss for the period | – | – | – | – | (23,250,653) | (23,250,653) |
| **Total recognized income and expense for the period** | – | (332,428) | – | – | (23,250,653) | (23,583,081) |
| Shares issued | 32,869,695 | – | – | – | – | 32,869,695 |
| Transaction costs | (2,020,790) | – | – | – | – | (2,020,790) |
| Employee share based compensation | – | – | 1,044,435 | 130,185 | – | 1,174,620 |
| **Balance at 31 December 2006** | 59,673,110 | (220,218) | 3,452,791 | 274,421 | (38,788,625) | 24,391,479 |
| Currency translation | – | (621,543) | – | – | – | (621,543) |
| Net income recognized directly in equity | – | (621,543) | – | – | – | (621,543) |
| Loss for the period | – | – | – | – | (26,376,647) | (26,376,647) |
| **Total recognized income and expense for the period** | – | (621,543) | – | – | (26,376,647) | (26,998,190) |
| Shares issued | 37,051,408 | – | – | – | – | 37,051,408 |
| Transactions costs | (2,077,411) | – | – | – | – | (2,077,411) |
| Employee share based compensation | – | – | 2,715,627 | 46,692 | – | 2,762,319 |
| **Balance at 31 December 2007** | 94,647,107 | (841,761) | 6,168,418 | 321,113 | (65,165,272) | 35,129,605 |

*The Financial Statements should be read in conjunction with the accompanying notes.*

# Statement of Changes in Equity (continued)

**For the year ended 31 December 2007**

| | Parent entity | | | | | |
|---|---|---|---|---|---|---|
| | Share capital $ | Foreign currency translation reserve $ | Share option reserve $ | Exercised options reserve $ | Retained earnings $ | Total $ |
| **Balance at 1 January 2006** | 74,408,014 | – | 2,408,356 | 144,236 | (5,766,452) | 71,194,154 |
| Net income recognized directly in equity | – | – | – | – | – | – |
| Loss for the period | – | – | – | – | (5,223,804) | (5,223,804) |
| **Total recognized income and expense for the period** | – | – | – | – | (5,223,804) | (5,223,804) |
| Shares issued | 32,869,695 | – | – | – | – | 32,869,695 |
| Transaction costs | (2,020,790) | – | – | – | – | (2,020,790) |
| Employee share based compensation | – | – | 1,044,435 | 130,185 | – | 14,174,620 |
| **Balance at 31 December 2006** | 105,256,919 | – | 3,452,791 | 274,421 | (10,990,256) | 97,993,875 |
| Net income recognized directly in equity | – | – | – | – | – | – |
| Loss for the period | – | – | – | – | (5,592,329) | (5,592,329) |
| **Total recognized income and expense for the period** | – | – | – | – | (5,592,329) | (5,592,329) |
| Shares issued | 37,051,408 | – | – | – | – | 37,051,408 |
| Transaction costs | (2,077,411) | – | – | – | – | (2,077,411) |
| Employee share based compensation | – | – | 2,715,627 | 46,692 | – | 2,762,319 |
| **Balance at 31 December 2007** | 140,230,916 | – | 6,168,418 | 321,113 | (16,582,585) | 130,137,862 |

*The Financial Statements should be read in conjunction with the accompanying notes.*

# Cash Flow Statement

**For the year ended 31 December 2007**

| | Note | Consolidated group 2007 $ | Consolidated group 2006 $ | Parent entity 2007 $ | Parent entity 2006 $ |
|---|---|---|---|---|---|
| Cash flows from operating activities | | | | | |
| Receipts from customers | | – | – | – | – |
| Payments to suppliers and employees | | (23,836,052) | (22,343,699) | (3,861,599) | (5,054,570) |
| Interest received | | 1,085,157 | 1,157,557 | 1,024,316 | 1,114,509 |
| Finance costs | | (690) | (488) | (690) | (488) |
| **Net cash used in operating activities** | 23(a) | **(22,751,585)** | **(21,186,630)** | **(2,837,973)** | **(3,940,549)** |
| Cash flows from investing activities | | | | | |
| Loans to subsidiary | | – | – | 12,040 | 17,214 |
| Proceeds from sale of property plant and equipment | | 9,569 | 3,735 | 6,546 | – |
| Payments for purchase of property, plant and equipment | | (908,984) | (1,827,710) | – | (15,167) |
| Payments for shares in subsidiary | | – | – | (21,196,918) | (19,995,843) |
| Payments for intangible assets | | (265,311) | (393,072) | – | (4,988) |
| **Net cash used in investing activities** | | **(1,164,726)** | **(2,217,047)** | **(21,178,332)** | **(19,998,784)** |
| Cash flows from financing activities | | | | | |
| Proceeds from issues of shares | | 37,051,408 | 32,869,695 | 37,051,408 | 32,869,695 |
| Payments for share issue expenses | | (2,077,411) | (2,020,790) | (2,077,411) | (2,020,790) |
| **Net cash provided by financing activities** | | **34,973,997** | **30,848,905** | **34,973,997** | **30,848,905** |
| **Net increase in cash held** | | **11,057,686** | **7,445,228** | **10,957,692** | **6,909,572** |
| **Cash at beginning of the year** | | **21,101,693** | **13,679,897** | **20,267,573** | **13,358,001** |
| Effect of exchange rates on cash holdings in foreign currencies | | (85,437) | (23,432) | – | – |
| **Cash at end of the year** | 8 | **32,073,942** | **21,101,693** | **31,225,265** | **20,267,573** |

*The Financial Statements should be read in conjunction with the accompanying notes.*

## 1. STATEMENT OF SIGNIFICANT ACCOUNTING POLICIES

The Annual Financial Report is a general purpose financial report which has been prepared in accordance with Australian Accounting Standards, Australian Accounting Interpretations, other authoritative pronouncements of the Australian Accounting Standards Board and the Corporations Act 2001 ("the Corporations Act").

The Annual Financial Report covers the Consolidated Group of HeartWare Limited ("HeartWare" or "the Company") and its controlled entity, HeartWare, Inc., a Delaware corporation ("the Consolidated Group" or "the HeartWare Group"). The Annual Financial Report also covers HeartWare as an individual parent entity. HeartWare is a listed public company, the ordinary shares of which are listed for quotation on the Australian Securities Exchange Limited. HeartWare is incorporated and domiciled in Australia.

The Annual Financial Report is prepared on a going concern basis as the directors consider that the Company has, or will be able to access, sufficient cash resources to enable it to continue as a going concern.

### Reporting and Comparative Periods

The financial results set out in this Annual Financial Report are the consolidated financial results for the HeartWare Group for the twelve-month period ended 31 December 2007.

### Basis of Preparation

The Annual Financial Report of HeartWare and its controlled entity, and HeartWare an individual parent entity, complies with Australian Accounting Standards, which include Australian equivalents to International Financial Reporting Standards ("AIFRS"), in their entirety. Compliance with AIFRS ensures that the financial report also complies with International Financial Reporting Standards in their entirety.

The accounting policies set out below have been consistently applied to all years presented, with the exception of the change in accounting policy (refer to Note 32 to the Financial Statements).

### Reporting Basis and Conventions

The Annual Financial Report has been prepared on an accruals basis and is based on historical costs modified by the revaluation of selected non-current assets, financial assets and financial liabilities for which the fair value basis of accounting has been applied.

### Denomination

All figures ("$") referred to in this Annual Financial Report are denominated in Australian dollars.

### Accounting Policies

#### (a) Principles of Consolidation

A controlled entity is any entity controlled by the Company whereby the Company has the power to control the financial and operating policies of that entity so as to obtain benefits from its activities.

A list of controlled entities is contained in Note 12 to the Financial Statements. All controlled entities have a December financial year-end.

All inter-company balances and transactions between entities in the Consolidated Group, including any unrealised profits or losses, have been eliminated on consolidation. Accounting policies of subsidiaries have been changed where necessary to ensure consistencies with those policies applied by the parent entity.

Where controlled entities have entered or left the Consolidated Group during the year, their operating results have been included/excluded from the date control was obtained or until the date control ceased.

In Australia, the accounting treatment for business combinations is set out in AASB 3: Business Combinations ("AASB 3"). However, the business combination whereby HeartWare Limited acquired HeartWare, Inc. on 24 January 2005 falls within the definition of a "business combination involving entities under common control" and this type of business combination is specifically scoped out of AASB 3. Further, there is presently no prescribed accounting treatment in Australia for business combinations involving entities under common control.

## 1. STATEMENT OF SIGNIFICANT ACCOUNTING POLICIES (continued)

For the purposes of this Annual Financial Report, the Consolidated Group has accounted for the acquisition of HeartWare, Inc. by HeartWare Limited as a business combination involving entities under common control and has recorded the transaction at the historical cost of the assets and liabilities of HeartWare, Inc. at the time of the acquisition (being 24 January 2005). Further information in this regard is contained in Note 32 to the Financial Statements. This represents a change of accounting policy from that adopted in the prior year's Annual Financial Report.

### (b) Income Tax

Deferred tax is accounted for using the balance sheet liability method in respect of temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the financial statements. No deferred income tax will be recognized from the initial recognition of an asset or liability, excluding a business combination, where there is no effect on accounting or taxable profit or loss.

Deferred tax is calculated at the tax rates that are expected to apply to the period when the asset is realised or liability is settled. Deferred tax is credited in the income statement except where it relates to items that may be credited directly to equity, in which case the deferred tax is adjusted directly against equity.

Deferred income tax assets are recognized to the extent that it is probable that future tax profits will be available against which deductible temporary differences can be utilised.

The amount of benefits brought to account or which may be realised in the future is based on the assumption that no adverse change will occur in income taxation legislation and the anticipation that the Consolidated Group will derive sufficient future assessable income to enable the benefit to be realised and comply with the conditions of deductibility imposed by the law.

### (c) Inventories

Inventories are measured at the lower of cost and net realisable value. The cost of manufactured products includes direct materials, direct labour and an appropriate portion of variable and fixed overheads. Overheads are applied on the basis of normal operating capacity. Costs are assigned on the basis of weighted average costs.

### (d) Property, Plant and Equipment

Each class of property, plant and equipment is carried at cost or fair value less, where applicable, any accumulated depreciation and impairment losses.

#### Plant and Equipment

Plant and equipment is measured on the cost basis less depreciation and impairment losses.

The carrying amount of plant and equipment is reviewed annually by Directors to ensure it is not in excess of the recoverable amount from these assets. The recoverable amount is assessed on the basis of the expected net cash flows that will be received from the assets employment and subsequent disposal. The expected net cash flows have been discounted to their present values in determining recoverable amounts.

The cost of fixed assets constructed within the Consolidated Group includes the cost of materials, direct labour, borrowing costs and an appropriate proportion of fixed and variable overheads.

Subsequent costs are included in the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Consolidated Group and the cost of the item can be measured reliably. All other repairs and maintenance are charged to the income statement during the financial period in which they are incurred.

#### Depreciation

The depreciable amount of all fixed assets including building and capitalised lease assets is depreciated on a straight line basis over their useful lives to the Consolidated Group commencing from the time the asset is held ready for use.

Leasehold improvements are depreciated over the shorter of either the unexpired period of the lease or the estimated useful lives of the improvements.

The depreciation rates used for each class of depreciable assets are:

| *Class of Fixed Asset* | *Depreciation Rate* |
|---|---|
| Leasehold improvements | 33% |
| Plant and equipment | 8–33% |

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at each balance sheet date.

## 1. STATEMENT OF SIGNIFICANT ACCOUNTING POLICIES (continued)

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Gains and losses on disposals are determined by comparing proceeds with the carrying amount. These gains and losses are included in the income statement.

### (e) Leases

Leases of fixed assets where substantially all the risks and benefits incidental to the ownership of the asset, but not the legal ownership are transferred to entities in the Consolidated Group are classified as finance leases.

Finance leases are capitalised by recording an asset and a liability at the lower of the amounts equal to the fair value of the leased property or the present value of the minimum lease payments, including any guaranteed residual values. Lease payments are allocated between the reduction of the lease liability and the lease interest expense for the period.

Leased assets are depreciated on a straight-line basis over their estimated useful lives where it is likely that the Consolidated Group will obtain ownership of the asset or over the term of the lease.

Lease payments for operating leases, where substantially all the risks and benefits remain with the lessor, are charged as expenses on a straight-line basis over the life of the lease term.

Lease incentives under operating leases are recognized as a liability and amortised on a straight-line basis over the life of the lease term.

### (f) Financial Instruments

The Consolidated Group has adopted AASB 7 Financial Instruments: Disclosures and all consequential amendments that became applicable on 1 January 2007. The adoption of this standard has only affected the disclosure in the financial statements. There has been no impact on profit and loss or the financial position of the Consolidated Group.

#### Recognition

Financial instruments are initially measured at cost on trade date, which includes transaction costs, when the related contractual rights or obligations exist. Subsequent to initial recognition these instruments are measured as set out below.

#### Loans and receivables

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market and are stated at amortised cost using the effective interest rate method.

#### Investments in subsidiaries

Investments in subsidiaries are measured at cost but are subject to impairment write-down to recoverable amount.

#### Financial liabilities

Non-derivative financial liabilities are recognized at amortised cost, comprising original debt less principal payments and amortization.

#### Impairment

At each reporting date, the Consolidated Group assesses whether there is objective evidence that a financial instrument has been impaired. Impairment losses are recognized in the Income Statement.

### (g) Impairment of assets

At each reporting date, the Consolidated Group reviews the carrying values of its tangible and intangible assets to determine whether there is any indication that those assets have been impaired. If such an indication exists the recoverable amount of the asset being the higher of the asset's fair value less costs to sell and value in use, is compared to the assets carrying value. Any excess of the asset's carrying value over its recoverable amount is expensed to the income statement.

Impairment testing is performed annually for intangible assets with indefinite lives.

Where it is not possible to estimate the recoverable amount of an individual asset, the Consolidated Group estimates the recoverable amount of the cash-generating unit to which the asset belongs.

### (h) Intangibles

#### Patents and trademarks

Patents and trademarks are recognized at cost of acquisition. Patents and trademarks have a definite life and are carried at cost less any accumulated amortization and any impairment losses. Patents and trademarks are amortized on a straight-line basis over their useful life, estimated at 15 years.

### Software

Software is recognized at cost. It has a finite life and is amortized on a systematic basis matched to the future benefits of the asset. Software is currently amortized on a straight-line basis over their estimated useful life ranging from 5 to 7 years.

### Research and development

Expenditure during the research phase of a project is recognized as an expense when incurred.

Development costs are capitalised only when technically feasibility studies identify that the project will deliver future economic benefits and these benefits can be measured reliably.

Development costs have a finite life and are amortized on a systematic basis matched to the future economic benefits over the useful life of the project.

## (i) Foreign Currency Transactions and Balances

### Functional and presentation currency

The functional currency of each of the Consolidated Group's entities is measured using the currency of the primary economic environment in which that entity operates. The consolidated financial statements are presented in Australian dollars which is the parent entity's functional and presentation currency.

### Transaction and balances

Foreign currency transactions are translated into functional currency using the exchange rates prevailing at the date of the transaction. Foreign currency monetary items are translated at the year-end exchange rate. Non-monetary items measured at historical cost continue to be carried at the exchange rate at the date of the transaction. Non-monetary items measured at fair value are reported at the exchange rate at the date when fair values were determined.

Exchange differences arising on the translation of monetary items are recognized in the income statement, except where deferred in equity as a qualifying cash flow or net investment hedge.

Exchange difference arising on the translation of non-monetary items are recognized directly in equity to the extent that the gain or loss is directly recognized in equity, otherwise the exchange difference is recognized in the income statement.

### Consolidated Group companies

The financial results and position of foreign operations whose functional currency is different from the Consolidated Group's presentation currency are translated as follows:

- Assets and liabilities are translated at year-end exchange rates prevailing at that reporting date.
- Income and expenses are translated at average exchange rates for the period.
- Retained profits are translated at the exchange rates prevailing at the date of the transaction.

Exchange differences arising on translation of foreign operations are transferred directly to the Consolidated Group's foreign currency translation reserve in the balance sheet. These differences are recognized in the income statement in the period in which the operation is disposed.

## (j) Employee Benefits

Provision is made for the Consolidated Group's liability for employee benefits arising from services rendered by employees to balance date. Employee benefits that are expected to be settled within one year have been measured at the amounts expected to be paid when the liability is settled, plus related on-costs. Employee benefits payable later than one year have been measured at the present value of the estimated future cash outflows to be made for those benefits.

## (k) Equity-settled compensation

The Consolidated Group operates two share-based compensation plans, being share option arrangements. The total amount to be expensed over the vesting period is determined by reference to the fair value of the shares of the options granted.

## (l) Provisions

Provisions are recognized when the Consolidated Group has a legal or constructive obligation, as a result of past events, for which it is probable that an outflow of economic benefits will results and that outflow can be reliably measured.

## 1. STATEMENT OF SIGNIFICANT ACCOUNTING POLICIES (continued)

### (m) Cash and Cash Equivalents

Cash and cash equivalents includes cash on hand, deposits held at call with banks, other short-term highly liquid investments with original maturities of three months or less, and bank overdrafts. Bank overdrafts are shown within short-borrowings in current liabilities on the balance sheet.

### (n) Goods and Services Tax ("GST")

Revenues, expenses and assets are recognized net of the amount of GST, except where the amount of GST incurred is not recoverable from the Australian Tax Office. In these circumstances the GST is recognized as part of the cost of acquisition of the asset or as part of an item of the expense. Receivables and payables in the balance sheet are shown inclusive of GST.

Cash flows are presented in the cash flow statement on a gross basis, except for the GST component of investing and financing activities, which are disclosed as operating cash flows.

### (o) Comparative Figures

When required by Accounting Standards, comparative figures have been adjusted to conform to changes in presentation for the current financial year.

### (p) Critical Accounting Estimates and Judgments

The directors evaluate estimates and judgments in the Annual Financial Report based on historical knowledge and best available current information. Estimates assume a reasonable expectation of future events and are based on current trends and economic data, obtained both externally and within the Consolidated Group.

#### Key Estimates — Impairment

The Consolidated Group assesses impairment at each reporting date by evaluating conditions specific to the Consolidated Group that may lead to impairment of assets. Where an impairment trigger exists, the recoverable amount of the asset is determined. Value-in-use calculations performed in assessing recoverable amounts incorporate a number of key estimates.

#### Key Estimates — Option Valuations

The Consolidated Group uses a Black-Scholes option value method in connection with the calculation of share-based payments expense and this requires the input of highly subjective judgment and assumptions, including an estimated expected life of the option, share price volatility and a forfeiture rate.

The assumptions used in calculating the fair value of share-based awards represent management's best estimates, but these estimates involve inherent uncertainties and the application of management judgment.

There are no other key estimates or assumptions that require specific disclosure.

## 2. REVENUE AND OTHER INCOME

| | Consolidated group | | Parent entity | |
|---|---|---|---|---|
| | 2007 $ | 2006 $ | 2007 $ | 2006 $ |
| **Operating activities** | | | | |
| Sales | - | - | - | - |
| Interest received from other persons/corporations | 1,150,040 | 1,143,912 | 1,089,199 | 1,100,864 |
| **Total Revenue** | 1,150,040 | 1,143,912 | 1,089,199 | 1,100,864 |

Sales – the Company has not yet sold any of its heart pumps as it does not yet have regulatory approval. Regulatory approval and revenue are anticipated in 2008 (as reimbursement is expected through clinical trials conducted in the United States of America).

## 3. LOSS FOR THE YEAR

| | Consolidated group | | Parent entity | |
|---|---|---|---|---|
| | 2007 $ | 2006 $ | 2007 $ | 2006 $ |
| (a) Expenses | | | | |
| Finance costs – external | 30,470 | 29,679 | 30,470 | 29,679 |
| Net Foreign exchange losses | 1,042,508 | 770,227 | 1,042,508 | 770,227 |
| Rental expenses on operating leases – minimum lease payments | 903,501 | 631,590 | 121,814 | 155,645 |
| Research and development costs | 550,306 | 1,695,837 | – | – |
| Raw materials and consumables used – write down of inventories to net realisable value | 1,043,583 | 1,621,556 | – | – |
| (b) Significant Expenses | | | | |
| The following significant expense items are relevant in explaining the financial performance: | | | | |
| Depreciation of plant and equipment | 485,182 | 349,733 | 23,519 | 26,303 |
| Amortization of intangible assets | 273,745 | 321,457 | 829 | 598 |
| Amortization of leasehold improvements | 51,954 | 75,631 | 36,276 | 73,358 |
| **Total depreciation and amortization** | **810,881** | **746,821** | **60,624** | **100,259** |

## 4. AUDITORS' REMUNERATION

| | Consolidated group | | Parent entity | |
|---|---|---|---|---|
| | 2007 $ | 2006 $ | 2007 $ | 2006 $ |
| Remuneration of the auditor of the parent entity and economic entities: | | | | |
| Auditing or reviewing the Australian financial reports – Grant Thornton NSW | 100,674 | 79,587 | 100,674 | 79,587 |
| Auditing of HeartWare, Inc. in connection with the preparation of the Australian financial report – Grant Thornton LLP | – | 59,670 | – | – |
| Auditing or reviewing the US financial reports – Grant Thornton LLP | 193,040 | 25,275 | 193,040 | 25,275 |
| Taxation services – Grant Thornton NSW | 20,350 | 9,190 | 20,350 | 9,190 |
| Taxation services – Grant Thornton LLP | – | 7,764 | – | – |
| Advisory fees in conjunction with US SEC and Australian reporting requirements during the year –Grant Thornton NSW | 14,857 | 2,650 | 14,857 | 2,650 |
| Advisory fees in conjunction with US SEC reporting requirements during the year – Grant Thornton LLP | – | 2,332 | – | – |
| | 328,921 | 186,468 | 328,921 | 116,702 |

## 5. INCOME TAX EXPENSE

| | Consolidated group | | Parent entity | |
|---|---|---|---|---|
| | 2007 $ | 2006 $ | 2007 $ | 2006 $ |
| (Loss) before income tax | (26,376,647) | (23,250,653) | (5,592,329) | (5,223,804) |
| The prima facie tax on (loss) before income tax is reconciled to the income tax as follows: | | | | |
| Prima facie tax benefit on (loss) at 30% (2006: 30%) | | | | |
| – Consolidated Group | (7,912,994) | (6,975,196) | – | – |
| – Parent Entity | – | – | (1,677,699) | (1,567,141) |
| Tax effect of overseas losses taxed at higher than 30% | (475,753) | (412,635) | – | – |
| Add: | | | | |
| Tax effect of: | | | | |
| Non deductible depreciation and amortization | 72,733 | 101,973 | 23,519 | 30,078 |
| Other non allowable items | 5,466 | 3,115 | 1,997 | 3,115 |
| | (8,310,548) | (7,282,743) | (1,652,183) | (1,533,948) |
| Adjusted income tax benefit attributable to the entity | (8,310,548) | (7,282,743) | (1,652,183) | (1,533,948) |
| Deferred tax asset not brought to account | 8,310,548 | 7,282,743 | (1,652,183) | 1,533,948 |
| **Income tax attributable to entity** | – | – | – | – |
| The applicable weighted average effective tax rates are as follows: | 0% | 0% | 0% | 0% |
| Deferred tax assets in respect of tax losses not brought to account: | 20,103,785 | 11,793,237 | 4,890,500 | 3,238,317 |

Potential deferred tax assets will only be obtained in certain limited circumstances. Specifically, a deferred tax asset cannot be obtained unless:

(a) the relevant company derives future assessable income of a nature and an amount sufficient to enable the asset to be realised, or the asset can be utilised by another company in the Consolidated Group in accordance with Division 170 of the Income Tax Assessment Act 1997;

(b) the relevant company and/or the Consolidated Group continues to comply with the conditions for deductibility imposed by the law; and

(c) no changes in tax legislation adversely affect the relevant company and/or the Consolidated Group in realising the benefit.

At the date of this report, HeartWare and its controlled entities do not have revenues or profit which would be sufficient to allow deferred tax assets to be accrued with a substantial degree of certainty. This issue will be closely monitored as the Company moves toward the commercialisation of its range of implantable circulatory assist devices.

## 6. EARNINGS PER SHARE ("EPS")

| | Consolidated group | | Parent entity | |
|---|---|---|---|---|
| | 2007 $ | 2006 $ | 2007 $ | 2006 $ |
| Earnings used in the calculation of basis EPS and dilutive EPS | (26,376,647) | | (23,250,653) | |
| Weighted average number of ordinary shares outstanding during the year used in calculating basic EPS | | 213,029,192 | | 174,689,977 |
| Weighted average number of options outstanding not treated as dilutive | | 4,395,718 | | 2,652,745 |
| Weighted average number of ordinary shares outstanding during the year used in calculating dilutive EPS | | 213,029,192 | | 174,689,997 |

The number of options referred to above is not dilutive because the Consolidated Group incurred a loss for the year ended 31 December 2007.

## 7. SEGMENT INFORMATION

The HeartWare Group is developing and commercialising its range of circulatory assist devices or "heart pumps" which are used for the treatment of congestive heart failure. The Company does not yet have regulatory approvals so as to permit it to sell its products into the global market. On this basis, the Consolidated Group operates in one business segment, being the medical devices sector. It conducts integrated operations in the United States of America (mainly Miami), and Sydney, Australia and the primary reporting segment is therefore geographical.

| | Sydney, Australia | | Miami, USA | | Eliminations | | Consolidated Group | |
|---|---|---|---|---|---|---|---|---|
| | 2007 $ | 2006 $ | 2007 $ | 2006 $ | 2007 $ | 2006 $ | 2007 $ | 2006 $ |
| **Total Segment Revenue:** | | | | | | | | |
| Total revenue | 1,089,199 | 1,100,864 | 60,841 | 43,048 | – | – | 1,150,040 | 1,143,912 |
| **Segment Result:** | | | | | | | | |
| (Loss) before income tax expense | (5,592,329) | (5,223,804) | (20,784,318) | (18,026,849) | – | – | (26,376,647) | (23,250,653) |
| Income tax expense | – | – | – | – | – | – | – | – |
| (Loss) after income tax | (5,592,329) | (5,223,804) | (20,784,318) | (18,026,849) | – | – | (26,376,647) | (23,250,653) |
| **Assets:** | | | | | | | | |
| Segment assets | 131,787,084 | 99,765,794 | 6,931,976 | 7,587,882 | (100,094,335) | (79,463,535) | 38,624,725 | 27,890,141 |
| **Liabilities:** | | | | | | | | |
| Segment liabilities | 1,649,222 | 1,771,919 | 1,845,898 | 1,726,743 | – | – | 3,495,120 | 3,498,662 |
| **Other:** | | | | | | | | |
| Acquisition of non-current segment assets | – | 20,155 | 1,174,294 | 2,200,627 | – | – | 1,174,294 | 746,821 |
| Depreciation and amortization of segment assets | 60,624 | 100,259 | 750,257 | 646,562 | – | – | 810,881 | 746,821 |

## 8. CASH AND CASH EQUIVALENTS

| | Consolidated group | | Parent entity | |
|---|---|---|---|---|
| | 2007 $ | 2006 $ | 2007 $ | 2006 $ |
| Cash at bank and in hand | 1,158,350 | 916,076 | 309,172 | 81,956 |
| Short-term bank deposits | 30,915,592 | 20,185,617 | 30,916,093 | 20,185,617 |
| | **32,073,942** | **21,101,693** | **31,225,265** | **20,267,573** |

The effective interest rate on short-term bank deposits was 5.32% (2006: 5.44%); these deposits have an average maturity of 77 days (2006: 32 days).

## 9. TRADE AND OTHER RECEIVABLES

| | Consolidated group | | Parent entity | |
|---|---|---|---|---|
| | 2007 $ | 2006 $ | 2007 $ | 2006 $ |
| Current | | | | |
| Trade receivables | – | – | – | – |
| Other receivables | 180,035 | 153,905 | 191,062 | 166,658 |
| | **180,035** | **153,905** | **191,062** | **166,658** |

Due to the short-term nature of these receivables, their carrying value is assumed to approximate their fair value. Refer to Note 20 to the Financial Statements for further information regarding foreign currency and interest rate risk in relation to the above.

## 10. OTHER ASSETS

| | Consolidated group | | Parent entity | |
|---|---|---|---|---|
| | 2007 $ | 2006 $ | 2007 $ | 2006 $ |
| Current | | | | |
| Prepayments | 274,625 | 255,728 | 79,214 | 77,693 |
| Advances – suppliers and employees | 230,654 | 161,409 | – | – |
| Security and other deposits | 200,506 | 192,779 | 165,462 | 158,657 |
| | **705,785** | **609,916** | **244,676** | **236,350** |
| Non Current | | | | |
| Security and other deposits | – | 2,527 | – | – |

Due to the short-term nature of these other assets, their carrying value is assumed to approximate their fair value. Refer to Note 20 to the Financial Statements for further information regarding foreign currency and interest rate risk in relation to the above.

## 11. FINANCIAL ASSETS

| | Consolidated group | | Parent entity | |
|---|---|---|---|---|
| | 2007 $ | 2006 $ | 2007 $ | 2006 $ |
| **Unlisted investments at cost – shares in controlled entities** | – | – | 100,094,335 | 78,897,414 |

## 12. CONTROLLED ENTITIES

| Name of entity | Country of incorporation | Class of shares | Percentage owned 2007 % | Percentage owned 2006 % | Carrying value 2007 $ | Carrying value 2006 $ |
|---|---|---|---|---|---|---|
| HeartWare, Inc. | USA | Series B | 100 | 100 | 45,238,921 | 45,238,921 |
| HeartWare, Inc. | USA | Series C | 100 | 100 | 54,855,414 | 33,658,493 |
| | | | **100** | **100** | **100,094,335** | **78,897,414** |

On 24 January 2005, the Company acquired all of the voting stock of HeartWare, Inc. HeartWare, Inc. was incorporated in Delaware, United States of America.

The purchase consideration for the acquisition was $44 million, payable by the issue of ordinary shares in the capital of the Company.

Subsequent to this transaction, HeartWare, Inc. has issued Series C Stock to the Company.

In addition to the above (and as part of the above purchase consideration), the Company has issued a convertible note in the amount of $1,420,000 which will accrue interest at 2.0% per annum (capitalised monthly in arrears). The conversion price is $1.00 per ordinary share in the capital of the Company. The principal and capitalised interest on the convertible note is repayable to the holder on the secondary anniversary of the date of issue of the convertible note.

## 13. PROPERTY, PLANT AND EQUIPMENT

| | Consolidated group 2007 $ | Consolidated group 2006 $ | Parent entity 2007 $ | Parent entity 2006 $ |
|---|---|---|---|---|
| **Plant and equipment:** | | | | |
| At cost | 4,091,274 | 3,735,228 | 68,993 | 120,651 |
| Accumulated depreciation | (1,110,111) | (746,423) | (40,808) | (37,722) |
| | 2,981,163 | 2,988,805 | 28,185 | 82,929 |
| Leasehold improvements: | | | | |
| At cost | 108,838 | 264,268 | - | 220,679 |
| Accumulated amortization | (17,127) | (112,744) | - | (110,199) |
| | 91,711 | 151,524 | - | 110,480 |
| **Total plant and equipment** | **3,072,874** | **3,140,329** | **28,185** | **193,409** |
| **Movements in carrying amounts** | | | | |
| Movement in the carrying amount for each class of plant and equipment between the beginning and end of the current financial year | | | | |
| **Plant and equipment:** | | | | |
| Balance at the beginning of the year | 2,988,805 | 1,680,652 | 82,929 | 134,422 |
| Exchange differences | (307,558) | (52,975) | - | - |
| Additions | 835,679 | 1,790,061 | - | 15,167 |
| Disposals | (50,581) | (79,200) | (31,225) | (40,357) |
| Depreciation expense | (485,182) | (349,733) | (23,519) | (26,303) |
| **Carrying amount at the end of the year** | **2,981,163** | **2,988,805** | **28,185** | **82,929** |
| **Leasehold Improvements:** | | | | |
| Balance at the beginning of the year | 151,524 | 189,865 | 110,480 | 183,838 |
| Exchange differences | (6,960) | (359) | - | - |
| Additions | 73,305 | 37,649 | - | - |
| Disposals | (74,204) | - | (74,204) | - |
| Amortization expense | (51,954) | (75,631) | (36,276) | (73,358) |
| **Carrying amount at the end of the year** | **91,711** | **151,524** | - | **110,480** |

## 14. INTANGIBLE ASSETS

| | Consolidated group | | Parent entity | |
|---|---|---|---|---|
| | 2007 $ | 2006 $ | 2007 $ | 2006 $ |
| Patents and Trademarks – at cost | 415,019 | 308,590 | – | – |
| Accumulated amortization | (54,071) | (34,108) | – | – |
| | 360,948 | 274,482 | – | – |
| Development – at cost | 2,362,388 | 2,631,833 | – | – |
| Accumulated amortization | (435,919) | (310,108) | – | – |
| | 1,926,469 | 2,321,775 | – | – |
| Software – at cost | 440,958 | 348,910 | 4,988 | 4,988 |
| Accumulated amortization | (136,286) | (63,396) | (1,427) | (598) |
| | 304,672 | 285,514 | 3,561 | 4,390 |
| | **2,592,089** | **2,881,771** | **3,561** | **4,390** |
| Intangible assets have finite useful lives. The current amortization charges for intangible assets are included under depreciation and amortization expense in the Income Statement. | | | | |

| | Consolidated group | | Parent entity | |
|---|---|---|---|---|
| | 2007 $ | 2006 $ | 2007 $ | 2006 $ |
| **Movements in carrying amounts** | | | | |
| Movement in the carrying amount for each class of intangible assets between the beginning and end of the current financial year | | | | |
| **Patents and trademarks at cost:** | | | | |
| Balance at the beginning of the year | 274,482 | 270,928 | – | – |
| Exchange differences | (27,039) | 48,528 | – | – |
| Additions | 138,037 | 23,402 | – | – |
| Amortization charge | (24,532) | (68,376) | – | – |
| **Carrying amount at the end of the year** | **360,948** | **274,482** | – | – |
| **Development at cost:** | | | | |
| Balance at the beginning of the year | 2,321,775 | 2,696,671 | – | – |
| Exchange differences | (229,350) | (188,095) | – | – |
| Additions | – | – | – | – |
| Amortization charge | (165,956) | (186,801) | – | – |
| **Carrying amount at the end of the year** | **1,926,469** | **2,321,775** | – | – |
| **Software at cost:** | | | | |
| Balance at the beginning of the year | 285,514 | – | 4,390 | – |
| Exchange differences | (24,859) | 2,884 | – | – |
| Additions | 127,274 | 348,910 | – | 4,988 |
| Amortization charge | (83,257) | (66,280) | (829) | (598) |
| **Carrying amount at the end of the year** | **304,672** | **285,514** | **3,561** | **4,390** |

## 15. TRADE AND OTHER PAYABLES

| | Consolidated group | | Parent entity | |
|---|---|---|---|---|
| | 2007 $ | 2006 $ | 2007 $ | 2006 $ |
| Current | | | | |
| Trade payables | 588,327 | 435,216 | 1,424 | 64,013 |
| Sundry payables and accrued expenses | 1,077,234 | 1,347,023 | 101,260 | 172,763 |
| | **1,665,561** | **1,782,239** | **102,684** | **236,776** |

Due to the short-term nature of these payables, their carrying value is assumed to approximate their fair value. Refer to Note 20 to the Financial Statements for further information regarding foreign currency and interest rate risk in relation to the above.

## 16. PROVISIONS

| | Consolidated group | | Parent entity | |
|---|---|---|---|---|
| | 2007 $ | 2006 $ | 2007 $ | 2006 $ |
| Current | | | | |
| Employee benefits | 311,870 | 200,608 | 28,849 | 19,328 |
| Number of employees | | | | |
| Number of employees at year end | 76 | 65 | 2 | 3 |
| **Movements in provisions** | | | | |
| Employee benefits: | | | | |
| Opening balance | 200,608 | 145,018 | 19,328 | 21,698 |
| Additional provisions | 416,293 | 246,726 | 25,753 | 62,429 |
| Amounts used | (305,031) | (191,136) | (16,232) | (64,799) |
| Closing balance | **311,870** | **200,608** | **28,849** | **19,328** |

## 17. FINANCIAL LIABILITIES

| | | | | |
|---|---|---|---|---|
| Current | | | | |
| Lease incentive | 12,513 | 20,280 | 12,513 | 20,280 |
| Convertible note* | 1,505,176 | 1,475,396 | 1,505,176 | 1,475,396 |
| | **1,517,689** | **1,495,676** | **1,517,689** | **1,495,676** |
| Non-Current | | | | |
| **Lease incentive** | - | 20,139 | - | 20,139 |

* The Company issued a convertible note in the amount of $1,420,000 that accrues interest at 2.0% per annum (capitalised monthly in arrears). The conversion price is $1.00 per ordinary share in the capital of the Company. The principal and capitalised interest on the convertible note is repayable to the holder on the second anniversary of the date of issue of the convertible note. The Company issued the convertible note in favour of Apple Tree Partners as part of the consideration for the acquisition of HeartWare, Inc. As at the reporting date, the Company has received written confirmation that Apple Tree Partners has no present intention to require repayment of the convertible note.

## 18. ISSUED CAPITAL

| | Consolidated group | | Parent entity | |
|---|---|---|---|---|
| | 2007 $ | 2006 $ | 2007 $ | 2006 $ |
| 248,100,277 (2006: 186,262,597) fully paid ordinary shares | 94,647,107 | 59,673,110 | 140,230,916 | 105,256,919 |

| | Issue Price | No. of Shares | $ |
|---|---|---|---|
| **Movements during the year ended 31 December 2007** | | | |
| Opening balance as at 1 January 2007 | | 186,262,597 | 59,673,110 |
| Share issue on exercise of options granted under the Company's ESOP on 17 January 2007 | $0.20 | 40,000 | 8,000 |
| Share issue under shareholder share purchase plan on 17 July 2007 | $0.60 | 2,002,933 | 1,201,760 |
| Share issue pursuant to a private placement on 26 July 2007 | $0.60 | 59,706,747 | 35,824,048 |
| Share issue on exercise of options granted under the Company's ESOP on 12 December 2007 | $0.20 | 88,000 | 17,600 |
| Issue costs relating to private placement | – | – | (2,077,411) |
| **Closing balance as at 31 December 2007** | | 248,100,277 | 94,647,107 |

### Share options

For information relating to the HeartWare Limited Employee Share Option Plan ("ESOP") and the Performance Rights Plan, including details of grants, exercises and lapses during the financial year and the equity at year-end, please refer to Note 25 to the Financial Statements.

For information relating to share options issued to directors and other key management personnel during the financial year, please refer to Note 26 to the Financial Statements.

### Capital Management

When managing capital, the Company's objective is to ensure that the Consolidated Group continues as a going concern as well as to maintain optimal returns to shareholders and benefits for other stakeholders. The Company also aims to maintain a capital structure that ensures the lowest cost of capital available to the Consolidated Group.

The Company will need to raise capital in the future and it intends to do so via the issue of new ordinary shares in the Company at the appropriate time. The Company does not presently intend to raise funds via the use of debt instruments, however the Company monitors the market constantly and may change its approach in this regard depending on developments therein.

The Consolidated Group is not subject to any externally imposed capital requirements.

## 19. RESERVES

### (a) Foreign currency translation reserve

The foreign currency translation reserve records exchange differences arising on translation of HeartWare, Inc.

### (b) Share options reserve

The share options reserve records items recognized as expense in relation to the calculated value of vested options granted under the Company's ESOP and the PRP.

### (c) Exercised options reserve

The exercised options reserve records items recognized as expense items in relation to the calculated value of options that have been exercised.

## 20. FINANCIAL INSTRUMENTS

### (a) Financial risk management

The Consolidated Group's financial instruments consist mainly of deposits with banks, local money market instruments, short-term investments, accounts receivable and payable, loans to and from subsidiaries, leases and the convertible note (issued on 27 January 2005).

### (b) Foreign currency risk

The Consolidated Group is exposed to fluctuations in foreign currencies arising from the fact that the bulk of the Consolidated Group's expenditure is incurred in U.S. dollars, which is not the same as the Consolidated Group's measurement currency (being Australian dollars).

During the year, the Consolidated Group purchased and held US dollars in order to minimise its foreign currency risk associated with its short-term US dollar commitments.

Details regarding foreign exchange risk exposure is set out in Note 3 to the Financial Statements.

### (c) Liquidity risk

Liquidity risk represents the ability of the Consolidated Group to meet is obligations as and when they fall due.

The Consolidated Group manages liquidity risk by monitoring forecast cash flows.

### (d) Credit risk

Credit risk represents the loss that would be recognized if counter-parties failed to perform as contracted.

*Recognized financial instruments*

The credit risk on financial assets, excluding investments, of the Consolidated Group that have been recognized in the Income Statement is the carrying amount, net of any provision for doubtful debts. The Consolidated Group is not materially exposed to any individual overseas country or individual customer.

### (e) Interest rate risk

The Consolidated Group's exposure to interest rate risk, which is the risk that a financial instrument's value will fluctuate as a result of changes in the market interest rates and the effective weighted average interest rates on classes of financial assets and financial liabilities is set out below:

| | Fixed interest rate maturing | | | | |
|---|---|---|---|---|---|
| **Consolidated Group** | **Within Year $** | **Over 1 to 5 years $** | **Floating interest rate $** | **Non-interest bearing $** | **Total $** |
| **2007 Financial Year** | | | | | |
| *Financial assets* | | | | | |
| Cash and cash equivalents | – | – | 1,157,850 | 500 | 1,158,350 |
| Deposit at call | 30,915,592 | – | – | – | 30,915,592 |
| Receivables | – | – | – | 180,035 | 180,035 |
| Other current assets | 158,006 | – | – | 547,779 | 705,785 |
| | **31,073,598** | – | **1,157,850** | **728,314** | **32,959,762** |
| Weighted Average Effective Interest Rate | **5.32%** | – | **4.63%** | – | – |
| *Financial liabilities* | | | | | |
| Trade payables | – | – | – | 1,665,561 | 1,665,561 |
| Provisions | – | – | – | 311,870 | 311,870 |
| Borrowings | 1,505,176 | – | – | 12,513 | 1,517,689 |
| | **1,505,176** | – | – | **1,989,994** | **3,495,120** |
| Weighted Average Effective Interest Rate | **2.0%** | – | – | – | – |
| **2006 Financial Year** | | | | | |
| *Financial assets* | | | | | |
| Cash and cash equivalents | – | – | 915,576 | 500 | 916,076 |
| Deposit at call | 20,185,617 | – | – | – | 20,185,617 |
| Receivables | – | – | – | 315,314 | 315,314 |
| Other current assets | 158,006 | – | – | 290,501 | 448,507 |
| | **20,343,623** | – | **915,576** | **606,315** | **21,865,514** |
| Weighted Average Effective Interest Rate | **5.44%** | – | **4.04%** | – | – |
| *Financial liabilities* | | | | | |
| Payables | – | – | – | 1,782,239 | 1,782,239 |
| Provisions | – | – | – | 200,608 | 200,608 |
| Borrowings | 1,495,676 | – | – | – | 1,495,676 |
| | **1,495,676** | – | – | **1,982,847** | **3,478,523** |
| Weighted Average Effective Interest Rate | **2.00%** | – | – | – | – |

Details regarding interest rate risk exposure is set out in Note 3 to the Financial Statements.

## (e) Interest rate risk (continued)

| Parent entity | Fixed interest rate maturing: Within Year $ | Over 1 to 5 years $ | Floating interest rate $ | Non-interest bearing $ | Total $ |
|---|---|---|---|---|---|
| **2007 Financial Year** | | | | | |
| *Financial assets* | | | | | |
| Cash and cash equivalents | – | – | 308,672 | 500 | 309,172 |
| Deposit at call | 30,916,093 | – | – | – | 30,916,093 |
| Receivables | – | – | – | 191,062 | 191,062 |
| Other current assets | 158,006 | – | – | 86,670 | 244,676 |
| | 31,074,099 | – | 308,672 | 278,232 | 31,661,003 |
| Weighted Average Effective Interest Rate | 5.32% | – | 4.35% | – | – |
| *Financial liabilities* | | | | | |
| Payables | – | – | – | 102,684 | 102,684 |
| Provisions | – | – | – | 28,849 | 28,849 |
| Borrowings | 1,505,176 | – | – | 12,513 | 1,517,689 |
| | 1,505,176 | – | – | 144,046 | 1,649,222 |
| Weighted Average Effective Interest Rate | 2.00% | – | – | – | – |
| **2006 Financial Year** | | | | | |
| *Financial assets* | | | | | |
| Cash and cash equivalents | – | – | 81,456 | 500 | 81,956 |
| Deposit at call | 20,185,617 | – | – | – | 20,185,617 |
| Receivables | – | – | – | 166,658 | 166,658 |
| Other current assets | 158,006 | – | – | 78,344 | 236,350 |
| | 20,343,623 | – | 81,456 | 245,502 | 20,670,581 |
| Weighted Average Effective Interest Rate | 3.90% | – | 2.45% | – | – |
| *Financial liabilities* | | | | | |
| Payables | – | – | – | 236,776 | 236,776 |
| Provisions | – | – | – | 19,328 | 19,328 |
| Borrowings | 1,495,676 | – | – | – | 1,495,676 |
| | 1,495,676 | – | – | 256,104 | 1,751,780 |
| Weighted Average Effective Interest Rate | 2.00% | – | – | – | – |

## (f) Net fair values

The net fair value of cash and cash equivalents and non-interest bearing liabilities of the Consolidated Group approximates their carrying value.

Net fair values of monetary financial assets and liabilities are based upon market prices where a market exists or by discounting the expected future cash flows by the current interest rate for assets and liabilities with similar risk.

Aggregate net fair values are materially in line with the carrying amounts for the HeartWare Group's financial assets and financial liabilities at balance date.

## 21. CAPITAL AND LEASING COMMITMENTS

| | Consolidated group | | Parent entity | |
|---|---|---|---|---|
| | 2007 $ | 2006 $ | 2007 $ | 2006 $ |
| **Capital expenditure commitments contracted for:** | | | | |
| Plant and equipment purchases | 31,543 | 73,043 | - | - |
| **Capital expenditure commitments payable:** | | | | |
| Not later than 12 months | 110,321 | 73,043 | - | - |
| **Operating lease commitments** | | | | |
| Non-cancellable operating leases contracted for but not capitalised in the Financial Statements | | | | |
| Payable – minimum lease payments: | | | | |
| Not later than 12 months | 206,309 | 910,343 | 44,256 | 183,593 |
| Between 12 months and 5 years | 189,209 | 404,183 | - | 160,805 |
| | 395,518 | 1,314,526 | 44,256 | 344,398 |

The Consolidated Group leases property under non-cancellable operating leases expiring for periods of up to twenty months. Leases generally provide the relevant entity with a right of renewal. Lease payments comprise a base amount plus an incremental contingent rental. Contingent rentals are based on either movements in the Consumer Price Index or criteria.

## 22. CONTINGENT LIABILITIES

As set out in the Company's prospectus (dated 17 December 2004), the Consolidated Group and the parent entity has the following contingent liabilities resulting from the acquisition by HeartWare, Inc. of a business that previously held the Company's technology:

(a) a milestone payment of US$750,000 within 6 months of the date when the first circulatory assist device is approved for sale in Europe, provided that the Company has a least US$15,000,000 in cash on hand* and, if the Company does not have $15,000,000 in cash on hand at that time, then the payment is deferred until such time that the Company has $15,000,000 in cash on hand;

(b) a milestone payment of US$1,250,000 when the first circulatory assist device is approved for sale in the US, provided that the Company has at least US$25,000,000 in cash on hand* and, if the Company does not have $25,000,000 in cash on hand at that time, then the payment is deferred until such time that the Company has $25,000,000 in cash on hand; and

(c) a special payment of up to US$500,000 upon a sale of HeartWare, Inc. if such sale generated proceeds in excess of the aggregate liquidation preferences of all of HeartWare, Inc.'s then outstanding preferred stock.

Except as stated above, the Company is not aware of any contingent liabilities at the date of the Directors' Report.

* The date when this will occur, and the Company's cash balance at the relevant time, is indeterminate at this stage and, as such, no provision is made for this liability.

## 23. CASH FLOW INFORMATION

| | Consolidated group | | Parent entity | |
|---|---|---|---|---|
| | 2007 $ | 2006 $ | 2007 $ | 2006 $ |
| **Reconciliation of Cash Flow from Operations with Loss After Income Tax** | | | | |
| (Loss) after income tax | (26,376,647) | (23,250,653) | (5,592,329) | (5,223,804) |
| Non-cash flows in (Loss): | | | | |
| Depreciation | 485,182 | 349,733 | 23,519 | 26,303 |
| Amortization | 325,699 | 397,088 | 37,105 | 73,956 |
| Share Based Payment | 2,762,319 | 1,174,620 | 2,762,319 | 1,174,620 |
| Loss on disposal of plant and equipment | 114,416 | 17,539 | 98,883 | 13,912 |
| Proceeds of sale asset not yet received | – | 26,445 | – | 26,445 |
| Changes in assets and liabilities, net of the effects of the purchase of HeartWare, Inc.: | | | | |
| Increase/(decrease) in accrued expenses/employee benefits | 129,832 | 55,590 | 9,521 | (2,370) |
| Decrease/(Increase) in trade and term receivables | 204,201 | (166) | 32,677 | (21,388) |
| Increase/(decrease) in other provisions | 234,934 | (17,763) | (27,906) | (17,763) |
| (Decrease)/increase in other creditors | (422,923) | 384,282 | (164,777) | (36,278) |
| Increase in interest payable | 29,780 | 29,191 | 29,780 | 29,191 |
| Decrease/(increase) in other debtors | 175,999 | (190,557) | 19,639 | (20,378) |
| (Increase)/decrease in interest receivable | (64,899) | 13,645 | (64,883) | 13,645 |
| (Increase)/decrease in prepaid expenses | (267,786) | (108,889) | (1,521) | 23,360 |
| Exchange rate adjustment | (81,692) | (66,735) | | – |
| Cash Flow from Operations | **(22,751,585)** | **(21,186,630)** | **(2,837,973)** | **(3,940,549)** |
| Reconciliation of Cash: | | | | |
| Cash – Note 8 | 1,158,350 | 916,076 | 309,172 | 81,956 |
| Deposits at call – Note 8 | 30,915,592 | 20,185,617 | 30,916,093 | 20,185,617 |
| | 30,073,942 | 21,101,693 | 31,225,265 | 20,267,573 |

The Company has provided guarantees and indemnities totalling $258,006 (2006: $258,006) to its bankers in respect to banking facilities provided to the Company.

## 24. DIRECTOR AND OTHER KEY MANAGEMENT PERSONNEL INFORMATION

**(a) Names and positions held of directors and other key management personnel in office at anytime during the financial year are as follows:**

### Directors

| Name | Position | Entity | Tenure |
|---|---|---|---|
| Mr R B Thomas | Non-executive Chairman | (i) | 26 November 2004 – Current |
| Dr S L Harrison | Non-executive Deputy Chairman | (i) | 26 November 2004 – Current |
| Mr R B Stockman | Non-executive Director | (i) | 11 December 2007 – Current |
| Dr D N Wade | Non-executive Director | (i) | 15 December 2004 – Current |
| Dr C C Bennett | Non-executive Director | (i) | 15 December 2004 – Current |
| Mr D E Godshall | Chief Executive Officer Executive Director | (i), (ii) | 18 September 2007 – Current<br>28 October – Current |

### Other Key Management Personnel

| Name | Position | Entity | Tenure |
|---|---|---|---|
| Mr D J McIntyre | Chief Financial Officer Company Secretary | (i), (ii) | 28 February 2006 – Current<br>28 February 2006 – Current |
| Mr D A Rowe | Chief Operating Officer | (ii) | 17 April 2007 – Current |
| Mr J A LaRose | Chief Scientific Officer | (ii) | 10 July 2003 – Current |
| Ms J H Foley | Vice President, Clinical & Regulatory | (ii) | 2 January 2007 – Current |
| Ms J E Reedy | Vice President, Sales & Marketing (Former) | (ii) | 16 May 2006 – 31 December 2007 |
| Mr J F Schuermann | Vice President, Sales & Marketing | (ii) | 4 September 2007 – Current |

(i) HeartWare Limited
(ii) HeartWare, Inc.

### (b) Director and other key management personnel compensation

The Company has applied the provisions of the Corporations Amendments Regulation 2007 that allow the Company to transfer director and other key management personnel remuneration disclosures required by AASB 124: Related Party Disclosures paragraphs Aus 25.4 to Aus 25.7.2 to the Remuneration Report section of the Directors' Report.

In accordance with the above, information concerning the compensation for directors and other key management personnel may be found in the Remuneration Report (see Section 4 to Appendix A to the Remuneration Report).

## 25. SHARE-BASED PAYMENTS

During the financial year, the Company granted options to its employees under the HeartWare Limited Employee Share Option Plan ("ESOP") and the HeartWare Limited Performance Rights Plan ("PRP") as follows:

(a) On 2 January 2007 and following the appointment of Ms Jennifer Foley as Vice President, Clinical & Regulatory Affairs of the Company, 1,000,000 ESOP options were granted to Ms Foley at an exercise price of $1.10 per option, with a further 200,000 ESOP options being granted to another senior appointee on the same terms.

(b) On 26 July 2007 and following shareholder approval, 200,000 ESOP options were granted to Mr Bob Stockman, non-executive director. The exercise price of these options was $0.75 per option.

(c) On 16 November 2007, the Company granted 2.05 million performance rights under the PRP to 11 employees. The exercise price of the performance rights is zero and vesting is subject to various performance hurdles.

(d) On 16 November 2007, the Company granted 2.9 million ESOP options to 31 employees. The exercise price of the ESOP options is $0.75 and vesting is subject to various performance hurdles.

(e) On 16 November 2007, the Company granted 350,000 Incentive Options to two corporate advisers. The exercise price is $0.75.

Each of the options and performance rights referred to above expire on the tenth (10th) anniversary of the respective grant date. All ESOP options and PRP performance rights are unlisted and are not transferable; hold no voting or dividend rights; and, entitle the holder to purchase one ordinary share in the capital of the Company (at the relevant exercise price and subject to performance conditions, if any).

| | Consolidated group | | | | Parent entity | | | |
|---|---|---|---|---|---|---|---|---|
| | 2007 | | 2006 | | 2007 | | 2006 | |
| | Number of options | Weighted average exercise price $ | Number of options | Weighted average exercise price $ | Number of options | Weighted average exercise price $ | Number of options | Weighted average exercise price $ |
| Outstanding at the beginning of the year | 20,501,250 | 0.82 | 16,145,410 | 0.64 | 20,501,250 | 0.82 | 16,145,140 | 0.64 |
| Granted | 6,650,000 | 0.58 | 10,116,324 | 1.13 | 6,650,000 | 0.58 | 10,116,324 | 1.13 |
| Forfeited | (190,480) | 1.08 | (5,349,333) | 0.90 | (190,480) | 1.08 | (5,349,433) | 0.90 |
| Exercised | (128,000) | 0.20 | (411,151) | 0.34 | (128,000) | 0.20 | (411,051) | 0.34 |
| Outstanding at year-end | 26,832,770 | 0.76 | 20,501,250 | 0.82 | 26,832,770 | 0.76 | 20,501,250 | 0.82 |
| Exercisable at year-end | 9,894,724 | $0.64 | 5,524,880 | 0.41 | 9,894,724 | $0.64 | 5,524,880 | 0.41 |

There were 128,000 options exercised during the year ended 31 December 2007. These options had a weighted average share price of $0.20 at exercise date.

The ESOP options outstanding at 31 December 2007 had a weighted average exercise price of $0.64 and a weighted average remaining contractual life of 7.13 years. Exercise prices range from $0.20 to $1.41 in respect of options outstanding at 31 December 2007. The weighted average fair value of the options granted during the year was $0.58.

The PRP performance rights outstanding at 31 December 2007 had a weighted average exercise price of $0.00 and a weighted average remaining contractual life of 9.88 years. Exercise price for these is zero and vesting is subject to satisfaction of various performance hurdles. The weighted average fair value of the performance rights granted during the year was $0.75.

The fair value for ESOP options was calculated by using a Black Scholes option pricing model applying the following inputs:

(a) Weighted average exercise price.

(b) Weighted average life of the option.

(c) Underlying share price.

(d) Expected share price volatility.

(e) Risk free interest rate.

Historic volatility has been the basis for determining expected share price volatility as it is assumed that this is indicative of future trends, which may not eventuate.

The life of the options is based on the historical exercise patterns, which may not eventuate in the future.

Included under employee benefits expense in the Income Statement is $2,762,319 (2006: $1,174,620) and relates, in full, to equity-settled share-based payment transactions.

The fair value of performance rights granted under the PRP is the share price on the date of grant, being $0.75.

| | Consolidated group | | Parent entity | |
|---|---|---|---|---|
| | 2007 $ | 2006 $ | 2007 $ | 2006 $ |
| **Detail of number of shares issued on exercise of remuneration options during the year:** | | | | |
| Proceeds from shares issued | 25,600 | 139,576 | 25,600 | 139,576 |
| Fair value of shares issued during the year | 93,440 | 352,057 | 93,440 | 352,057 |

No amount remains unpaid on any of the shares referred to above.

Fair value of shares issued during the year at their issue date is estimated to be the market price of shares of HeartWare Limited on the Australian Securities Exchange as at closing of trading on the issue dates.

Fair value of shares issued during the year at their issue date is estimated to be the market price of shares of HeartWare Limited on the Australian Securities Exchange as at closing of trading on the issue dates. The fair value of shares at date of issue was:

| Issue date | Fair value | Number of shares issued |
|---|---|---|
| 17 January 2007 | 33,600 | 40,000 |
| 12 December 2007 | 59,840 | 88,000 |
| | **93,440** | **128,000** |

Details of share options outstanding as at end of the reporting period are set out in the Directors' Report.

## 26. COMPENSATION OPTIONS FOR DIRECTORS AND OTHER KEY MANAGEMENT PERSONNEL

The Company has applied the provisions of the Corporations Amendments Regulation 2007 that allow the Company to transfer director and other key management personnel remuneration disclosures required by AASB 124: Related Party Disclosures paragraphs Aus 25.4 to Aus 25.7.2 to the Remuneration Report section of the Directors' Report.

In accordance with the above, information concerning the compensation options for directors and other key management personnel may be found in the Remuneration Report (see Section 2 to Appendix A to the Remuneration Report).

## 27. OPTION HOLDINGS OF DIRECTORS AND OTHER KEY MANAGEMENT PERSONNEL

| | Note | Balance 1 January 2007 | Granted as compen-sation | Net change | Options exercised | Balance 31 December 2007 | Vested 31 December 2007 Total | Not exer-cisable | Exer-cisable |
|---|---|---|---|---|---|---|---|---|---|
| **Parent Entity Directors** | | | | | | | | | |
| Thomas, R | (a), (b) | 1,264,204 | - | - | - | 1,264,204 | 782,102 | - | 782,102 |
| Harrison, S | | - | - | - | - | - | - | - | - |
| Stockman, R | (b) | - | 200,000 | - | - | 200,000 | - | - | - |
| Wade, D | (a) | 250,000 | - | - | - | 250,000 | 200,000 | - | 200,000 |
| Bennett, C | (a) | 250,000 | - | - | - | 250,000 | 200,000 | - | 200,000 |
| Godshall, D* | (b) | 5,581,264 | - | - | - | 5,581,264 | 1,395,316 | - | 1,395,316 |
| **Total** | | **7,345,468** | **200,000** | - | - | **7,545,468** | **2,577,418** | - | **2,577,418** |

* On 20 November 2007, the Company announced its intention to seek shareholder approval in 2008 to grant 1.1 million performance rights to Mr Godshall with a zero strike price. No such approval has been obtained, and therefore no performance rights have been issued (or recorded above), at the date of this report.

| | Note | Balance 1 January 2007 | Granted as compen-sation | Net change | Options exercised | Balance 31 December 2007 | Vested 31 December 2007 Total | Not exer-cisable | exer-cisable |
|---|---|---|---|---|---|---|---|---|---|
| **Other Key Management Personnel** | | | | | | | | | |
| Rowe, D | (b), (c) | 1,200,000 | 200,000 | - | - | 1,400,000 | 300,000 | - | 300,000 |
| LaRose, J | (b), (c) | 2,504,204 | 300,000 | - | - | 2,804,204 | 1,972,102 | - | 1,972,102 |
| McIntyre, D | (b), (c) | 1,728,408 | 400,000 | - | - | 2,128,408 | 814,204 | - | 814,204 |
| Foley, J | (b), (c) | - | 1,200,000 | - | - | 1,200,000 | - | - | - |
| Reedy, J | (b), (c) | 1,346,306 | - | - | - | 1,346,306 | 623,153 | - | 623,153 |
| Schuermann, J | (b), (c) | - | 1,000,000 | - | - | 1,000,000 | - | - | - |
| **Total** | | **6,778,918** | **3,100,000** | - | - | **9,878,918** | **3,709,459** | - | **3,709,459** |

Notes:

(a) The options refer to Incentive Options, further details of which are set out below under the heading "Options". In relation to Mr Thomas, 764,204 of his options were granted under the Company's ESOP with the balance comprising Incentive Options.

(b) The options refer to performance rights granted under the Company's Performance Rights Plan ("PRP"). Ms Foley's equity includes 1,000,000 options granted under the Company's ESOP with the remainder constituting performance rights. Mr Schuermann's equity includes 900,000 options granted under the Company's ESOP with the remainder constituting performance rights.

(c) In accordance with the terms of the Company's ESOP Rules and the PRP Rules, each option/performance right entitles the holder to purchase one ordinary share at the relevant exercise price (with the strike price under the PRP being zero) and subject to satisfaction of performance hurdles, if any.

Net Change refers to those options that have been forfeited or cancelled in accordance with the terms of the Company's ESOP Rules.

## 28. COMPENSATION FOR DIRECTORS AND OTHER KEY MANAGEMENT PERSONNEL

The Company has applied the provisions of the Corporations Amendments Regulation 2007 that allow the Company to transfer director and other key management personnel remuneration disclosures required by AASB 124: Related Party Disclosures paragraphs Aus 25.4 to Aus 25.7.2 to the Remuneration Report section of the Directors' Report.

In accordance with the above, information concerning the compensation for directors and other key management personnel may be found in the Remuneration Report (see Section 4 to Appendix A to the Remuneration Report).

## 29. SHAREHOLDINGS OF DIRECTORS AND OTHER KEY MANAGEMENT PERSONNEL

| | Note | Balance 1 January 2007 | Granted as Remuneration | Options Exercised | Net Change* Other | Balance 31 December 2007 |
|---|---|---|---|---|---|---|
| **Parent Entity Directors** | | | | | | |
| Thomas, R | (a) | 1,758,000 | – | – | 600,000 | 2,358,000 |
| Harrison, S | (b) | 91,588,782 | – | – | – | 91,588,782 |
| Stockman, R | | – | – | – | 300,000 | 300,000 |
| Wade, D | (c) | 1,000,000 | – | – | 8,333 | 1,008,333 |
| Bennett, C | | – | – | – | – | – |
| Godshall, D | | 37,305 | – | – | 63,000 | 100,305 |
| **Other Key Management Personnel** | | | | | | |
| Rowe, D | | 10,000 | – | – | – | 10,000 |
| LaRose, J | | – | – | – | – | – |
| McIntyre, D | | 28,000 | – | – | – | 28,000 |
| Foley, J | | – | – | – | – | – |
| Reedy, J | | – | – | – | – | – |
| Schuermann, J | | – | – | – | – | – |
| **Total** | | **94,422,087** | – | – | **971,333** | **95,393,420** |

* Net Change Other refers to shares purchased or sold during the year.

(a) Mr Thomas owns shares in the Company through a variety of direct and indirect holdings. The bulk of Mr Thomas' indirect shareholding is held by himself and his wife (Mrs Kyrenia Thomas) as trustee of the Robert Thomas Superannuation Fund. The options referred to above include 500,000 Incentive Options and 764,204 ESOP options, further details of which are set out below under the heading "Options".

(b) As noted elsewhere in this Directors' Report, Dr Harrison is the Managing General Partner of Apple Tree Partners I LP ("Apple Tree Partners"), the Company's largest shareholder. To this end, the shares set out in the table above refer to shares owned by Apple Tree Partners.

Under Dr Harrison's employment arrangement with Apple Tree Partners, he is prohibited from having an interest, directly or indirectly, in any entity in which Apple Tree Partners has invested. For this reason, Dr Harrison has no share or option holding in HeartWare (other than indirectly via Apple Tree Partners).

It should also be noted that, in connection with the acquisition of HeartWare, Inc. by HeartWare Limited, the Company issued a convertible note in favour of Apple Tree Partners in the amount of $1,420,000 which will accrue interest at 2.0% per annum (capitalised monthly in arrears). The conversion price is $1.00 per ordinary share. The principal and capitalised interest on the convertible note is repayable on the secondary anniversary of the date of issue of the convertible note (being 24 January 2007). As at the reporting date, the Company has received written confirmation that Apple Tree Partners has no present intention to require repayment of the convertible note. As Managing General Partner of Apple Tree Partners and for the purposes of the Corporations Act 2001, Dr Harrison is deemed to have an indirect interest in this convertible note.

(c) The shares are held by Nickeli Holdings Pty Limited as trustee of the Wade Family Superannuation Fund. The options refer to Incentive Options, further details of which are set out below under the heading "Options".

### Remuneration Benefits

Apart from the details disclosed in this note, no Director has entered into a material contract with the Company or the Consolidated Group during the year and there were no material contracts involving Directors' interests subsisting at anytime. At 31 December 2007, there were no amounts receivable from or payable to directors and their director-related entities.

## 30. RELATED PARTIES

On 26 July 2007, Mr Robert Stockman was granted 200,000 options under the Company's ESOP with an exercise price of $0.75 per option.

On 26 July 2007, Mr Stockman and Mr Thomas each subscribed for 500,000 shares under the Company's placement with an exercise price of $0.60 per share.

Shareholders at an Extraordinary General Meeting held on 26 July 2007 approved all of the above.

Except as stated above, there were no transactions between the Consolidated Group and related parties during the year.

## 31. EVENTS SUBSEQUENT TO BALANCE DATE

Other than the matters disclosed elsewhere in this Annual Report, there has not arisen in the interval between the end of the reporting period and the date of the Directors' Report any item, transaction or event of a material and unusual nature likely, in the opinion of the Directors, to significantly effect the operations of the Consolidated Group, the results of those operations or the state of affairs of the Consolidated Group.

## 32. CHANGE IN ACCOUNTING POLICY

### (a) Accounting for business combinations

The Consolidated Group changed its accounting policy for the financial year ended 31 December 2007 relating to the acquisition of HeartWare, Inc. by HeartWare Limited in January 2005. This acquisition is a "business combination", the accounting treatment for which is set out in AASB 3: Business Combinations ("AASB 3").

The business combination whereby HeartWare Limited acquired HeartWare, Inc. falls within the definition of a "business combination involving entities under common control" and this type of business combination is specifically scoped out of AASB 3. Further, there is presently no prescribed accounting treatment in Australia for business combinations involving entities under common control.

As a result of being scoped out of AASB 3 and in the absence of an Australian accounting standard governing common control transactions, the Consolidated Group considered the requirements of AASB 108: Accounting Policies, Changes in Accounting Estimates and Errors ("AASB 108") in relation to the first-time adoption of Australian Equivalents to International Financial Reporting Standards for the year ended 31 December 2006 and determined to continue to apply the accounting policy that it had previously adopted for the year ended 31 December 2005 (under previous Australian GAAP), being the purchase method by the legal parent, as the appropriate accounting policy for business combinations involving entities under common control.

For the half-year ended 30 June 2007 and the year ended 31 December 2007, the Consolidated Group has continued to account for the acquisition of HeartWare, Inc. by HeartWare Limited as a business combination involving entities under common control but it has changed its accounting policy, as allowed under AASB 108, and has now recorded the transaction at the historical cost of the assets and liabilities of HeartWare, Inc. at the time of the acquisition (being 24 January 2005). As a result, the Consolidated Group no longer recognises intangible assets or goodwill as a consequence of the transaction.

It should be noted that the above revised approach has been taken in order to provide more relevant and reliable information to users on the basis that this approach is consistent with the accounting policy as it applies to the Company's separate US financial statements which are filed with United States Securities & Exchange Commission and which are prepared in accordance with applicable accounting standards in the United States.

In changing the Australian accounting policy such that it is consistent with the US accounting policy, the Board of Directors believe that this will reduce investor confusion and better align the Consolidated Groups' financial results as reported in both Australia and the United States.

The aggregate effect of the change in accounting policy on the financial statements is as follows (no taxation effect results from these changes):

### (a) Accounting for business combinations (continued)

| | Previously stated | Adjustment | Revised |
|---|---|---|---|
| **Consolidated Income Statement for 12 Months Ended 31 December 2006** | | | |
| Depreciation and amortisation expense ($) | (2,911,525) | 2,211,235 | 756,160 |
| Loss before income tax expense ($) | (25,461,888) | 2,211,235 | (23,250,653) |
| Basic and diluted earnings per share (cents per share) | (14.6) | 1.3 | (13.3) |
| **Consolidated Balance Sheet as at 31 December 2006** | | | |
| Intangible assets ($) | 43,806,476 | (40,924,705) | 2,881,771 |
| Issued capital ($) | (105,256,919) | 45,583,809 | (59,673,110) |
| Reserves ($) | (3,270,362) | (236,632) | (3,506,994) |
| Retained earnings ($) | 43,211,097 | (4,422,472) | 38,788,625 |

### (b) Changes to Australian Accounting Standards

The following Australian Accounting Standards have been issued or amended and are applicable to the Parent Entity and Consolidated Group but are not yet effective. They have not been adopted in preparation of the financial statements at reporting date.

| AASB Amendment | AASB Standard affected | Nature of change in accounting policy and impact | Application date of the standard | Application date for the Consolidated group |
|---|---|---|---|---|
| AASB 2007-1 | AASB 2: Share-based Payment | No change, no impact | 1 March 2007 | 1 January 2008 |
| AASB 2007-2 | Various standards | No change, no impact | 1 January 2008 | 1 January 2008 |
| AASB 2007-3 | Various standards | No change, no impact | 1 January 2009 | 1 January 2009 |
| AASB 2007-4 | Various standards | No change, no impact | 1 July 2007 | 1 January 2008 |
| AASB 2007-6 | Various standards | No change, no impact | 1 January 2009 | 1 January 2009 |
| AASB 2007-7 | Various standards | No change, no impact | 1 July 2007 | 1 January 2008 |
| New Standard | AASB 8: Operating Segments | No change, no impact | 1 January 2009 | 1 January 2009 |
| Interpretation 11 | AASB 2: Share-based payment – Group and Treasury Share Transactions | No change, no impact | 1 March 2007 | 1 January 2008 |

All other pending Standards issued between the previous financial report and the current reporting dates have no application to either the Parent Entity or Consolidated Group.

## 33. COMPANY DETAILS

The registered office of the Company is:

HeartWare Limited
Level 57
MLC Centre
19–29 Martin Place
SYDNEY NSW 2000

The principal places of business are as follows:

**Corporate Offices:**
HeartWare Limited
Level 57
MLC Centre
19–29 Martin Place
SYDNEY NSW 2000

**Operations Facility:**
HeartWare, Inc.
3351 Executive Way
MIRAMAR FLORIDA USA 33025

# ASX Additional Information

**for the year ended 31 December 2007**

Additional information required by the Australian Securities Exchange Limited Listing Rules and not disclosed elsewhere in this Annual Report is set out below.

**Shareholder information set out below was applicable as at 3 February 2008.**

## Distribution of equity security holders

| | Ordinary Shares | | Options (unlisted) | |
|---|---|---|---|---|
| | Number of holders | Number of shares | Number of holders | Number of options |
| 1 - 1,000 | 102 | 81,098 | - | - |
| 1,001 - 5,000 | 286 | 924,904 | - | - |
| 5,001 - 10,000 | 268 | 2,329,433 | - | - |
| 10,001 - 100,000 | 601 | 21,610,054 | 39 | 1,645,960 |
| 100,001 - and over | 122 | 223,154,788 | 43 | 25,186,810 |
| | 1,379 | 248,100,277 | 82 | 26,832,770 |

The number of shareholders holding less than a marketable parcel was 19.

## Twenty largest shareholders

| Name | | Number of ordinary shares held | Percentage of capital held % |
|---|---|---|---|
| 1 | Apple Tree Partners I L P | 91,588,782 | 36.92 |
| 2 | HSBC Custody Nominees (Australia) Limited - GSCO ECSA | 20,667,965 | 8.33 |
| 3 | HSBC Custody Nominees (Australia) Limited - A/C 2 | 14,846,843 | 5.98 |
| 4 | National Nominees Limited | 14,301,102 | 5.76 |
| 5 | ANZ Nominees Limited <Cash Income A/C> | 11,299,388 | 4.55 |
| 6 | J P Morgan Nominees Australia Limited | 9,714,776 | 3.92 |
| 7 | Mr Jon B Platt | 8,000,000 | 3.23 |
| 8 | HSBC Custody Nominees (Australia) Limited | 6,157,574 | 2.48 |
| 9 | Merrill Lynch (Australia) Nominees Pty Limited | 4,449,259 | 1.79 |
| 10 | Citicorp Nominees Pty Limited | 3,123,728 | 1.26 |
| 11 | Bond Street Custodians Limited <Macquarie Smaller Co's A/C> | 2,583,333 | 1.04 |
| 12 | Asia Union Investments Pty Limited | 2,061,359 | 0.83 |
| 13 | Mr Matthew Rosenthal | 1,777,947 | 0.72 |
| 14 | Warman Investments Pty Ltd | 1,650,000 | 0.67 |
| 15 | Moore Family Nominee Pty Ltd <moore Family Super Fund A/C> | 1,200,000 | 0.48 |
| 16 | Equity Trustees Limited <SGH Pi Smaller Co's Fund> | 1,192,355 | 0.48 |
| 17 | Mr Robert Thomas & Mrs Kyrenia Thomas <Rob Thomas Super Fund A/C> | 1,100,000 | 0.44 |
| 18 | Nickeli Holdings Pty Limited <Wade Family S/Fund A/C> | 1,051,333 | 0.42 |
| 19 | Mr Stan Siejka | 814,820 | 0.33 |
| 20 | Mr Paul Burgess Cave | 800,000 | 0.32 |
| **Total** | | **198,380,564** | **79.96** |

### Options Unlisted

The Company has 26,832,770 options on issue under both the Company's Employee Share Option Plan ("ESOP") and the Performance Rights Plan. These options are held by 72 individuals with 2 directors holding 6,345,468 options under the ESOP.

The Company has an addition 1.85 million Incentive Options on issue, with 1.5 million of these being held by 3 directors and the balance being held by 2 individuals.

### Escrowed Securities

The Company has no escrowed securities.

### Substantial Shareholders

The number of shares held by the substantial shareholders and their associated interests are set out below:

| | Number of Ordinary Shares | Percentage % |
|---|---|---|
| Apple Tree Partners | 91,588,782 | 36.9 |
| Mr Muneer A. Satter | 18,450,000 | 7.44 |
| Pequot Capital Management, Inc. | 12,662,135 | 5.10 |

### Voting Rights

### Ordinary shares

The voting rights set out in the Company's Constitution are:

(a) at meetings of members or classes of members each member entitled to vote may vote in person or by proxy or attorney; and

(b) on a show of hands every person who is a member has one vote and on a poll every person present in person or by proxy or attorney has one vote for each ordinary share held.

### General Information

The name of the Company Secretary is Mr David John McIntyre.

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

Registers of securities are held at Registries Limited, Level 7, 207 Kent Street, Sydney, NSW 2000.

Quotation has been granted for all ordinary shares of the Company (excluding escrowed securities) on all Member Exchanges of the Australian Securities Exchange Limited.

Details on options over unissued shares, including the convertible note, are set out in the Directors Report.

### Statement on use of cash and assets in a form readily convertible to cash

Since admission to the Australian Securities Exchange Limited on 31 January 2007, the Company has used the cash and assets in a form readily convertible to cash that it had at the time of admission in a manner consistent with its business objectives.

# Corporate Directory

**Robert Thomas**
Non-Executive Chairman

**Douglas Godshall**
Chief Executive Officer

**Dr Seth Harrison**
Non-Executive Director

**Robert Stockman**
Non-Executive Director

**Dr Denis Wade**
Non-Executive Director

**Dr Christine Bennett**
Non-Executive Director

**Douglas Godshall**

Level 57
MLC Centre
19–29 Martin Place
SYDNEY NSW 2000
AUSTRALIA
PH: (02) 9238 2064

Registries Limited
Level 2
28 Margaret Street
SYDNEY NSW 2000
AUSTRALIA

O. Howard "Bud" Frazier, MD (Chairman)
Steven Boyce, MD
Laman Gray Jr., MD
Georg Wieselthaler, MD
Gerry O'Driscoll, MD
Asghar Khaghani, MD

David McIntyre

3351 Executive Way
Miramar
MIAMI FLORIDA 33025
UNITED STATES OF AMERICA

Grant Thornton NSW
Level 17
383 Kent Street
SYDNEY NSW 2000
AUSTRALIA

DESIGN: COLLIER & ASSOCIATES THE STRATEGIC DESIGN COMPANY # 12880


HeartWare

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

# FORM 10-K

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

**For The Fiscal Year Ended December 31, 2007**

**OR**

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

**COMMISSION FILE NUMBER: 000-52595**

# 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.) |

**Level 57, MLC Centre**
**19-29 Martin Place**
**Sydney NSW 2000**
**Australia**
**+61 2 9238 2064**

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

**Securities registered pursuant to Section 12(b) of the Act: None**
**Securities registered pursuant to Section 12(g) of the Act:**
**Ordinary Shares, No Par Value**
**(Title of class)**

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. Yes ☐ No ☑

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

| Large accelerated filer ☐ | Accelerated filer ☐ | Non-accelerated filer ☐ (Do not check if a smaller reporting company) | Smaller reporting company ☑ |
|---|---|---|---|

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

The aggregate market value of the outstanding ordinary shares, other than shares held by persons who may be deemed affiliates of the registrant, computed by reference to the closing sales price for the registrant's ordinary shares on June 29, 2007, as reported on the Australian Securities Exchange, was approximately $47.5 million (AU$56 million).

As of January 31, 2008, the registrant had 248,100,277 ordinary shares outstanding.

**References**

Unless the context requires otherwise, references in this Annual Report on Form 10-K 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 8, 2003. HeartWare, Inc. was acquired by HeartWare Limited on January 24, 2005.

**Forward-Looking Statements**

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

- our 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.

Our management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on our forward-looking statements because they speak only as of the date when made. We do not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. We may not actually achieve the plans, projections or expectations disclosed in our forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including without limitation those described in Part I, "Item 1A. Risk Factors" and elsewhere in this report and those described from time to time in our future reports filed with the Securities and Exchange Commission.

**Corporate Information**

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 Level 57, MLC Centre, 19-29 Martin Place, Sydney NSW 2000, Australia. Our telephone number is 011-61-2-9238-2064. Our website address is www.heartware.com. We have included our website address in this Annual Report on Form 10-K as an inactive textual reference only. The information on, or that can be accessed through, our website is not part of this Annual Report on Form 10-K.

**US Dollars**

Unless indicated otherwise in this Annual Report, all references to $ or dollars refer to United States dollars, the lawful currency of the United States of America. References to AU$ refer to Australian dollars, the lawful currency of the Commonwealth of Australia.

**Trademarks**

HeartWare, the HeartWare LVAD System, MVAD, and IV VAD, are the trademarks of the Company, in the United States, Australia and other countries. All other trademarks and trade names mentioned in this Annual Report on Form 10-K are the property of their respective owners.

**PART I.**

**Item 1. BUSINESS**

**Overview**

HeartWare is a medical device company focused on driving innovation in the left ventricular assist device, or LVAD, market by developing a family of blood pumps that are significantly smaller and that are implanted by progressively less invasive surgical techniques.

Our pumps 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 believe that the unique design, smaller size, less invasive implant techniques, increased durability and reliability of our pumps will enable physicians to treat a wider range of patients. 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 and products include:

- small size which allows for routine implantation in the space immediately surrounding the heart, known as the pericardial space, unlike other full-output LVADs that are currently available and which are implanted in the abdomen;
- a hybrid passive 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 hydrodynamic coupling with motor design to maximize power efficiency and enable the delivery of up to ten liters of blood flow per minute.

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

We are a development stage company and as such have not generated revenue from any of our products. We are currently conducting a combined European and Australian human clinical trial for the HeartWare LVAD System. This international trial began in March 2006 and called for the implantation of our pump in 20 patients with advanced heart failure. The endpoint for the trial is patient survival to the earlier of 180 days or transplantation. On August 31, 2007, we successfully implanted our 20th patient. We have since decided to expand the number of patients in our international clinical trial to 50. Although there is no requirement to conduct additional implants, we believe that the expansion of the international trial will provide us with a good opportunity to maintain our

relationships with our European and Australian clinical sites while also providing increased depth of clinical data. As of the date of this report, we have implanted 30 patients across our 5 international clinical centers, with more than 6,050 cumulative implant days, or approximately 16.5 years of patient data. 18 of our first 20 patients have reached successful completion of the 180-day primary endpoint. Our European and Australian clinical trial results will be compiled into a single data set and submitted for European regulatory approval. We plan to seek regulatory approval in Australia after we receive regulatory approval in Europe.

The data from our European and Australian clinical trial was also used to support our application for approval by the US Food and Drug Administration, or FDA, for a bridge-to-transplant study in the United States. As of the date of this report, we have not yet received final approval from the FDA to commence our US clinical trial. Receipt of such FDA approval in this regard is critical as this will mark the commencement of revenue as the Company believes it will be reimbursed during the course of our US clinical trial.

Our next generation device, the Miniaturized Ventricular Assist Device, or MVAD, is based on the same technology platform as the HeartWare LVAD System but adopts an axial flow, rather than a centrifugal flow, configuration. The MVAD, which is currently at the prototype stage and undergoing implantation, or cannulation, studies in animals, is approximately one-third the size of the HeartWare LVAD System. We expect to initiate human clinical trials for the MVAD in 2009. We believe that the MVAD will be implantable by surgical techniques that are even less invasive than those required to implant the HeartWare LVAD System. 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 HeartWare LVAD System 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 HeartWare LVAD System.

**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 a cardiovascular disease 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 in the United States.

Heart failure means that the heart's pumping power is weaker than normal. In a healthy person, the left ventricle of the heart pumps oxygenated blood into the aorta and the blood is then circulated throughout the body until it returns through the venous system to the right side of the heart, which pumps it into the lungs where it is re-oxygenated. If the left ventricle is not working properly, the oxygenated blood is not fully cleared from the lungs and the blood is not circulated effectively. If the muscle of the left ventricle is damaged or is not working efficiently, it will tend to work harder in an effort to supply adequate blood flow into the aorta. 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. The symptoms of heart failure can be treated by pharmaceuticals or pacemaker technology but the underlying process is largely irreversible.

The traditional 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 patient symptoms to everyday activities and the patient's quality of life and overall functional limitations. 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. |

More recently, the American Heart Association and American College of Cardiology developed the "Stages of Heart Failure" which provides a different scale than that provided by the NYHA functional classifications referred to above. The Stages of Heart Failure emphasize the evolution and progression of heart failure and are described below:

| Stage | Definition |
|---|---|
| Stage A | Those patients who are at risk of developing heart failure. |
| Stage B | Those patients who have known heart failure, more commonly referred to as a "structural abnormality of the heart", but have never had heart failure. This includes patients diagnosed with "systolic" heart failure which occurs when the heart muscle doesn't contract with enough force, so there is not enough oxygenated blood being pumped throughout the body. |
| Stage C | Those patients who have a structural abnormality of the heart and current or previous symptoms of heart failure. |
| Stage D | Those patients who have late, fully developed symptoms of heart failure that is not readily yielding to medical treatment. |

While not constituting an "exact match", we believe that Stage C and D are broadly equivalent to NYHA Class III and IV.

***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. We estimate that the number of Class III or Class IV heart failure patients worldwide is approximately 7 million and that approximately 20% of these patients could be assisted by a circulatory assist device. We believe that there is a significant market opportunity for LVADs that are smaller, easier to use and more reliable than the devices that are currently available.

We estimate that there are approximately 5 million Class III heart failure patients worldwide. Of these 5 million patients, we estimate that approximately 1 million patients are severely impacted by CHF but are not yet nearing the end stages of the disease. While these patients suffer on a daily basis, they do not need the same full support as the sicker, later-stage Class IV patients and they may be less willing to undergo the open chest procedure required for the placement of the HeartWare LVAD System or other LVADs. We believe that up to one-third of these 1 million patients would be candidates for a less invasive surgical approach such as the one we are developing with the MVAD. We believe that this less invasive surgical approach should make more patients and their physicians comfortable with the benefits of the implant because of the potential for reduced surgical risk and shorter post-operative recovery periods.

We expect the IV VAD to address the clinical needs of the balance of these 1 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.

***CHF Treatment Options***

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

Drug treatment and pacing devices that are designed to stimulate the heart do not halt the progression of 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. Drug regimens aim to improve the effectiveness of the heart's contractions and slow CHF progression but some investigations have suggested that the increase in survival is limited and that drug treatments merely delay the advance of CHF.

***LVAD Treatment for Advanced Heart Failure***

Circulatory assist devices are designed to take over some or all of the pumping function of the heart by mechanically pumping blood into the aorta. Implantation of circulatory assist devices is the only therapy that has been shown to fully rehabilitate a patient from NYHA Class IV to Class I. 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, concluded that "the use of a left ventricular assist device in patients with advanced heart failure resulted in a clinically meaningful survival benefit and an improved quality of life. A left ventricular assist device is an acceptable alternative therapy in selected patients who are not candidates for cardiac transplantation."

A large population of end-stage heart failure patients can benefit from LVAD therapy, such as our HeartWare LVAD System. 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. According to information available in 2006, there are approximately 3,000 heart transplant procedures conducted each year. We estimate that approximately 58% of patients spend 1 year or more on the transplant waiting list and approximately 37% of patients wait as long as 3 years or more. 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 and cardiologists 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 75%. We believe that device durability and reliability, together with ease of implantation, are important factors in determining whether destination therapy will become accepted by physicians and patients. Since we believe that our devices will offer exceptional durability and reliability, we expect that the HeartWare LVAD System 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 approximately 75% in the Harefield Hospital study. Confirmatory studies are underway in the United States by Thoratec Corporation, which has

established the Harefield Recovery Protocol Study, or HARPS, with initial patient enrollment in the trial occurring in the first half of 2007. We believe that if use of LVADs in these circumstances achieves widespread physician acceptance, the potential market for use of our HeartWare LVAD System in bridge-to-recovery therapy could increase significantly since removal of the device reduces the clinical risks presented by pumps that are left in place for multiple years.

**Our Solution and Products**

***Proprietary Pump Technology***

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

***The HeartWare LVAD System***

The first product in our portfolio, the HeartWare LVAD System, is a small, permanently implantable LVAD capable of generating up to ten liters of blood flow per minute. With a displaced volume of only 45 cubic centimeters and a mass of 145 grams, the HeartWare LVAD System 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 HeartWare LVAD System in the pericardial space generally leads to significantly shorter surgery time and a less invasive procedure relative to alternative devices, which are generally implanted in the abdomen.

Device reliability of the HeartWare LVAD System 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 are designed to help minimize the risk of pump-induced damage to blood cells, or thrombus, which means blood clotting.

Upon commercialization, we intend to provide the HeartWare LVAD System and its related components in 1 of 3 separate "kits" to be purchased in combination or separately, depending upon intended use. One kit will be a patient kit that will include the HeartWare LVAD System, a patient control unit, multiple battery packs, 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 HeartWare LVAD System implant programs that will include a contracted number of patient kits, a center support kit and associated training materials.

The HeartWare LVAD System product design is fundamentally complete as it is currently in use in human clinical trials. We have made and will likely continue to make design improvements or enhancements as data from these trials are returned and preliminary feedback is received by us. In order for the HeartWare LVAD System to be available for commercialization, the current international clinical trial, together with all post-implant data

aggregation, must be successfully completed. The successful completion of this international clinical trial will enable us to commercialize the HeartWare LVAD System in Australia and certain European countries without further regulatory approval. In the United States, we must obtain the approval of the FDA before the HeartWare LVAD System can be commercialized. In November 2007, we filed a submission with the FDA requesting an Investigational Device Exemption, or IDE, to commence a bridge-to-transplant clinical trial in the United States. The resulting international clinical trial data forms the basis for our application to the FDA for approval of the HeartWare LVAD System. Once regulatory approvals have been obtained, availability of the HeartWare LVAD System will depend upon our ability to manufacture larger quantities of the product and be subject to other general business risks and uncertainties identified elsewhere in this Annual Report on Form 10-K.

***Implantable Devices***

Currently, the HeartWare LVAD System and all commercially available LVADs are powered by a controller and battery pack worn external to the body. Power is transferred to the implanted pump via a thin electrical cable, called a driveline, which exits the patient's skin in the abdominal area.

We are working to develop an implantable system including transcutaneous energy transfer, or TET, which will be compatible across the HeartWare family of pumps. This system will be designed to provide inductive energy transfer, or recharging, across the skin, eliminating the need for a driveline and allowing complete implantation of the LVAD system, including the controller and batteries. TET technology is already used to recharge neurostimulators and other implantable electronic devices.

We believe that a fully implantable system will be appealing to physicians and patients. The system will enable patients to charge their implanted batteries and "detach" for periods of time, thereby allowing them to more easily engage in normal daily activities and further improving their quality of life. The implantable system is in the early stages of development. We are beginning to selectively recruit personnel who have previously developed implantable as well as TET technology for other companies. Before the implantable system will be available for clinical trials, the Company must undertake significant work, including building functional prototypes of the implantable system, completing animal studies, developing manufacturing processes and completing formal verification testing and GLP animal testing.

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

We believe that the Company may also have a unique opportunity to provide a leading TET system due to the inherently lower power consumption and energy efficiency advantages in our HeartWare LVAD System 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 HeartWare LVAD System. The MVAD has been shown in animal trials to have comparable blood flow characteristics to the HeartWare LVAD System 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 HeartWare LVAD System 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. Before the MVAD product will be available for commercial sale, we need to achieve the following milestones:

- finalization of surgical implantation techniques and procedures, including identification of necessary surgical implant tools;
- completion of the rotor hydraulic and suspension system designs;
- finalization of device (pump) prototypes and performance of confirmatory in-vivo (animal) studies;
- development of system peripherals (e.g., control, batteries, power adapters) utilizing the HeartWare LVAD System components;
- successfully conduct a clinical trial; and
- obtain regulatory approvals.

***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 HeartWare LVAD System. 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 HeartWare LVAD System but who also are not sufficiently advanced in their disease to warrant thoracic, or chest, surgery. The IV VAD either will likely be 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 1 million of the 5 million patients in the United States who suffer from Class III heart failure would be potential candidates for the IV VAD. Treating patients early in the progression of their heart failure, and with a less invasive device such as the IV VAD, could halt disease progression and improve the possibility that the heart would fully recover.

Before the IV VAD product will be available for commercial sale, we need to achieve the following milestones:

- completion of a working prototype;
- completion of marketing requirements study to determine the system requirements;
- selection of the surgical implantation techniques and procedures and identification of necessary implant tools;
- development of the device support and anchoring systems;
- completion of the rotor hydraulic and suspension system designs;
- development of system peripherals (e.g., control, batteries, power adapters) utilizing the HeartWare LVAD System components, if appropriate;
- successfully conduct a clinical trial; and
- obtain regulatory approvals.

*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 HeartWare LVAD System, and begin commercial HeartWare LVAD System sales, while at the same time develop new products. Our plan includes:

***Obtaining regulatory approval and commercially launching the HeartWare LVAD System*** — Our first priority is to obtain regulatory approval, internationally and in the United States, for the HeartWare LVAD System and to launch the HeartWare LVAD System commercially. We have completed our initial enrollment of 20 patients in our combined European and Australian clinical trial and have recently determined to expand the international trial to 50 patients. This international clinical trial is aimed at achieving European and Australian regulatory approval for the HeartWare LVAD System. In November 2007, we filed a submission with the FDA seeking an IDE to commence a multi-center bridge-to-transplant trial in the United States. The FDA is continuing to review our request for an IDE and we expect the FDA to shortly make its decision regarding our IDE application.

***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, Australia and some European countries and eventually engage distributors elsewhere.

***Focusing on continuous product development*** — In parallel with the clinical development of the HeartWare LVAD System, 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 in 2007 we focused on cannulation techniques for our MVAD via additional animal studies, with this work expected to continue throughout 2008. We expect our first IV VAD animal trial to begin in 2010. We also have a working 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 development work for our TET system to continue throughout 2008. We are also continuing to develop enhancements to our existing HeartWare LVAD System peripheral equipment based upon early clinician and patient feedback as well as continuing to develop physiological control algorithms. The objective of these projects is improved ease of implantation and use of the HeartWare LVAD 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.

**Sales and Marketing**

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

Once we obtain regulatory approval to sell our product commercially, we intend to develop a network of training centers. We plan to use selected trial centers in Australia, Europe and the United States as training centers and the participating physicians as instructors for the HeartWare LVAD System 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 where appropriate. We expect that our Australian operations center will serve as a base of operations to enter the Asian market for the HeartWare LVAD System.

**Intellectual Property**

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

We have an extensive patent portfolio which includes 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, Italy and Israel. We also have 23 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;
- flow estimation based on impeller speed and viscosity; and
- use of platinum alloy for blood pump impellers.

Major patents and pending patent applications covering technologies for our HeartWare LVAD 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, upon the proprietary rights of third parties. If third parties successfully assert infringement or other claims against us, we may not be able to sell our products. In addition, patent or intellectual property disputes or litigation may be costly, result in product development delays or divert the efforts and attention of our management and technical personnel. If any such disputes or litigation arise, we may seek to enter into a royalty or licensing arrangement. However, such an arrangement may not be available on commercially acceptable terms, if at all. We may decide, in the alternative, to litigate the claims or to design around the patented or otherwise proprietary technology. At this time we are not party to any legal proceedings that relate to patents or proprietary rights.

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

We own a registered trademark in the United States, Europe and Australia for HEARTWARE. 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 HeartWare LVAD System. In addition, the FDA will conduct a pre-approval inspection of our and our suppliers' facilities to evaluate compliance with the quality system regulation. 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 required to support a PMA. Clinical trials for a "significant risk" device such as ours require submission of an application for an 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 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 are presently compiling our initial submission for CE marking approval for our HeartWare LVAD System and expect to have final CE marking approval during mid 2008. The method of assessing conformity with applicable regulatory requirements varies depending on the class of the device, but for our HeartWare LVAD System, 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 5 classes of medical devices and HeartWare's circulatory assist device falls under the category of "active implantable medical devices."

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

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 and 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 2 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 many private insurers will cover our devices if they are also covered by Medicare.

European reimbursement varies from country to country and often hospital to hospital. The European system is more effective at focusing resource intensive procedures in a small number of centers within each country and LVAD's fall into that category of resource intensive procedures. In those hospitals that perform LVAD implantation, we believe that there 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, Jarvik Heart, MicroMed Technology, Inc, Ventracor Limited, Berlin Heart AG, Abiomed, Inc. and Terumo Heart, Inc., and a range of other smaller, specialized medical device companies with devices at varying stages of development. We are not aware of whether any of these competitors is currently developing a new full-output pump that is equivalent or lesser in size to the HeartWare LVAD System and which is designed to be implanted by minimally invasive techniques, including implantation above the diaphragm in all patients. Further, there may be companies unknown to us that are developing competitive pumps of lesser or similar output levels or other competitive products, and we can offer no assurance that the above competitors or these other parties will not be successful in their efforts.

We believe that the key features of our technology that provide us with a competitive advantage over our competitor's products include:

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

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

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

**Research and development**

From the date of our inception through December 31, 2007, we have incurred approximately $37 million on research and development of our LVAD technologies. Research and development costs include activities related to the research, development, design, testing, and manufacturing of prototypes of our products. It also includes clinical activities and regulatory costs. Research and development costs also include cost associated with certain HeartWare employees engaged in research and development activities, as well as external consultants and contractors that we may engage from time to time. We expect our research and development expenses to increase significantly as we continue the development of our HeartWare LVAD System, initiate commercialization activities, research the application of, and develop our miniaturized heart pump technology, conduct additional clinical trials and hire additional employees.

**Manufacturing**

Our products are currently being utilized only in connection with clinical trials and are not approved for sale. Our manufacturing activities to date, and for the foreseeable future, will continue to consist primarily of process development, component assembly, quality control testing and research and development activities.

A number of critical components of our HeartWare LVAD System, including the center post, pump housing and impeller, are provided by outside suppliers and then assembled and tested by us in-house. We do not presently have supply agreements in place with our suppliers, other than a production services agreement with Minnetronix, Inc., which is described elsewhere herein. We have not secured second source suppliers for 2 of our critical suppliers.

**Employees**

As of December 31, 2007, we had 75 employees, of whom approximately 57 employees are engaged in operations activities including research and development, quality assurance and manufacturing activities, 7 are engaged in marketing and clinical activities and 11 are engaged in finance, legal and other administrative functions. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relations with our employees to be good.

**Legal Proceedings**

We are not currently involved in any legal proceedings.

**Corporate History**

HeartWare 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 HeartWare LVAD System since approximately 1995.

In May 2003, Kriton filed for protection from creditors under Chapter 11 of the United States Bankruptcy Code. On May 20, 2003, Kriton and its lead investor Apple Tree Partners I, L.P. proposed a joint plan of liquidation for Kriton. On June 20, 2003, the United States Bankruptcy Court of the Southern District of Florida issued a court order confirming the plan of liquidation. This court order, together with a supplemental court order approving a settlement between Apple Tree Partners and various stockholders of Kriton issued on July 3, 2003, approved the sale of substantially all the assets of Kriton to HeartWare, Inc., and on July 10, 2003, HeartWare, Inc. purchased substantially all of the assets of Kriton free and clear of any and all liens, security interests, encumbrances and claims. The assets included all of Kriton's patents and other intellectual property which was assigned to HeartWare, Inc.

In connection with the asset purchase, HeartWare, Inc. issued Series A-1 and Series A-2 Preferred Stock to certain creditors of Kriton. The Series A-1 and Series A-2 Preferred Stock do not have any voting rights or the right to receive dividends but entitle the holders thereof to receive upon certain liquidation events of HeartWare, Inc. and amount equal to $10 per share of Series A-1 and an amount of $21 per share of Series A-2.

HeartWare, Inc. continued to operate as an independent entity until 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 $21.9 million and $17.4 million for the fiscal years ended December 31, 2007 and 2006, respectively. As of December 31, 2007, our accumulated deficit was $53.2 million. We do not currently have any products that have been approved for sale and we continue to incur significant 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, initiate and 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 competitive, commercial products. We may never succeed in these activities, and we may never obtain regulatory approvals or otherwise generate revenues sufficient to achieve profitability. If we do achieve profitability, we may not be able to sustain it.

***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 revenue from commercial sales or any other significant revenue. Although, we believe our cash and cash equivalents on hand and expected cash flows from operations, including expected sales, will be sufficient to fund our operations for at least the next twelve months notwithstanding that we do plan to seek additional funding in this period. Our ability to conduct our operations over the long-term is dependent on our ability to obtain additional funding by the first half of 2009. 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 or reduced or may cease entirely.

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

***We have no products approved for commercial sale, and our success will depend heavily on the success of our clinical trial program for our lead device, the HeartWare LVAD System, particularly our US clinical trial which has not yet commenced. If the results of our international clinical trial are uncompetitive or we are unable to complete our US trial or if we experience significant delays in the completion of any of our clinical trials, our ability to obtain regulatory approval to commercialize our products and to generate revenues will be harmed.***

On August 31, 2007, we completed enrollment for our international clinical trial by implanting our 20th patient with our lead device, the HeartWare LVAD System. Having completed enrollment, we plan to make a submission to the Ethics Committee at each of the 5 centers in the trial to increase the number of patients to 50. Currently, we have received permission to extend our international clinical trial to 30 patients from all 5 of international centers. Though there is no requirement to conduct further implants, we believe extending patient numbers and increasing the depth of clinical data will be beneficial.

As of the date of this report, we have completed implants in 30 patients with cumulative support duration of more than 6,050 days. Once the primary endpoint, 180 days or transplant, is reached for at least 20 patients we will submit data for our CE Mark in Europe.

In November 2007, we made a submission to the US Food and Drug Administration for an IDE to commence a bridge-to-transplant clinical trial in the United States for our HeartWare LVAD System. The purpose of the proposed study is to evaluate the safety and effectiveness of the HeartWare LVAD System in patients eligible for cardiac transplantation with refractory, advanced heart failure. The proposed primary endpoint is survival to anesthetic induction for heart transplantation, survival to explant for myocardial recovery, or survival to 180 days on device support, whichever occurs first. As of the date of this report, we have not yet received final approval from the US Food and Drug Administration to commence our clinical trial.

Completion of our clinical trial program could be delayed or adverse events during the trial could cause us to repeat or terminate the trial. If 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 or we may never obtain such regulatory approvals. Our clinical trials may also be suspended or terminated at any time by regulatory authorities or by us. Any failure or significant delay in completing clinical trials for our products candidates will harm our financial results and the commercial prospects for our products candidates.

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

- slower than expected rates of patient recruitment and enrollment, including as a result of our competitors undertaking similar clinical trials or having equivalent products that have received approved for sale;
- failure of patients to complete the clinical trial;
- patients preferring to use approved devices rather than experimental devices such as our HeartWare LVAD System;
- unforeseen safety issues;
- lack of efficacy during clinical trials;
- inability or unwillingness of patients or medical investigators to follow our clinical trial protocols;
- inability to monitor patients adequately during or after treatment;
- risks associated with trial design, which may result in a failure of the trial to show statistically significant results even if the product is effective;
- governmental and regulatory delays or changes in regulatory requirements, policies or guidelines; and
- varying interpretation of data by regulatory agencies.

***If either of our international or our US clinical trial does not demonstrate the safety and efficacy of the HeartWare LVAD System or if we do not receive regulatory approval in Europe, Australia and the United States, we will be unable to commercialize our product and generate revenues in those locations.***

Before we can obtain regulatory approval to commercialize the HeartWare LVAD System 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 for our international clinical trial is that 20 patients with advanced heart failure shall have been implanted with the HeartWare LVAD System and shall have survived to the earlier of 180 days or to the time that they have received a heart transplant. As of February 28, 2008, we have implanted 30 patients with an average implant duration exceeding 200 days per patient. Our first

20 patients in our international clinical trial, which will form the basis of our CE mark submission, have been supported for an average duration of approximately 261 days, with 18 of these patients having reached the primary endpoint of our international clinical trial. Despite the encouraging results that we have observed to date, we may not be able to demonstrate the safety and efficacy of the HeartWare LVAD System. 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.

We must also demonstrate the safety and efficacy of our products in the United States by undertaking a separate clinical trial, which will initially be pursued by us conducting a bridge-to-transplant clinical trial in the United States. As of the date of this report, we have applied for, but have not yet received, our IDE to commence our bridge-to-transplant clinical trial in the United States for our HeartWare LVAD System. As such, we have not yet implanted any patients in the United States and, accordingly, it is uncertain as to whether we will be able to demonstrate the safety and efficacy of the HeartWare LVAD System for the purposes of seeking US regulatory approval.

***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 HeartWare LVAD System, or any of our other products, in the United States. We can offer no assurance that our HeartWare LVAD System, or any of our future products, will receive FDA approval.

In order to obtain FDA approval to commence sales of our HeartWare LVAD System in the United States, we will be required to receive a pre-market approval, or 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 as noted above before we can commence a clinical trial, we must receive an IDE, and we do not yet know the outcome of our request to the FDA for an IDE. On October 31, 2007 we shipped our submission to the US Food and Drug Administration for an IDE for the HeartWare LVAD System and we have not yet received a final determination.

Even if we receive an IDE, we do not know if our US clinical trials will begin or be completed on schedule or at all. Even if these trials are completed, we do not know if they 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 HeartWare LVAD System, or any future products or enhancements or modifications to any products, could:

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

There can be no assurance that we will receive the required approvals from the FDA or, if we do receive the required approvals, that we will receive them on a timely basis or that we will otherwise be able to satisfy the conditions of such approval, if any. The failure to receive product approval clearance by the FDA will have a material adverse effect on our business, financial condition or results of operations.

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

Even after products have received marketing approval or clearance, product approvals and clearances by the FDA can be withdrawn due to failure to comply with regulatory standards or the occurrence of problems following initial approval. As a device manufacturer, we are required to demonstrate and maintain compliance with the FDA's Quality System Regulation, or QSR. The QSR is a complex regulatory scheme that covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. The FDA enforces the QSR through periodic unannounced site inspections. In addition, the US federal Medical Device Reporting regulations require us to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, could cause or contribute to a death or serious injury. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA. Our failure to comply with the QSR or to take satisfactory corrective action in response to an adverse QSR inspection could result in enforcement actions, including a public warning letter, a shutdown of or restrictions on our manufacturing operations, delays in approving or clearing a product, refusal to permit the import or export of our products, a recall or seizure of our products, fines, injunctions, civil or criminal penalties, or other sanctions, any of which could cause our business and operating results to suffer.

In the European Union, we are required to maintain certain ISO certifications in order to sell our products and must undergo periodic inspections by notified bodies to obtain and maintain these certifications. 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 HeartWare LVAD System or any other product that we may develop, sales of our products in other jurisdictions will be subject to regulatory requirements that vary from country to country. The time and cost required to obtain approvals from these countries may be longer or shorter than that required for FDA approval, and requirements for licensing may differ from those of the FDA. Laws and regulations regarding the manufacture and sale of our products are subject to future changes, as are administrative interpretations and policies of regulatory agencies. If we fail to comply with applicable foreign, federal, state or local market laws or regulations, we could be subject to enforcement actions. Enforcement actions could include product seizures, recalls, withdrawal of clearances or approvals, and civil and criminal penalties, which in each case would harm our business.

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

Even if we obtain regulatory approvals to commercialize the HeartWare LVAD System or any other product that we may develop, our products may not gain market acceptance among physicians, patients, health care payers or the medical community. The degree of market acceptance of any of the devices that we may develop will depend on a number of factors, including:

- the perceived effectiveness of the product;
- the prevalence and severity of any side effects;
- potential advantages over alternative treatments or competitive products;
- the strength of marketing and distribution support; and
- sufficient third party coverage or reimbursement.

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

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

The availability and levels of reimbursement by governmental and other third party payers affect the market for our product candidates. The efficacy, safety, performance and cost-effectiveness of our product candidates and of any competing products will determine the availability and level of reimbursement. Reimbursement and health care payment systems 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 or 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 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 material and adverse on our future results.

***We have limited sales, marketing and distribution experience.***

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

- we may not be able to attract and build a significant, successful or qualified marketing or sales force;
- the cost of establishing, training and providing regulatory oversight for a marketing or sales force may be substantial; and

- there are significant legal and regulatory risks in medical device marketing and sales, and any failure to comply with all legal and regulatory requirements for sales, marketing and distribution could result in enforcement action by the FDA or other authorities that could jeopardize our ability to market the product or could subject us to substantial liability.

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

We currently manufacture our 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 substantially the production process 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 with similar, additional, approvals required in order to achieve CE marking in Europe. Suppliers of components of, and products used to manufacture, our products must also comply with FDA and foreign regulatory requirements, which often require significant time, money, resources and record-keeping and quality assurance efforts and subject us and our suppliers to potential regulatory inspections and stoppages. If we or our suppliers fail to comply with the regulatory requirements for our manufacturing operations, our commercialization efforts could be delayed, which would harm our business and our results of operations.

***We rely on specialized suppliers for certain components and materials.***

We depend on a number of suppliers to successfully manufacture sufficient quantities of the components we use in our products. We rely on suppliers for critical components including the center post, housing and impeller that are assembled into our primary product, the HeartWare LVAD System, as well as finished products that comprise our peripheral and external equipment that is included in the HeartWare LVAD System. Lead times for our components are significant and can be up to as long as sixteen weeks and many of our components are manufactured to very tight tolerances. We are in the process of negotiating supply agreements with our key suppliers but have not formalized any supply arrangements, with the exception of the productions service agreement described below.

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

We have a production services agreement with Minnetronix, Inc., located in Minnesota, as the supplier of the patient monitor and controllers. The agreement, effective August 17, 2006, is for an initial term of one year, and automatically renews for additional periods of one year unless either party elects not to renew the agreement by giving at least 90 days prior written notice. This agreement has been renewed through August 17, 2008 and we expect to renegotiate this arrangement during the course of 2008 for 2009 and beyond. The agreement may also be terminated in an event of a breach upon specified notice, or for convenience by either party giving the other party 180 days prior written notice. Although we are required to submit 12-month forecasts to Minnetronix, we cannot assure you that they will be able to have the capacity to accommodate our demand.

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

Additionally, we may experience problems or delays in our own manufacturing process, which may be harmful to our financial status or reputation and therefore make it more difficult or expensive for us to continue with or enter into relationships with specialized suppliers. Our business plan is predicated on entering into and renewing agreements with one or more external parties to manufacture components of our technology. If we are unable to secure or maintain agreements with these manufacturers on favorable terms or at all, then our ability to commercialize our technology and expand our operations will be impaired.

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

Our success depends in part on our ability to obtain and maintain protection in the United States and other countries of the intellectual property relating to or incorporated into our technology and products. As of December 31, 2007, we have 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 and Canada, and Israel. We also have 23 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 pending and future patent applications may not issue as patents or, if issued, may not issue in a form that will provide us any competitive advantage. Even if issued, existing or future patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of terms of patent protection we may have for our products. Changes in patent laws or their interpretation in the United States and other countries could also diminish the value of our intellectual property or narrow the scope of our patent protection. In addition, the legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. In order to preserve and enforce our patent and other intellectual property rights, we may need to make claims or file lawsuits against third parties. This can entail significant costs to us and divert our management's attention from developing and commercializing our products.

***Intellectual property litigation could be costly and disruptive to us.***

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

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

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

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

In addition to patented technology, we rely on our unpatented proprietary technology, trade secrets, processes and know-how. We generally seek to protect this information by confidentiality agreements with our employees, consultants, scientific advisors and third parties. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

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

We expect to continue to expand our operations and grow our research and development, product development, regulatory, manufacturing, sales, marketing and administrative operations. This expansion has placed, and is expected to continue to place, a significant strain on our management and operational and financial resources. To manage any further growth and to commercialize our products, we will be required to improve existing and implement new operational and financial systems, procedures and controls and expand, train and manage our growing employee base. In addition, we will need to manage relationships with various manufacturers, suppliers and other organizations, including various regulatory bodies in the United States and other jurisdictions. Our ability to manage our operations and growth will require us to improve our operational, financial and management controls, as well as our internal reporting systems and controls. We may not be able to implement such improvements to our management information and internal control systems in an efficient and timely manner and may discover deficiencies in existing systems and controls. Our failure to accomplish any of these tasks could materially harm our business.

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

Competition in the medical device industry is intense. Our products will compete against products offered by public companies, such as Thoratec, Inc. and Ventracor Limited, as well as several private companies, such as Jarvik Heart, Inc and Terumo Heart, Inc. Some of these competitors have significantly greater financial and human resources than we do and have established reputations or products, as well as distribution channels and sales and marketing capabilities that are larger and more established than ours. Additional competitors may enter the market, and we are likely to compete with new companies in the future. We also face competition from other medical therapies which may focus on our target market as well as competition from manufacturers of pharmaceutical and other devices that have not yet been developed. Competition from these companies could adversely affect our business.

Our ability to compete effectively depends upon our ability to distinguish our company and our products from our competitors and their products. Factors affecting our competitive position include:

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

***The competition for qualified personnel is particularly intense in our industry. If we are unable to retain or hire key personnel, we may not be able to sustain or grow our business.***

Our ability to operate successfully and manage our potential future growth depends significantly upon our ability to attract, retain and motivate highly skilled and qualified research, technical, clinical, regulatory, sales, marketing, managerial and financial personnel. We face intense competition for such personnel, and we may not be able to attract, retain and motivate these individuals. We compete for talent with numerous companies, as well as universities and non-profit research organizations. Our future success also depends on the personal efforts and abilities of the principal members of our senior management and scientific staff to provide strategic direction, manage our operations and maintain a cohesive and stable environment. Although we have employment and incentive compensation agreements with all of our executive officers and incentive and compensation plans for our other personnel providing them with various economic incentives to remain employed with us, these incentives may not be sufficient to retain them. We do not maintain key man life insurance on the lives of any of the members of our senior management other than for Mr. LaRose, our Chief Scientific Officer. The loss of key personnel for any reason or our inability to hire, retain and motivate additional qualified personnel in the future could prevent us from sustaining or growing our business.

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

The design, manufacture and marketing of human medical devices carries an inherent risk of product liability claims. Such liability claims may be expensive to defend and may result in large judgments against us. While our products are "investigational devices" and not approved for sale, we maintain clinical trial insurance and limited product liability insurance. We cannot be certain that such insurance will be sufficient to cover all claims that may be made against us. Our insurance policies generally must be renewed on an annual basis. We may not be able to maintain or increase such insurance on acceptable terms or at reasonable costs. A successful claim brought against us in excess, or outside, of our insurance coverage could seriously harm our financial condition and results of operations. Generally, our clinical trials will be conducted in patients with serious life-threatening diseases for whom conventional treatments have been unsuccessful or for whom no conventional treatment exists, and, during the course of treatment, these patients could suffer adverse medical effects or die for reasons that may or may not be related to our medical devices. Any of these events could result in a claim of liability. Such claims against us, regardless of their merit, could result in significant awards against us that could materially harm our business, financial condition and results of operations.

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

This annual report does not include a report of our management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by SEC rules for newly public companies. We will be required to include both of such reports in our annual report on Form 10-K for fiscal years ending on or after December 31, 2008, unless the SEC provides further extension to the compliance date.

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 will identify areas requiring improvement and will design enhanced processes and controls to address issues identified through this review. Remediating any deficiencies, significant deficiencies or material weaknesses that have been or could be identified by us or our independent registered public accounting firm may require us to incur significant costs and expend significant time and management resources. We cannot assure you that any of the measures we implement to remedy any such deficiencies will effectively mitigate or remedy such deficiencies. The existence of one or more such deficiencies or weaknesses could affect the accuracy and timing of our financial reporting. Investors could lose confidence in our financial reports, and the value of our 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 capital raising activities are undertaken in Australian dollars while most of our expenditures are incurred in US dollars. We try to mitigate our exposure to currency exchange risks by holding some 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 Australian Securities Exchange, or ASX, there is not any current trading market for our ordinary shares in the United States. In addition, in order to comply with the U.S. Securities Act, restrictions placed on our ordinary shares traded on the ASX provide that they may not be sold to US persons. In the future, we may seek to list our ordinary shares 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, except for trading on the ASX, you may not be able to transfer or resell your shares within the United States 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, 2007, we had a convertible note payable to our largest shareholder, with an amount due of approximately AU$1.5 million, including principal and accrued interest. The note has a conversion price of AU$1.00 which may be converted into 1.5 million 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$0.53 to AU$0.92 in the 12 months ended December 31, 2007. 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 largest shareholder.***

As of December 31, 2007, Apple Tree Partners I, L.P., or Apple Tree, owned approximately 37% 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 significant influence 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 significant influence 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 substantially all of our revenue 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 Australian Corporations Act ("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" of our Registration Statement on Form 10 (File No. 000-52595) filed with the Securities and Exchange Commission on April 30, 2007, as amended. 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 1B. UNRESOLVED STAFF COMMENTS

None.

## Item 2. PROPERTIES

Our corporate headquarters are located in Sydney, Australia and we have an operations facility in Miramar, Florida and a satellite office in Framingham, Massachusetts.

The Sydney, Australia office space is approximately 1,100 square feet. The lease expires in June 2008 and we do not have a right to renew this lease. However, we expect to be able to renew the lease on favorable terms if so desired.

Our office in Framingham, Massachusetts consists of 3,530 square feet of office space. The lease expires on January 31, 2011 and we have the right to renew for an additional 3 year period under the same terms and conditions as the current agreement.

As of December 31, 2007, 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 and a clean room, quality control functions, research and development operations and some administrative functions. This lease expires in April 2008, and we are in negotiations with the landlord to extend the lease term. We are also considering alternative leasehold facilities, close to this facility, on terms broadly equivalent to, or better than, our existing leasehold commitments. Any such new facilities would be leased provided that the premises are suitable and adequate for our needs for the foreseeable future.

Our products are currently being utilized only in connection with clinical trials. Our manufacturing activities to date consist primarily of process development, component assembly, quality control testing and research and development activities. Currently, approximately two-thirds of our space in Miramar is being used for these production activities.

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 notwithstanding that we may consider alternative operations facilities as noted above. We believe that the current or any replacement facilities of ours and our specialized suppliers will be sufficient to meet our needs now and for the foreseeable future. We intend to continue utilizing our suppliers and assembling our products for the foreseeable future in the same manner in which we have been operating.

## Item 3. LEGAL PROCEEDINGS

None.

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

During the fourth quarter of fiscal 2007, no matter was submitted to a vote of our security holders.

## Part II

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

Our ordinary shares are traded on the Australian Securities Exchange ("ASX") under the symbol "HTW". The following table sets forth, for the periods indicated, the high and low closing price of our ordinary shares in Australian and US dollars.

| Period | High (AU$) | Low (AU$) | High (US$) | Low (US$) |
|---|---|---|---|---|
| **Fiscal Year 2007:** | | | | |
| First Quarter | 0.87 | 0.64 | 0.70 | 0.52 |
| Second Quarter | 0.92 | 0.60 | 0.78 | 0.51 |
| Third Quarter | 0.65 | 0.55 | 0.57 | 0.49 |
| Fourth Quarter | 0.80 | 0.53 | 0.71 | 0.47 |
| **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 |

As of January 31, 2008, the Company had 248,100,277 ordinary shares outstanding and there were 1,388 holders of record of our ordinary shares.

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

### Equity Compensation Plans

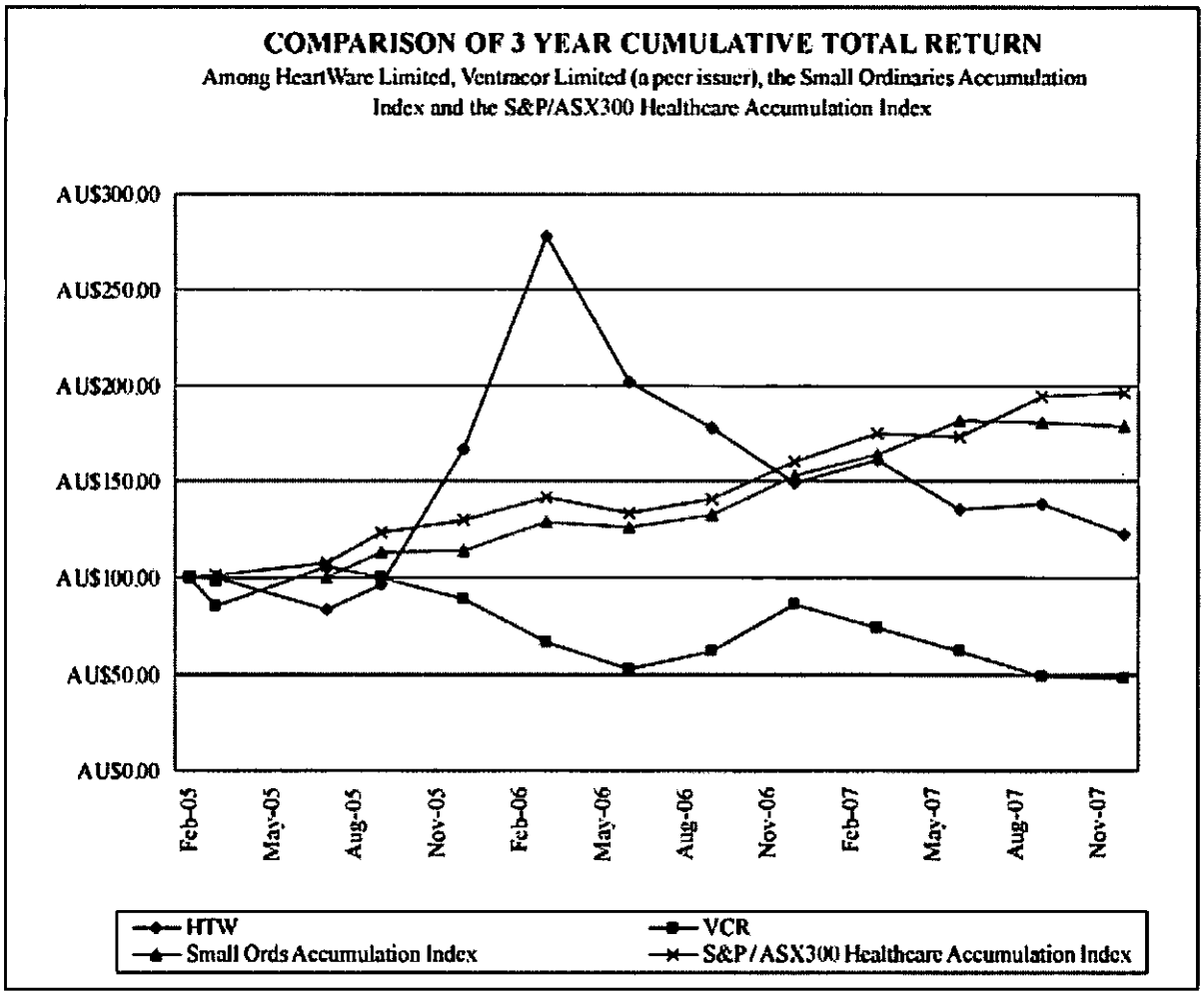
The following table sets forth information regarding the Company's Equity Compensation Plan as of December 31, 2007:

| Plan Category | Number of securities to be issued upon exercise of outstanding options, warrants and rights (a) | Weighted average exercise price of outstanding options, warrants and rights (b) | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c) |
|---|---|---|---|
| Equity compensation plans approved by security holders: | | | |
| HeartWare Limited Employee Share Option Plan | 22,387,170 | $ 0.65 | 4,903,860 |
| HeartWare Limited Performance Rights Plan | 2,050,000 | $ 0.00 | 1,450,000 |
| Equity compensation plans not approved by security holders: | | | |
| Non-plan incentive options | 2,395,600 | $ 0.66 | — |

**Share Price Performance Graph**

The graph below compares the cumulative total shareholder return on investment in our ordinary shares, in Ventracor Limited, a peer issuer, the ASX Small Ords Accumulation Index and the S&P/ASX300 Healthcare Accumulation Index for the 3 year period commencing on January 31, 2005, the first day our shares began trading to December 31, 2007.

The graph assumes an investment of AU$100 in our ordinary shares, in Ventracor Limited and in the ASX Small Ords Accumulation Index at January 31, 2005 and the reinvestment of all dividends, if any.




**Item 6. SELECTED FINANCIAL DATA**

The selected consolidated statement of operations data for the years ended December 31, 2007, 2006 and 2005 and for the period from November 26, 2004 (inception) to December 31, 2007 and the balance sheet data as of December 31, 2007 and 2006 (referred to as "Successor") have been derived from our consolidated audited financial statements included elsewhere in this Annual Report on Form 10-K. The selected consolidated statement of operations data for the year ended December 31, 2004 and the selected consolidated balance sheet data as of December 31, 2005 and 2004 have been derived from our audited consolidated financial statements which are not included in this Annual Report. The selected consolidated financial data set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" below and our audited consolidated financial statements and notes thereto appearing elsewhere in this Annual Report.

On January 24, 2005, we acquired all of the voting stock of HeartWare, Inc., a Delaware corporation, (the "Predecessor"). Our consolidated financial statements reflect the results of the Predecessor for all periods after January 24, 2005. The selected financial data for the Predecessor are derived from the audited financial statements which are not included in this annual report.

| | 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) | 2007 | 2006 | 2005 | 2004 | 2007 | 2004 | 2003 | 2004 |
| **Statement of Operations data:** | | | | | | | | |
| Revenues | $ — | $ — | $ — | $ — | $ — | $ — | $ — | $ — |
| General and administrative expenses | 7,303 | 6,024 | 4,312 | — | 17,639 | 138 | 166 | 304 |
| Research and development expenses | 14,636 | 11,650 | 10,732 | — | 37,018 | 4,795 | 1,271 | 6,066 |
| Depreciation | — | — | — | — | — | 88 | 35 | 123 |
| In process research and development expensed when acquired | — | — | — | — | — | — | 3,984 | 3,984 |
| Other income (expense), net | — | 248 | 1,211 | — | 1,459 | (982) | (248) | (1,230) |
| Provision for income taxes | — | — | — | — | — | — | — | — |
| Net loss | (21,939) | (17,427) | (13,833) | — | (53,199) | (6,003) | (5,704) | (11,707) |
| Basic and diluted loss per share | (0.10) | (0.10) | (0.10) | | | | | |

| | As of December 31, | | | | As of December 31, | |
|---|---|---|---|---|---|---|
| **Balance Sheet Data:** | 2007 | 2006 | 2005 | 2004 | 2004 | 2003 |
| Cash and cash equivalents | $ 28,276 | $ 16,698 | $ 10,037 | $ 1 | $ 139 | $ 197 |
| Total assets | 32,355 | 20,243 | 11,970 | — | 372 | 419 |
| Total liabilities | 3,083 | 2,779 | 2,245 | — | 12,027 | 6,070 |
| Total shareholders' equity | 29,272 | 17,464 | 9,725 | 1 | 11,654 | 5,651 |

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

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

We believe that our first product, the HeartWare LVAD System, is the smallest full-output left ventricle assist device, or LVAD, 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.

Beyond the HeartWare LVAD System, we are also evaluating our next generation device, the Miniaturized Ventricular Assist Device, or MVAD. The MVAD is based on the same technology platform as the HeartWare LVAD System but adopts an axial flow, rather than a centrifugal flow, configuration. The MVAD, which is currently at the prototype stage and undergoing animal studies focused on minimally invasive implantation techniques, is approximately one-third the size of the HeartWare LVAD System. We believe that the MVAD will be implantable by surgical techniques that are even less invasive than those required to implant the HeartWare LVAD System. We expect to initiate human clinical trials for the MVAD in 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 HeartWare LVAD System 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 HeartWare LVAD System.

We are currently conducting a combined European and Australian human clinical trial for the HeartWare LVAD System. This international trial began in March 2006 and called for the implantation of 20 patients. The trial is presently being expanded to 50 patients to enable us to maintain our relationships with our European and Australian and clinical sites and to provide increased depth of clinical data. We have submitted an Investigational Device Exemption application to the US Food and Drug Administration (the "FDA") and hope to begin a bridge-to-transplant clinical study in the US upon receipt of regulatory approval in early 2008.

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 HeartWare LVAD System and the development of future products. As of December 31, 2007, we had an accumulated deficit of approximately $53.2 million.

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 net proceeds of approximately $23.4 million and subsequent private placements in May 2006, which raised net proceeds of approximately $23.4 million, and July 2007, which raised net proceeds of approximately $30.9 million.

**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: accounting for research and development costs, share based payments and income taxes and translation of foreign currency. 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.

***Research and Development***

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

***Share-Based Payments***

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

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

We estimate the volatility of our 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 past forfeitures and our employee retention rate. If our actual forfeiture rate is materially different from our estimate, the share-based compensation expense could be significantly different from what we have recorded in the current period.

The assumptions used in calculating the fair value of share-based awards represent our best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our share-based compensation expense could be materially different in the future.

***Income Taxes***

We account for income taxes in accordance with Statement of Financial Accounting Standard No. 109, or SFAS 109, *Accounting for Income Taxes*, as clarified by FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* ("FIN No. 48"). Under this method, deferred income taxes are determined based on the estimated future tax effects of differences between the financial statement and tax basis of assets and liabilities given the provisions of enacted tax laws. Deferred income tax provisions and benefits are based on changes to the assets or liabilities from year to year. In providing for deferred taxes, we consider tax regulations of the jurisdictions in which we operate, estimates of future taxable income, and available tax planning strategies. If tax regulations, operating results or the ability to implement tax-planning strategies vary, adjustments to the carrying value of deferred tax assets and liabilities may be required. Valuation allowances are recorded related to deferred tax assets based on the "more likely than not" criteria of SFAS No. 109.

FIN No. 48 requires that we recognize the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the "more-likely-than-not " threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority.

***Translation of Foreign Currency***

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

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

**Fiscal Years 2007 and 2006**

***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 HeartWare LVAD System, 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 in Europe.

***Cost of Goods Sold***

There was no cost of goods sold recognized during the years ended December 31, 2007 or 2006, 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 and include all operating costs not associated with or otherwise classified as research and development costs

During 2007, we experienced significant growth as we continued enrollment in our first human clinical trial, became a US SEC reporting company subject to periodic filings in the US in addition to our continued Australian reporting and compliance requirements, raised additional capital and continued to expand research and development and manufacturing activities. As a result, we experienced expansion of our staff, including senior management, and a related expansion in infrastructure costs.

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

***Research and Development***

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

***Other Income***

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

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

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

***Income Taxes***

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

As of December 31, 2007, we did not have revenues or profit which would be sufficient to allow any portion of our deferred tax assets to be recorded. We intend to monitor closely the question of whether to record a deferred tax asset as we progress toward the commercialization of our products.

**Fiscal Years 2006 and 2005**

***Revenue***

We are a development stage company and had no revenue during the years ended December 31, 2006 and 2005. We are currently conducting a combined European and Australian clinical trial with our first product, the HeartWare LVAD System, 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 and include all operating costs not associated with or otherwise classified as research and development 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 a HeartWare LVAD System. 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 34% of operating expenses, compared to $4.3 million, or 29% of operating expenses, in 2005. The increase was primarily attributable to increased salaries and wages and related employee costs including severance paid to the former Chief Executive Officer. 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 66% of operating expenses, compared to $10.7 million, or 71% 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.

***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 under 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 in both jurisdictions. Changes in share ownership, as well as other factors, may limit our ability to utilize any net operating loss carry-forwards, and as such a 100% valuation allowance has been recorded against our net deferred tax assets.

As of December 31, 2006, we did not have revenues or profit which would be sufficient to allow any portion of our deferred tax assets to be recorded. We intend to monitor closely the question of whether to record a deferred tax asset as we progress toward the commercialization of our products.

***Liquidity and Capital Resources***

At December 31, 2007, our cash and cash equivalents were $28.3 million as compared to $16.7 million at December 31, 2006. The increase is primarily a result of net cash receipts of $30.9 million resulting from the issuance of ordinary shares in July 2007, partially offset by cash used in operating activities.

Cash used in operating activities for the year ended December 31, 2007 was approximately $19.0 million as compared to $15.9 million for the year ended December 31, 2006. For the year ended December 31, 2007, this amount included a net loss of $21.9 million and non-cash adjustments to net income of approximately $2.9 million which primarily consisted of approximately $539,000 of depreciation and amortization and $2.3 million of share-based compensation.

For the year ended December 31, 2006, cash used in operating activities included a net loss of $17.4 million, non-cash adjustments to net income of $1.5 million, primarily comprising approximately $388,000 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.

Investing activities used cash of approximately $1.0 million and $1.7 million for the years ended December 31, 2007 and 2006, respectively. These amounts in 2007 and 2006 were primarily to acquire property, plant and equipment and capitalized patent costs.

Cash provided by financing activities for years ended December 31, 2007 and 2006 was $30.9 million and $23.5 million, respectively from the net proceeds from the issuance of ordinary shares. We describe our issuances of ordinary shares in Note 11 — Shareholders' Equity to the consolidated financial statements included elsewhere in this Annual Report. We used the proceeds from the sales of our ordinary shares in 2007 and 2006 to fund the on-going cost of operations, including continued research and development, marketing costs, manufacturing and operational costs and other regulatory and compliance costs as well general working capital. We intend to use the remainder of the proceeds for similar operating activities.

In July 2007, in conjunction with a capital raise and shareholder placement plan, we issued an aggregate of 61,709,680 ordinary shares at a price per share of $0.53 (AU$0.60) for aggregate gross proceeds of $32.8 million. Offering costs associated with the issuance were approximately $1.9 million.

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 be sufficient to fund our operations for at least the next twelve months. However, we will require additional capital in order to continue to move toward commercialization of our products.

**Contractual Obligations**

At December 31, 2007, our debt and contractual financial obligations and commitments by due dates were as follows:

| | Payments due by period (in thousands of dollars) | | |
|---|---|---|---|
| | Total | Less than 1 year | 1-3 years |
| Convertible note | $1,327 | $ 1,327 | $ — |
| Operating lease obligations | 473 | 306 | 167 |
| Purchase obligations | 1,507 | 1,507 | — |
| Total | $3,307 | 3,140 | $ 167 |

**Off-Balance Sheet Arrangements**

The Company has no off-balance sheet arrangements.

**Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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

**Interest Rate Risk**

Our exposure to interest rate risk is currently confined to interest earnings on our cash that is invested in highly liquid money market funds. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. We do not presently use derivative financial instruments in our investment portfolio. Our cash and investments policy emphasizes liquidity and preservation of principal over other portfolio considerations.

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 includes 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 in 2008. 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 consolidated financial statements as a component of shareholders' equity.

HeartWare Limited holds US dollar denominated cash accounts. Fluctuations in the exchange rate of the US dollar against the AU dollar can result in foreign currency exchange gains and losses. Theses foreign currency transaction gains and losses are included in other, net in the consolidated statements of operations. The gains and losses are recorded in AU dollars, the functional currency of HeartWare Limited, and translated to US dollars, at an average exchange rate, for US reporting purposes.

We do not presently utilize foreign currency forward contracts and instead hold cash reserves in the currency in which those reserves are anticipated to be expended.

## Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

## HEARTWARE LIMITED

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
HeartWare Limited

We have audited the accompanying consolidated balance sheets of HeartWare Limited (a Development Stage Company) as of December 31, 2007 and 2006, and the related consolidated statements of operations, comprehensive loss, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2007, and the cumulative period from November 26, 2004 (date of inception) through December 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of HeartWare Limited (a Development Stage Company) as of December 31, 2007 and 2006, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, and the cumulative period from November 26, 2004 (date of inception) through December 31, 2007, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Notes 3 and 12 to the consolidated financial statements, the Company adopted Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment", on a prospective basis on January 1, 2005. In addition, as discussed in Notes 3 and 9 to the consolidated financial statements, the Company adopted Financial Accounting Standards Board Interpretation No. 48, "Accounting for Uncertainty in Income Taxes", on a prospective basis on January 1, 2007.

/s/ Grant Thornton LLP

Fort Lauderdale, Florida
February 25, 2008

**HEARTWARE LIMITED**
**(A Development Stage Company)**
**CONSOLIDATED BALANCE SHEETS**

| | December 31, 2007 | December 31, 2006 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 28,276,388 | $ 16,697,769 |
| Prepaid expenses and other current assets | 782,922 | 616,843 |
| Total current assets | 29,059,310 | 17,314,612 |
| Property, plant and equipment, net | 2,977,645 | 2,710,870 |
| Other intangible assets, net | 318,211 | 217,197 |
| Total Assets | $ 32,355,166 | $ 20,242,679 |
| **LIABILITIES AND SHAREHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 509,487 | $ 308,364 |
| Accrued expenses and other current liabilities | 1,246,846 | 1,287,142 |
| Convertible notes, current | 1,326,963 | 1,167,481 |
| Total current liabilities | 3,083,296 | 2,762,987 |
| Other long-term payables | — | 15,936 |
| Commitments and contingencies | | |
| Shareholders' equity: | | |
| Ordinary shares, no par value — 248,100,277 and 186,262,597 shares outstanding in 2007 and 2006, respectively | — | — |
| Additional paid-in capital | 81,859,263 | 48,654,298 |
| Deficit accumulated during the development stage | (53,199,166) | (31,260,167) |
| Accumulated other comprehensive income: | | |
| Cumulative translation adjustments | 611,773 | 69,625 |
| Total Shareholders' Equity | 29,271,870 | 17,463,756 |
| Total Liabilities and Shareholders' Equity | $ 32,355,166 | $ 20,242,679 |

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, | | | Cumulative Period from November 26, 2004 (Inception) Through December 31, |
|---|---|---|---|---|
| | 2007 | 2006 | 2005 | 2007 |
| Revenues | $ — | $ — | $ — | $ — |
| Operating expenses: | | | | |
| General and administrative expenses | 7,303,145 | 6,024,374 | 4,311,639 | 17,639,158 |
| Research and development expenses | 14,636,198 | 11,649,822 | 10,732,764 | 37,018,784 |
| Total operating expenses | 21,939,343 | 17,674,196 | 15,044,403 | 54,657,942 |
| Loss from operations | (21,939,343) | (17,674,196) | (15,044,403) | (54,657,942) |
| Foreign exchange (loss) income | (851,032) | (583,805) | 493,823 | (941,014) |
| Interest income, net | 950,675 | 844,522 | 717,121 | 2,512,318 |
| Other, net | (99,299) | (13,229) | — | (112,528) |
| Loss before income taxes | (21,938,999) | (17,426,708) | (13,833,459) | (53,199,166) |
| Provision for income taxes | — | — | — | — |
| Net loss | (21,938,999) | $ (17,426,708) | $ (13,833,459) | $ (53,199,166) |
| Loss per ordinary share — basic and diluted | $ (0.10) | $ (0.10) | $ (0.10) | |
| Weighted average shares outstanding - basic and diluted | 213,029,192 | 174,689,977 | 144,648,898 | |

The accompanying notes are an integral part of these financial statements

**HEARTWARE LIMITED**
**(A Development Stage Company)**
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

| | Years Ended December 31, | | | Cumulative Period from November 26, 2004 (Inception) Through December 31, |
|---|---|---|---|---|
| | 2007 | 2006 | 2005 | 2007 |
| Net loss | $ (21,938,999) | $ (17,426,708) | $ (13,833,459) | $ (53,199,166) |
| Foreign currency translation | 542,148 | 732,661 | (663,036) | 611,773 |
| Comprehensive loss | $ (21,396,851) | $ (16,694,047) | $ (14,496,495) | $ (52,587,393) |

The accompanying notes are an integral part of these financial statements

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

| | Ordinary Shares, No Par Value | | Additional Paid-In Capital | Accumulated Other Comprehensive Income (Loss) | Deficit Accumulated During the Development Stage | Total |
|---|---|---|---|---|---|---|
| | Shares Issued | Amount | | | | |
| Balance December 31, 2004 | 2,000 | $ — | $ 794 | $ — | $ — | $ 794 |
| Issuance of ordinary shares pursuant to the acquisition of HeartWare, Inc. | 88,000,000 | — | (1,224,284) | — | — | (1,224,284) |
| Issuance of ordinary shares pursuant to initial public offering, net of offering costs | 64,838,876 | — | 23,437,597 | — | — | 23,437,597 |
| Issuance of ordinary shares pursuant to share 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 | — | — | — | — | (13,833,459) | (13,833,459) |
| Accumulated other comprehensive income (loss): Foreign currency translation adjustment | — | — | — | (663,036) | — | (663,036) |
| Balance December 31, 2005 | 156,096,274 | — | 24,221,220 | (663,036) | (13,833,459) | 9,724,725 |
| Issuance of ordinary shares pursuant to capital raise, net of offering costs | 29,679,720 | — | 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 share option exercise | 411,151 | — | 103,136 | — | — | 103,136 |
| Share-based compensation | — | — | 890,319 | — | — | 890,319 |
| Net loss | — | — | — | — | (17,426,708) | (17,426,708) |
| Accumulated other comprehensive income (loss): Foreign currency translation adjustment | — | — | — | 732,661 | — | 732,661 |
| Balance December 31, 2006 | 186,262,597 | — | 48,654,298 | 69,625 | (31,260,167) | 17,463,756 |
| Issuance of ordinary shares pursuant to shareholder purchase plan | 2,002,933 | — | 1,062,958 | — | — | 1,062,958 |
| Issuance of ordinary shares pursuant to share option exercise | 128,000 | — | 21,702 | — | — | 21,702 |
| Issuance of ordinary shares pursuant to capital raise, net of offering costs | 59,706,747 | — | 29,855,650 | — | — | 29,855,650 |
| Share-based compensation | — | | 2,264,655 | — | — | 2,264,655 |
| Net loss | — | — | — | — | (21,938,999) | (21,938,999) |
| Accumulated other comprehensive income (loss): Foreign currency translation adjustment | — | — | — | 542,148 | — | 542,148 |
| Balance December 31, 2007 | 248,100,277 | $ — | $ 81,859,263 | $ 611,773 | $ (53,199,166) | $ 29,271,870 |

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, | | | Cumulative Period from November 26, 2004 (Inception) Through December 31, 2007 |
|---|---|---|---|---|
| | 2007 | 2006 | 2005 | |
| CASH FLOWS FROM OPERATING ACTIVITIES | | | | |
| Net loss | $ (21,938,999) | $ (17,426,708) | $ (13,833,459) | $ (53,199,166) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | | |
| Depreciation | 518,367 | 371,497 | 247,229 | 1,137,093 |
| Amortization | 20,679 | 16,528 | 10,462 | 47,669 |
| Share-based compensation expense | 2,264,655 | 890,319 | 1,947,537 | 5,102,511 |
| Loss on disposal of assets | 100,739 | 13,229 | — | 113,968 |
| Accrued interest on convertible note | 26,254 | 22,126 | 19,227 | 67,607 |
| Increase (decrease) in operating assets and liabilities: | | | | |
| Prepaid expenses and other current assets | (129,688) | (229,689) | (46,239) | (405,616) |
| Note receivable, current | — | — | 794 | 794 |
| Accounts payable | 196,681 | (666,383) | 149,241 | (320,461) |
| Accrued expenses and other current liabilities | (78,567) | 1,071,959 | 260,855 | 1,254,247 |
| Net cash used in operating activities | (19,019,879) | (15,937,122) | (11,244,353) | (46,201,354) |
| CASH FLOWS FROM INVESTING ACTIVITIES | | | | |
| Additions to property, plant and equipment | (880,446) | (1,732,372) | (1,412,523) | (4,025,341) |
| Additions to patents | (121,693) | (34,945) | (209,242) | (365,880) |
| Net cash provided by acquisition | — | — | 126,380 | 126,380 |
| Proceeds from dispositions of assets | 8,435 | 23,701 | — | 32,136 |
| Net cash used in investing activities | (993,704) | (1,743,616) | (1,495,385) | (4,232,705) |
| CASH FLOWS FROM FINANCING ACTIVITIES | | | | |
| Proceeds from issuance of share capital | 32,839,448 | 25,083,953 | 25,119,802 | 83,043,203 |
| Payment of offering costs | (1,899,138) | (1,541,194) | (1,622,629) | (5,062,961) |
| Net cash provided by financing activities | 30,940,310 | 23,542,759 | 23,497,173 | 77,980,242 |
| Effect of exchange rate changes on cash | 651,892 | 798,807 | (720,494) | 730,205 |
| INCREASE IN CASH AND CASH EQUIVALENTS | 11,578,619 | 6,660,828 | 10,036,941 | 28,276,388 |
| CASH AND CASH EQUIVALENTS — BEGINNING OF PERIOD | 16,697,769 | 10,036,941 | — | — |
| CASH AND CASH EQUIVALENTS — END OF PERIOD | $ 28,276,388 | $ 16,697,769 | $ 10,036,941 | $ 28,276,388 |
| *Supplemental cash flow information:* | | | | |
| Cash paid during the year for: | | | | |
| Interest | $ 25,568 | $ 22,496 | $ 20,150 | $ 68,214 |

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.

We believe that our first product, the HeartWare LVAD System, is the smallest full-output left ventricle assist device, or LVAD, 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.

Beyond the HeartWare LVAD System, we are also evaluating our next generation device, the Miniaturized Ventricular Assist Device, or MVAD. The MVAD is based on the same technology platform as the HeartWare LVAD System but adopts an axial flow, rather than a centrifugal flow, configuration. The MVAD, which is currently at the prototype stage and undergoing animal studies focused on minimally invasive implantation techniques, is approximately one-third the size of the HeartWare LVAD System. We believe that the MVAD will be implantable by surgical techniques that are even less invasive than those required to implant the HeartWare LVAD System. We expect to initiate human clinical trials for the MVAD in 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 HeartWare LVAD System 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 HeartWare LVAD System.

We are currently conducting a combined European and Australian human clinical trial for the HeartWare LVAD System. This international trial began in March 2006 and called for the implantation of 20 patients. The trial is presently being expanded to 50 patients to enable us to maintain our relationships with our European and Australian and clinical sites and to provide increased depth of clinical data. We have submitted an Investigational Device Exemption application to the US Food and Drug Administration (the "FDA") and hope to begin a bridge-to-transplant clinical study in the US upon receipt of regulatory approval in early 2008

We are headquartered in Sydney, Australia and have administrative offices in Framingham, Massachusetts and an operations and manufacturing facility 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 HeartWare LVAD System and the development of future products. As of December 31, 2007, we had an accumulated deficit of approximately $53.2 million.

### 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 the 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 Standards ("SFAS") No. 7, "Accounting and Reporting by Development Stage Enterprises," issued by the Financial Accounting Standards Board ("FASB").

Prior to marketing its products in the United States, the Company's products must undergo rigorous pre-clinical and clinical testing and an extensive regulatory approval process implemented by the FDA and other regulatory authorities. There can be no assurance that the Company will not encounter problems in clinical trials that will cause 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 there under 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 Liquidity**

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States, which contemplate continuation of the Company as a going concern. However, the Company has sustained substantial losses from operations since its inception, and such losses have continued through December 31, 2007. As of December 31, 2007, the Company had a deficit accumulated during the development stage of $53.2 million. Although we believe our cash on hand is sufficient to support our planned operations for at least the next 12 months, our continuation as a going concern beyond that period is dependent on our ability to raise additional capital in order to continue to commercialize our technology, and as such, we are continually 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 implantable electronic devices and its next generation devices, the IV VAD and MVAD), regulatory and other compliance costs as well as for general working capital. The Company closely monitors its cash position.

**Note 3 Significant Accounting Policies**

***Principles of Consolidation***

The consolidated financial statements include the accounts of HeartWare Limited and its 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 3 months or less to be cash equivalents. The Company maintains the majority of its cash and cash equivalents in Australia, denominated in both Australian and United States dollars. As of December 31, 2007 and 2006, the Company had approximately $27.5 million and $16.0 million, respectively, maintained in banks in Australia, as translated into US dollars at the spot rate at the end of the respective year.

***Fair Value of Financial Instruments***

The carrying value of cash and cash equivalents, accounts payable and accrued expenses approximate their fair value due to the short maturity of these items. The carrying value of the Company's Convertible Note (See Note 7) approximates fair value based on the fixed interest rate on the debt. The convertible note's stated value, including principal and accrued interest, translated into US dollars at the year end spot rate, was $1.3 million and $1.2 million, at December 31, 2007 and 2006, respectively.

***Property, Plant and Equipment***

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

***Share-Based Payments***

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

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

We estimate the volatility of our 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 past forfeitures and our employee retention rate. If our actual forfeiture rate is materially different from our estimate, the share-based compensation expense could be significantly different from what we have recorded in the current period.

The assumptions used in calculating the fair value of share-based awards represent our best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our share-based compensation expense could be materially different in the future.

***Impairment of Long-Lived Assets***

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable from future undiscounted cash flows. Impairment losses are recorded for the excess, if any, of the carrying value over the fair value of the long-lived assets. As of December 31, 2007, no indicators of impairment existed.

***Income Taxes***

The Company accounts for income taxes in accordance with SFAS No. 109, "*Accounting for Income Taxes*" ("SFAS No. 109") as clarified by FASB Interpretation No. 48, "*Accounting for Uncertainty in Income Taxes* ("FIN No. 48"). Under this method, deferred income taxes are determined based on the estimated future tax effects of differences between the financial statement and tax basis of assets and liabilities given the provisions of enacted tax laws. Deferred income tax provisions and benefits are based on changes to the assets or liabilities from year to year. In providing for deferred taxes, the Company considers tax regulations of the jurisdictions in which it operates, estimates of future taxable income and available tax planning strategies. If tax regulations, operating results or the ability to implement tax-planning strategies varies, adjustments to the carrying value of the deferred tax assets and liabilities may be required. Valuation allowances are based on the "more likely than not" criteria of SFAS No. 109.

FIN No. 48 requires that the Company recognize the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority.

***Translation of Foreign Currency***

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

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

***Research and Development***

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

***Vendor Concentration***

For the year ended December 31, 2007, we purchased approximately 51% of our product supplies and components used in our research and development activities from two sources. In addition, one of the two vendors performs research and development consulting services for the Company. As of December 31, 2007, the amounts due to these vendors total approximately $301,000.

***Marketing and Advertising Costs***

Marketing, advertising and promotional costs are expensed when incurred.

***Reclassifications***

Certain prior year amounts have been reclassified to conform to current year presentation.

***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 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 be 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.

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

**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, 2007 | December 31, 2006 |
|---|---|---|---|
| **Property, Plant and Equipment** | | | |
| Machinery and equipment | 5 to 7 years | $ 3,327,331 | $ 2,811,800 |
| Leasehold improvements | 3 to 7 years | 95,951 | 209,116 |
| Office equipment, furniture and fixtures | 5 to 7 years | 279,536 | 143,886 |
| Software | 5 to 7 years | 388,749 | 276,092 |
| | | 4,091,567 | 3,440,894 |
| Less: accumulated depreciation | | (1,113,922) | (730,024) |
| | | $ 2,977,645 | $ 2,710,870 |

Depreciation expense was $518,367, $371,497 and $247,229 for the years ended December 31, 2007, 2006 and 2005, respectively.

| | December 31, 2007 | December 31, 2006 |
|---|---|---|
| **Accrued expenses and other current liabilities** | | |
| Accrued payroll and other employee costs | $ 837,881 | $ 409,441 |
| Accrued research and development materials | 181,172 | 504,528 |
| Accrued professional fees | 209,819 | 261,317 |
| Other accrued expenses | 17,974 | 111,856 |
| | $ 1,246,846 | $ 1,287,142 |

**Note 5 Exchange of Equity Interests Among Entities Under Common Control**

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

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

The following table summarizes the historical costs of the assets acquired and liabilities assumed at the date of acquisition:

| | |
|---|---|
| Cash | $ 126,380 |
| Receivable | 75,000 |
| Prepayments | 220,000 |
| Other non-current assets | 20,771 |
| Trade creditors | (558,103) |
| Other current payables | (256,099) |
| Other non-current payables | (100,000) |
| Property, plant and equipment | 205,453 |
| Total purchase price | $ (266,598) |

**Note 6 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:

| | 2007 | | 2006 | |
|---|---|---|---|---|
| Amortizable Intangible Assets | Gross Carrying Amount | Accumulated Amortization | Gross Carrying Amount | Accumulated Amortization |
| Patents | $ 365,880 | $ (47,669) | $ 244,187 | $ (26,990) |

Amortization expense for the years ended December 31, 2007, 2006 and 2005 was $20,679, $16,528 and $10,462, respectively.

Estimated amortization expense for each of the 5 succeeding fiscal years based upon the Company's intangible asset portfolio at December 31, 2007 is $24,392.

**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$1,420,000 outstanding at December 31, 2007 and 2006. Accrued interest at December 31, 2007 and 2006 was approximately AU$80,000 and AU$55,000, respectively. At December 31, 2007, the note translated into approximately $1.25 million in principal plus accrued interest of approximately $75,000 that would convert into 1.51 million shares. At December 31, 2006, the note converted into approximately $1.1 million plus accrued interest of approximately $44,000 that would convert into 1.48 million 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 accrued interest on the convertible note is repayable on demand as of January 31, 2007, and is therefore included as a current liability. As of December 31, 2007, the note has not been converted and the holder of the note, Apple Tree Partners I, L.P., a significant shareholder of the Company, has given a written indication to the Company that its present intention is to convert the note rather than demand repayment. Interest expense on this note was $24,967, $22,062 and $19,227 for the years ended December 31, 2007, 2006 and 2005, respectively.

**Note 8 Leases**

Rent expense was $738,559 in 2007, $484,226 in 2006 and $284,969 in 2005. Future minimum rental commitments at December 31, 2007 under non-cancelable operating lease agreements are as follows:

| | Operating Leases |
|---|---|
| Year Ending December 31, | |
| 2008 | $ 306,024 |
| 2009 | 80,304 |
| 2010 | 79,997 |
| 2011 | 6,506 |
| Total minimum lease payments | $ 472,831 |

**Note 9 Income Taxes**

At December 31, 2007 and 2006, the Company had gross deferred tax assets in excess of deferred tax liabilities of $17.6 and $10.4 million, respectively. The Company determined that it is not more likely than not that such assets will be realized, and as such has taken a valuation allowance of $17.6 million and $10.4 million as of December 31, 2007 and 2006, respectively. The Company evaluates its ability to realize its deferred tax assets each period and adjusts the amount of its valuation allowance, if necessary. If there is an ownership change, as defined under Internal Revenue Code Section 382, the use of carry-forwards may be subject to change. 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, 2007 and 2006.

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

| | For the Year Ended December 31, | | |
|---|---|---|---|
| | 2007 | 2006 | 2005 |
| United States | $ (17,354,330) | $ (13,467,250) | $ (9,433,864) |
| Non-US | (4,584,669) | (3,959,458) | (4,399,595) |
| | $ (21,938,999) | $ (17,426,708) | $ (13,833,459) |

The effective tax rate of 0% differs from the statutory United States federal income tax rate of 35% for all periods presented due primarily to the valuation allowance. The valuation allowance has increased by approximately $7.3 million, $6.0 million and $4.3 million for the years ended December 31, 2007, 2006 and 2005, respectively.

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

| | At December 31, | |
|---|---|---|
| | 2007 | 2006 |
| Net operating loss and other other carryforwards | $ 17,649,460 | $ 10,358,783 |
| Total deferred tax assets | 17,649,460 | 10,358,783 |
| Valuation allowance | (17,649,460) | (10,358,783) |
| Net deferred tax assets | $ — | $ — |

At December 31, 2007, the Company had net operating loss carryforwards of approximately $40 million for US federal income tax purposes and $7.8 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 | Year Generated | US Losses | Foreign Losses |
|---|---|---|---|
| unlimited | 2005 | | $ (2,452,059) |
| unlimited | 2006 | | (3,069,139) |
| unlimited | 2007 | | (2,320,105) |
| 2025 | 2005 | $ (9,433,864) | |
| 2026 | 2006 | (13,467,250) | |
| 2027 | 2007 | (17,354,330) | |
| | | $ (40,255,444) | $ (7,841,303) |

*Uncertain tax positions*

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

**Note 10 Commitments and Contingencies**

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

- a milestone payment of $750,000 within 6 months of the date when the first circulatory assist device is approved for sale in Europe, provided that the Company has at least $15,000,000 in cash on hand and, if the Company does not have $15,000,000 at that time, then the payment is deferred until such time that the Company has $15,000,000 in cash on hand;

- a milestone payment of $1,250,000 within 6 months of the date when the first circulatory assist device is approved for sale in the US, provided that the Company has at least $25,000,000 in cash on hand and, if the Company does not have $25,000,000 at that time, then the payment is deferred until such time that the Company has $25,000,000 in cash on hand; and

- a special payment of up to $500,000 upon a sale of HeartWare, Inc. if such sale generates proceeds in excess of the aggregate liquidation preferences of all of HeartWare, Inc.'s then outstanding preferred stock.

At December 31, 2007 we had purchase order commitments of approximately $1.5 million related to product costs and property, plant and equipment purchases.

In addition to the above, the Company has entered into employment agreements with all of its executive officers, including the Chief Executive Officer and the Chief Financial Officer. 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, 2007, the Company has 248,100,277 ordinary shares outstanding. 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 Securities 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 and cumulative voting is not permitted under the Company's Constitution. 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 in the Company 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 2004, in connection with the establishment of the Company, we issued 2,000 ordinary shares for aggregate consideration of $794 (AU$1,000).

- In connection with our initial public offering in Australia, on January 24, 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 24, 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 24, 2005, in connection with our acquisition of all of the voting 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 3 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 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 Employee Share Option Plan 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 5 individuals. The issuance of these ordinary shares was exempt from registration pursuant to Rule 701 under the Securities Act.

- From January to December 2007, we issued an aggregate of 128,000 ordinary shares pursuant to the exercise of options under our Employee Share Option Plan at an exercise price of AU$0.20 for aggregate proceeds of $21,702 (AU$25,600) to 2 individuals. The issuance of these ordinary shares was exempt from registration pursuant to Rule 701 under the Securities Act.

- On July 24, 2007, we issued 2,002,933 ordinary shares to our Australian shareholders pursuant to our Shareholder Purchase Plan for aggregate proceeds to us of US$1.1 million

- On July 26, 2007, we issued 59,706,747 ordinary shares in a private placement. The aggregate net proceeds to us in connection with this offering were US$29.9 million.

**Note 12 Equity Incentive Plans**

The Company issued share-based payment awards to employees, non-executive directors and outside consultants through an Employee Share Option Plan, a Purchase Rights Plan and outside of any formal plan. The Company issues new shares upon exercise of stock awards. A detailed discussion of share-based payment awards granted and outstanding is below.

*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 then outstanding ordinary shares. At December 31, 2007, the number of shares reserved for future issuance under the ESOP is 4,903,860.

Each option issued under the ESOP allows the holder to subscribe for and be issued 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 5 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, if any. The expiry date can be for periods of up to ten years from the date of grant of the option.

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

In 2007, the Company granted 2.9 million options with performance based vesting criteria. The performance based options will vest in four equal tranches contingent upon the achievement of pre-determined corporate milestones related primarily to the development of the Company's products and the achievement of certain prescribed clinical objectives. We currently estimate that the options will vest over a period of 18 to 54 months. Any options not vested after five years from the date of grant automatically expire.

At December 31, 2007, the Company has determined that only the first tranche of options (725,000), issued with performance criteria, meet the definition of "probable" under SFAS No. 5, Accounting for Contingencies. As such, share-based compensation expense has only been recorded for the first tranche of options. At each period, we will review the likelihood that any of the remaining three tranches will vest, and if the vesting is deemed probable, we will begin to recognize compensation expense at that time. If ultimately performance goals are not met, for any awards where vesting was previously deemed probable, previously recognized compensation cost will be reversed.

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

| | Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life (Years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding at December 31, 2004 | — | | | |
| Granted | 14,762,862 | $ 0.45 | | |
| Exercised | (395,400) | 0.15 | | |
| Forfeited | (263,652) | 0.31 | | |
| Expired | (4,000) | 0.15 | | |
| Outstanding at December 31, 2005 | 14,099,810 | 0.46 | 3.67 | $ 1,272,439 |
| Granted | 10,116,324 | 0.89 | | |
| Exercised | (411,051) | 0.27 | | |
| Forfeited | (4,155,363) | 0.78 | | |
| Expired | (1,194,070) | 0.47 | | |
| Outstanding at December 31, 2006 | 18,455,650 | 0.66 | 7.32 | $ — |
| Granted | 4,250,000 | 0.74 | | |
| Exercised | (128,000) | 0.18 | | |
| Forfeited | (169,110) | 0.95 | | |
| Expired | (21,370) | 0.93 | | |
| Outstanding at December 31, 2007 | 22,387,170 | $ 0.65 | 7.04 | $ — |
| Exercisable at December 31, 2007 | 7,849,124 | $ 0.54 | 5.04 | $ — |

The aggregate intrinsic value in the table above represents the quoted market value less the weighted average exercise price at year end times the number of options outstanding. As the weighted average exercise price was above the quoted market price on December 31, 2007 and 2006, there is no aggregate intrinsic value on these dates. The intrinsic value for options exercised during the year ended December 31, 2007 was approximately $60,500.

Cash received from share option exercises for the years ended December 31, 2007, 2006 and 2005 was approximately $22,000, $103,000 and $60,000, respectively.

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

The weighted average grant date fair value per share of options granted during the years ended December 31, 2007, 2006 and 2005 was $0.47, $0.46 and $0.19, respectively.

At December 31, 2007 the Company had approximately $3.7 million of unrecognized compensation cost related to non-vested share option awards, including performance based awards not yet deemed probable of vesting, that is expected to be recognized over a weighted average period of 1.73 years.

Weighted Average Black-Scholes Option Pricing Assumptions

| | 2007 | 2006 | 2005 |
|---|---|---|---|
| Dividend yield | 0% | 0% | 0% |
| Estimated annual volatility | 52.66% | 54.82% | 55.17% |
| Risk-free interest rate | 5.96% | 5.67% | 5.35% |
| Estimated forfeiture rate | 12.50% | 12.12% | 7.69% |
| Estimated holding period (years) | 7.47 | 10 | 6.23 |

***Performance Rights Plan***

On November 13, 2007, the Company adopted the HeartWare Limited Performance Rights Plan ("PRP"). The PRP permits the Company to grant performance rights to employees that allow the employee to acquire ordinary shares of the Company at an exercise price of $0.00. The PRP allows for the issuance of performance rights to acquire up to 3.5 million of the Company's ordinary shares. On November 19, 2007, the Company filed a Form S-8 Registration Statement with the United States Securities and Exchange Commission with respect to these ordinary shares. As of December 31, 2007, 1,450,000 shares were reserved for future issuance under the PRP. On November 13, 2007, the Board of Directors approved, subject to shareholder approval to be voted on in 2008, the issuance of 1.1 million of the remaining reserved shares under the PRP to the Company's Chief Executive Officer. These performance rights will be granted upon receipt of shareholder approval and as such they are not considered outstanding and there has been no accounting recognition to date. Each performance right issued under the PRP allows the holder to subscribe for and be issued one ordinary share in the capital of the Company. The performance rights that ultimately vest expire 10 years from the date of grant.

The performance rights vest in four equal tranches contingent upon the achievement of pre-determined corporate milestones, consistent with the performance ESOP shares mentioned above. We currently estimate that the performance rights will vest over a period of 18 to 54 months. Any performance rights not vested after five years from the date of grant automatically expire.

At December 31, 2007, the Company has determined that only the first tranche of awards under the PRP (512,500), issued with performance criteria, meet the definition of "probable" under SFAS No. 5, Accounting for Contingencies. As such, share-based compensation expense has only been recorded for the first tranche of awards. At the end of each period, we will review the likelihood that any of the remaining three tranches will vest and if the vesting is deemed probable, we will begin to recognize compensation expense at that time. If ultimately performance goals are not met, for any awards where vesting was previously deemed probable, previously recognized compensation cost will be reversed.

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

| | Shares | Weighted Average Remaining Contractual Life (Years) | Aggregate Intrinsic Value |
|---|---|---|---|
| Outstanding at December 31, 2006 | — | | |
| Granted | 2,050,000 | | |
| Exercised | — | | |
| Forfeited | — | | |
| Expired | — | | |
| Outstanding at December 31, 2007 | 2,050,000 | 9.88 | $ 994,004 |
| Exercisable at December 31, 2007 | — | — | $ — |

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

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

The weighted average grant date fair value per share of PRP awards granted during the year ended December 31, 2007 was $0.66.

At December 31, 2007, the Company had approximately $1.1 million of unrecognized compensation cost related to non-vested share PRP awards, including awards not yet deemed probable of vesting that is expected to be recognized over a weighted average period of 3.13 years.

Weighted Average Black-Scholes Option Pricing Assumptions

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

***Non-Plan Options***

The Company has also granted an aggregate of 2,395,600 options outside of any formal plan. Of these options, 1,000,000 were granted to 3 non-executive directors and 1,395,600 were granted to third parties for services rendered to the Company.

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

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

| | Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life (Years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding at December 31, 2004 | 1,000,000 | $ 0.73 | | $ — |
| Granted | 1,045,600 | 0.41 | | |
| Exercised | — | | | |
| Forfeited | — | | | |
| Expired | — | | | |
| Outstanding at December 31, 2005 | 2,045,600 | 0.54 | | $ 11,064 |
| Granted | — | | | |
| Exercised | — | | | |
| Forfeited | — | | | |
| Expired | | | | |
| Outstanding at December 31, 2006 | 2,045,600 | $ 0.59 | | $ — |
| Granted | 350,000 | $ 0.66 | | |
| Exercised | — | | | |
| Forfeited | — | | | |
| Expired | — | | | |
| Outstanding at December 31, 2007 | 2,395,600 | $ 0.66 | 3.17 | $ — |
| Exercisable at December 31, 2007 | 2,045,600 | 0.65 | 2.02 | $ — |

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

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

The weighted average grant date fair value per share of non-plan options granted during the years ended December 31, 2007 and 2005 was $0.10 and $0.38, respectively. There were no non-plan options granted during 2006.

At December 31, 2007, the Company had approximately $106,000 of unrecognized compensation cost related to non-vested share non-plan option awards that is expected to be recognized over a weighted average period of 1.68 years.

Weighted Average Black-Scholes Option Pricing Assumptions

| | 2007 | 2006 | 2005 |
|---|---|---|---|
| Dividend yield | 0% | — | 0% |
| Estimated annual volatility | 53.24% | — | 55.14% |
| Risk-free interest rate | 6.00 | — | 5.35 |
| Estimated forfeiture rate | 12.50% | — | 7.69% |
| Estimated holding period (years) | 10 | — | 5 |

*Summary*

The following table summarizes information about all outstanding awards, including the ESOP, PRP and non-plan options, as of December 31, 2007:

| | | Awards Outstanding | | | Awards Exercisable | | |
|---|---|---|---|---|---|---|---|
| Low | High | Shares Outstanding | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life (years) | Shares Outstanding | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life (years) |
| $ 0.00 | $ 0.00 | 2,050,000 | $ — | 9.88 | — | $ — | — |
| $ 0.01 | $ 0.65 | 7,446,416 | 0.30 | 3.63 | 5,749,059 | 0.29 | 3.08 |
| $ 0.66 | $ 1.23 | 15,654,252 | 0.87 | 8.20 | 3,595,665 | 0.89 | 6.47 |
| $ 1.24 | $ 1.32 | 1,682,102 | 1.27 | 5.80 | 550,000 | 1.29 | 4.87 |
| | | 26,832,770 | $ 0.67 | 6.91 | 9,894,724 | $ 0.56 | 4.41 |

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

We recognize share-based compensation for the value of the portion of awards that are ultimately expected to vest. Statement No. 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The term "forfeitures" is distinct from "cancellations" or "expirations" and represents only the unvested portion of the surrendered award. We have applied an annual forfeiture rate of approximately 12.5% to all unvested share awards as of December 31, 2007, which represents the portion that we expect will be forfeited each year over the vesting period. We will re-evaluate this analysis periodically and adjust the forfeiture rate as necessary. Ultimately, we will only recognize expense for those shares that vest.

For the years ended December 31, 2007, 2006 and 2005, the Company recorded share-based payment expenses as follows:

| (in thousands) | 2007 | 2006 | 2005 |
|---|---|---|---|
| General and administrative | $ 1,365 | $ 293 | $ 693 |
| Research and development | 900 | 597 | 1,255 |
| | $ 2,265 | $ 890 | $ 1,948 |

**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: | 2007 | 2006 |
|---|---|---|
| Exercise of share-based payment awards | 26,832,770 | 20,501,250 |
| Conversion of convertible note | 1,505,176 | 1,475,396 |

**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, 2007 and 2006:

| (In thousands, except per share data) | First | Second | Third | Fourth |
|---|---|---|---|---|
| **Fiscal Year 2007** | | | | |
| Revenue | $ — | $ — | $ — | $ — |
| Net loss | (4,835) | (6,127) | (5,446) | (5,531) |
| Basic and diluted net loss per share | (0.03) | (0.03) | (0.02) | (0.02) |
| **Fiscal Year 2006** | | | | |
| Revenue | $ — | $ — | $ — | $ — |
| Net loss | (3,151) | (3,930) | (4,333) | (6,013) |
| Basic and diluted net loss per share [1] | (0.02) | (0.02) | (0.02) | (0.03) |

[1] The sum of the quarters of the 2006 basic and diluted net loss per share does not sum to the year end net loss per share of ($0.10) due to rounding.

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

None.

**Item 9A. CONTROLS AND PROCEDURES**

**Disclosure Controls and Procedures**

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

The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures as of December 31, 2007. Based on that evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures are effective as of December 31, 2007.

**Internal Control over Financial Reporting**

This Annual Report does not include a report of our management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by SEC rules for newly public companies. We will be required to include both of such reports in our Annual Report on Form 10K for the fiscal years ending on or after December 31, 2008, unless the SEC provides further extension to the compliance date.

**Changes in Internal Control over Financial Reporting**

There were no changes in the Company's internal control over financial reporting during the Company's fiscal quarter ended December 31, 2007, that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**Item 9B. OTHER INFORMATION**

None.

## Part III

### Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

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

| Name | Age | Position (1) |
|---|---|---|
| **DIRECTORS:** | | |
| Robert Thomas | 62 | Chairman, Non-Executive Director |
| Dr. Seth Harrison | 47 | Deputy Chairman, Non-Executive Director |
| Douglas Godshall | 43 | Executive Director, Chief Executive Officer |
| Dr. Christine Bennett | 52 | Non-Executive Director |
| Dr. Denis Wade, AM | 70 | Non-Executive Director |
| Robert Stockman | 54 | Non-Executive Director |
| **EXECUTIVES:** | | |
| Douglas Godshall | 43 | Managing Director, Chief Executive Officer |
| David McIntyre | 37 | Chief Financial Officer, Company Secretary |
| Dozier Rowe | 55 | Chief Operating Officer |
| Jeffrey LaRose | 46 | Chief Scientific Officer |
| James Schuermann | 39 | Vice President, Sales and Marketing |
| Barry Yomtov | 52 | Vice President, Engineering |
| Jennifer Foley | 49 | Vice President, Clinical and Regulatory Affairs |
| Ramon Paz | 50 | Vice President, Quality Assurance |

(1) We use the term "Executive Director" with respect to Mr. Godshall to identify him as a member of our Board of Directors who is also an employee of the Company; the term "Managing Director" with respect to Mr. Godshall is a job title given to him by the Company.

**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 Tower Australia 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 a member 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 5 years as Vice President, Business Development, at Boston Scientific, where he was focused on acquisition strategies for the cardiology, electrophysiology, neuroradiology and vascular surgery divisions. Mr. Godshall has a Bachelor of Arts in Business from Lafayette College and Masters of Business Administration from Northeastern University in Boston, Massachusetts.

***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 25 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 Telectronics, 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 HeartWare LVAD System. Mr. LaRose also leads the development of our miniaturization technology and has twenty years of experience in hydraulic technology development including roles with AEA Technology Engineering Software and Babcock and Wilcox. He holds a Master of Science in Mechanical Engineering from the University of Akron, Ohio.

***James Schuermann.*** Mr. Schuermann joined HeartWare in September 2007. He has overall responsibility for HeartWare's sales and marketing activities across all markets. Jim has over 15 years sales and marketing experience in the medical device arena. Prior to joining HeartWare, he spent nine years in sales and marketing at Boston Scientific Corporation. Over this time he progressed from sales through product management until being appointed Director of Marketing in 2005. With 5 direct reports and a broader team of over 150 product managers and salespeople, Jim led the marketing activities for a US$280M worldwide business which emerged as one of the strongest in the company. Before joining Boston Scientific, he spent 5 years in medical sales and sales management at Sherwood Davis & Geck. Mr. Schuermann received his undergraduate degree in marketing from Kelley School of Business, Indiana University, Bloomington, and his MBA from Ageno School of Business, Golden Gate University, San Francisco.

***Barry Yomtov.*** Mr. Yomtov joined HeartWare in July 2006 as Vice President, Product Development and is responsible for the design and development of new products. He has over 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, 2 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 5 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.

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

**Compliance With Section 16(a) of the Exchange Act**

Section 16(a) of the Exchange Act requires our directors, executive officers and persons who own more than ten percent of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports of

changes in ownership of the common stock and other equity securities of our Company. Officers, directors, and greater than ten percent beneficial owners are required by SEC regulation to furnish us with copies of all Section 16(a) reports they file.

Based solely upon information furnished to us and contained in reports filed with the SEC, as well as any written representations that no other reports were required, we believe that all SEC filings of our directors, executive officers beneficial owners of greater than ten percent complied with Section 16 of the Exchange Act, except that Mr. Schuermann was late 75 days in his Form 3 filing and Mr. Paz was late 135 and 6 days in a Form 3 and Form 4 filing, respectively.

## *CORPORATE GOVERNANCE*

We are committed to developing, promoting and maintaining a strong culture of good corporate governance and ethical conduct. Copies of the Company's various codes, policies and charters relating to our corporate governance are available from the corporate governance section of our website at www.heartware.com.

### *Director Independence*

Our Board of Directors presently comprises six directors. Mr. Rob Thomas, Dr. Denis Wade, Dr. Christine Bennett and Mr. Bob Stockman are, and Dr. Seth Harrison and Mr. Doug Godshall are not, independent directors within the meaning of the NASDAQ listing standards, which we use to determine whether our directors are independent.

### *Board Meetings and Committees*

Our Board of Directors has an Audit & Compliance Committee (the "Audit Committee") and a Nomination & Remuneration Committee (the "Compensation Committee"). During the year ended December 31, 2007, the Board held 9 meetings, the Audit Committee held 5 meetings, and the Compensation Committee held 1 meeting. All directors attended more than 90% of the meetings of the Board, the Audit Committee and the Compensation Committee on which they are members, and none of them attended fewer than 75% of such meetings. We do not have a formal policy regarding directors' attendance at our annual meeting of shareholders, however, four of our then-current six directors attended our last annual meeting of shareholders.

The number of meetings attended by each of the directors during the fiscal year ended December 31, 2007 is as follows:

| | | | | | Committee Meetings | | | |
|---|---|---|---|---|---|---|---|---|
| | Directors' Meeting | | Non-Executive Directors' Meeting | | Audit & Compliance Committee | | Nomination & Remuneration Committee | |
| | A | B | A | B | A | B | A | B |
| Rob Thomas | 9# | 8 | — | — | 5 | 5 | 1# | 1 |
| Seth Harrison | 9 | 8 | — | — | * | * | 1 | 1 |
| Denis Wade | 9 | 9 | — | — | 5 | 5 | 1 | 1 |
| Christine Bennett | 9 | 8 | — | — | 5# | 5 | 1 | 1 |
| Doug Godshall | 9 | 9 | | * | | * | * | * |
| Bob Stockman | 9 | 8 | — | — | * | * | * | * |

A – Number of meetings held during the time the director held office during the year.

B – Number of meetings attended.

* — Not a member of the relevant committee.

# — Designates the Chair of the relevant committee.

***Continuous Disclosure Committee***

In addition to the Audit Committee and the Compensation Committee, our Board also has a Continuous Disclosure Committee, which currently comprises the Chairman and Deputy Chairman of our Board and our Chief Executive Officer. Our Chief Financial Officer acts as convenor for the Continuous Disclosure Committee. The Continuous Disclosure Committee has been established by the Board as a committee to be responsible for ensuring full compliance with the Company's policy in this regard, particularly in relation to the continuous disclosure obligations set out in the ASX Listing Rules and the Corporations Act. A copy of the Continuous Disclosure Policy is available on our website at www.heartware.com.

***Audit & Compliance Committee (the "Audit Committee")***

The Audit Committee of the Board of Directors provides oversight to our accounting and financial reporting processes and audits of our financial statements. The Audit Committee appoints our independent auditors, evaluates their qualifications, independence and performance, and reviews their reports and other services. The Audit Committee is governed by a written charter approved by our Board of Directors, a copy of which is available on our website at www.heartware.com.

The Audit Committee is comprised of Christine Bennett (Chairman), Rob Thomas and Denis Wade, all of whom are independent directors within the meaning of the NASDAQ listing standards. Our Board of Director currently does not have an "audit committee financial expert" as defined under the SEC rules, however, the Company is actively seeking a non-executive director with the requisite skill set who could fulfill this role.

***Audit Committee Report***

The Audit Committee reviews the Company's financial reporting process on behalf of the Board. Management is responsible for our internal controls, the financial reporting process and the preparation of our consolidated financial statements. Our Independent Registered Public Accounting Firm is responsible for performing an independent audit of the Company's consolidated financial statements in accordance with auditing standards generally accepted in the United States of America and issuing a report on the financial statements.

In this context, the Audit Committee has met and held discussions with management and Grant Thornton, the Company's Independent Registered Public Accounting Firm, on at least a quarterly basis. Management represented to the Audit Committee that the Company's consolidated financial statements were prepared in accordance with accounting principles generally accepted in Australia and the United States of America, and the Audit Committee has reviewed and discussed the consolidated financial statements with management and the Independent Registered Public Accounting Firm. The Audit Committee meets with management and the Independent Registered Public Accounting Firm together and individually, as required, at each meeting. The Audit Committee discussed with the Independent Registered Public Accounting Firm matters required to be discussed by Statement on Auditing Standards No. 61 (Communication with Audit Committees), as modified or supplemented.

During 2007, the Audit Committee reviewed management's documentation for maintaining adequate internal controls over financial reporting to meet continuing compliance requirements under Section 404 of the Sarbanes-Oxley Act of 2002. Based upon its assessment, management concluded that, as of December 31, 2007, the Company's internal control over financial reporting was effective.]

In addition, the Audit Committee has discussed with the Independent Registered Public Accounting Firm the accountants' independence from the Company and its management, and has received the written disclosures and letter required by the Independence Standards Board Standard No. 1 (Independence Discussion with Audit Committees).

In reliance on the reviews and discussions referred to above, the Audit Committee recommended to the Board, and the Board approved, that the 2007 audited financial statements be included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2007, for filing with the Securities and Exchange Commission.

THE AUDIT COMMITTEE

Christine Bennett (Chair)
Rob Thomas
Denis Wade

***Nomination & Remuneration Committee***

The Nomination & Remuneration Committee ("Compensation Committee") oversees the process of nominating candidates for the Board of Directors and remuneration arrangements. The Compensation Committee presently consists of four directors, namely Mr. Rob Thomas (Chairman), Dr. Seth Harrison, Dr. Denis Wade and Dr. Christine Bennett. Other than Dr. Harrison, the Compensation Committee members are independent directors within the meaning of the NASDAQ listing standards.

The Compensation Committee is governed by a written charter approved by our Board of Directors, a copy of which is available on our website at www.heartware.com.

Members of the Board of Directors are elected to three year terms. The Company requires that one-third of the Board of Directors retire each year. However, the Company does not employ term limits and retired directors can be immediately re-elected if approved by a vote of shareholders at the annual meeting. The Compensation Committee does not have a policy with regard to consideration of candidates to become new members of the Board of Directors. In general, the Compensation Committee considers recommendations by Directors, Executives of the Company, shareholders and other interested parties. The committee reviews a candidate's relevant experience and skills in conjunction with skills sought by the Board at that time. The Nomination and Remuneration Committee then makes a recommendation to the Board. The Board may make an interim appointment. If any member is appointed by the Board during the year, they are required to stand for re-election at the annual meeting for approval by shareholder vote.

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 HeartWare's 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 on behalf of the Compensation Committee in order to assist the Compensation Committee with its decision-making. The Board considers the recommendations of the Compensation Committee and makes the final determination of compensation.

***Code of Conduct***

The Company has adopted a Code of Conduct that is designed to convey the obligations and standards of behavior expected of the Chief Executive Officer, the Chief Financial Officer and other employees. It is also designed to help staff resolve any ethical issues that may arise during the course of their duties.

The Company also adopted a "Complaint Procedures for Accounting and Audit Matters". This policy established procedures that operate in addition to the Code of Conduct and which are primarily focused on dealing with employee complaints concerning any questionable accounting or auditing matters. These policies operate in addition to the Company's Operational Policies, Employee Handbook and other corporate policies such as the Risk Management Policy, Securities Trading Policy and Continuous Disclosure Policy.

The Board acknowledges that ethical conduct, together with responsible decision-making, is a matter of concerted diligence and effective promotion of the relevant principles by all employees, particularly senior executives. The establishment of the above policies reflects the Company's commitment in this regard and is, in simple terms, designed to ensure that a suitable framework is established whereby employees are promoted to observe the letter and spirit of the law, adhere to high standards of business conduct and comply with best practice.

A copy of the Code of Conduct is available on the corporate governance page of the Company's website at www.heartware.com.

***Shareholder Communications with the Board of Directors***

Our Board of Directors will give appropriate attention to written communications on issues that are submitted by shareholders and other interested parties, and will respond if and as appropriate. The chairman of our Audit Committee will be primarily responsible for monitoring communications from shareholders and other interested parties and will provide copies or summaries of such communications to the other directors as he considers appropriate.

Communications will be forwarded to all directors if they relate to substantive matters and include suggestions or comments that the chairman of the Audit Committee considers to be important for the directors to know.

Shareholders and other interested parties who wish to send communications on any topic to the Board of Directors should address such communications to chairman of the Audit Committee at our principal executive offices.

## Item 11. EXECUTIVE COMPENSATION

***Compensation Discussion and Analysis***

The following discussion and analysis of compensation arrangements of our named executive officers for 2007 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 the Compensation 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 on behalf of the Compensation Committee in order to assist the Compensation Committee with its decision-making. The Board considers the recommendations of the Compensation Committee and makes the final determination of compensation.

**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. It is also well-recognized that companies like HeartWare that are early-stage, pre-revenue companies, have limited clinical experience, are largely dependent on their ability to raise capital in order to remain viable and are perceived by employees to have a significantly higher risk profile than other more established medical device companies. This higher risk profile, combined with fierce competition for employees, creates an environment where attracting and retaining employees is challenging for HeartWare.

We believe that we need to take account of a number of factors when negotiating and determining compensation levels for our executives. For example, we consider the relevant executive's compensation level prior to joining HeartWare as well as wider medical device industry compensation practices, especially those compensation practices adopted by other development-stage companies. We also consider each executive's current or anticipated future contribution, responsibilities, previous experience, perceived importance to the Company, work ethic and seniority following commencement with the Company.

In order to confirm the appropriateness of the Company's compensation practices the Company retained an external consultant in 2007 to assist in reviewing our executives' compensation. This review, which is discussed below under the heading "—Benchmark Exercise", was undertaken to enable the Company to compare our executives' compensation with compensation practices of other medical device companies who are at a similar development stage. Using the benchmark exercise as a guide, we then considered each individual on a case-by-case basis and took into account the factors referred to above as well as years of experience, actual performance, the executives' role and importance and each individual executives' compensation and employment history.

While we believe that equity-based compensation is an important financial motivator for our executives, the Board of Directors recognizes that the Company's risk profile is such that the salary component of each executive's compensation will continue to constitute a critical component of an executive's total compensation from an executive's perspective.

Above all, we believe that that a combination of cash and equity compensation is currently appropriate to ensure that we are able to attract and retain talented executives to manage the business and affairs of the Company, to become a significant player in the growing circulatory assist market and to increase shareholder value. We continue to monitor both our cash and equity 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 executives, and that this will be especially critical 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 and applicable medical device experience, and competition for executives with relevant experience is intense. We also recognize that because the bulk of our facilities are located in the southeastern United States, many potential new executives are forced to consider the additional burden of both travel and relocation into their decision-making process.

During this period of growth and development, we acknowledge that 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 importance and directly impact our ability to achieve our corporate objectives in a timely manner.

Our compensation policies are therefore designed to attract, retain and motivate executives officers as well as the entire staff of the organization 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.

**Benchmark Exercise**

During 2007, the Company retained Frederick W. Cook & Co., Inc. ("F W Cook") to examine the compensation practices of a peer group of companies and to compare that data to our senior executives' compensation. F W Cook is an independent, third party, specialist in United States-based compensation norms.

The exercise included representatives of F W Cook:

- Meeting with management and selected members of the Board of Directors for the purposes of learning about the Company, its background, historical compensation practices and perceived shareholder views.
- Collecting and analyzing company-specific background data from management for the purposes of independent analysis.
- Identifying and examining the compensation practices of a peer group of comparable, publicly traded, development stage, biotechnology and medical device companies located in the United States, and comparing that data to HeartWare's data.

The analysis undertaken by F W Cook focused on base salaries, annual bonuses, long-term incentives and total "carried–interest ownership", which is a form of measurement of the equity awards received by each executive during the course of their employment. Carried-interest measures the amount of future increase in value captured by each executive arising through their equity awards and is calculated as the aggregate holding of options and shares plus recent share sales of an executive, divided by the number of Company shares outstanding.

The peer group consisted of 16 publicly traded biotechnology and medical device companies with market capitalizations ranging between approximately US$100 and US$450 million. Because of the nature and scope of the Company's business, only companies located in the United States were considered. The peer group comprised Aspect Medical Systems, Possis Medical, NeuorMetrix, VNUS Medical Technologies, Tutogen Medical, AtriCure, NMT Medical, NxStage Medical, SenoRx, Artes Medical, Dyax, XTENT, Hansen Medical, Inovio Biomedical, DexCom and Northstar Neuroscience (collectively, "the Peer Group"). In reviewing the compensation data of the Peer Group, F W Cook commented that there would be no impact on the resultant equity compensation benchmarks of the Peer Group if the larger revenue companies were excluded from the Peer Group data. Further, salary and cash benchmarks would be reduced by approximately 5-10% should these larger revenue companies be excluded from the Peer Group calculations.

In summary, the conclusions from the F W Cook review were as follows:

- Overall, base salaries for Company executives were lower than the median and most executives are almost 10% below the median of the Peer Group.
- HeartWare has not established an annual cash bonus despite most pre-commercial biotech companies maintaining a common annual bonus structure for their senior executives. HeartWare had pre-established target annual bonus for only 3 executives (i.e., Mr. Godshall, Mr. Rowe and Ms. Foley).

- Actual 2006 cash compensation (i.e., salary plus bonus) was approximately 10% below median for HeartWare's eight most highly compensated executives.

- HeartWare's senior executives have an aggregate carried-interest ownership that is below the 25th percentile of the Peer Group and the actual value of this ownership is diminished because the Company historically granted premium-priced equity (i.e., equity that is priced higher than the fair market value of the underlying security at the relevant grant date).

**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 is the most significant component 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 goals. Other relevant considerations include perceived long-term value to HeartWare, succession planning, retention and the executives' compensation history.

As noted above, the Company retained F W Cook during 2007 to undertake a benchmark exercise for our senior executives and this included a review of base salaries. The Company then considered the existing base salaries of our named executive officers in light of the information provided by F W Cook, together with the executives' historical salary level, overall contribution, work ethic, responsibilities, tenure with the Company and other subjective case-by-case factors such as replaceability or the perceived importance of that individual to the Company.

The Company did not attribute any specific weighting to the elements of individual performance or contribution or otherwise adopt any other formal mechanism in its determination of the relevant salary level for the named executive officers. The assessment of each individual, including base salary, was therefore undertaken following consideration of all of the above factors on an aggregated basis with particular emphasize on how the relevant executives' base salary compared with the Peer Group. Salaries are typically reviewed annually, and it is expected that another benchmark exercise will be undertaken not less than every second year.

The base salary for Mr. Godshall (Chief Executive Officer), Mr. McIntyre (Chief Financial Officer), Mr. LaRose (Chief Scientific Officer), Mr. Rowe (Chief Operating Officer) and Ms. Foley (Vice-President, Clinical & Regulatory Affairs) did not change during 2007 and their base salary will not be re-assessed until late in 2008. No changes were made to the named executive officers' salaries because each of those executives accept and acknowledge that the Company has limited financial resources at this time and therefore they did not seek, or otherwise request, an increase in their respective base salary levels.

With the exception of Mr. Godshall, the base salary of each of the above named executive officers was approximately 4%-19% less than the equivalent benchmarked position in the Peer Group. Mr. Godshall's base salary is substantially equivalent to the median base salary of chief executive officers in the Peer Group. Set out below is the relevant benchmark data.

| | | Base Salary of Peer Group | | | |
|---|---|---|---|---|---|
| Name | Title | 25th Percentile ($) | Average ($) | 75th Percentile ($) | Actual Base Salary ($) |
| Godshall, David | CEO | 319,000 | 357,000 | 371,000 | 350,000 |
| McIntyre, David | CFO | 216,000 | 239,000 | 252,000 | 225,000 |
| LaRose , Jeff | CSO | 196,000 | 227,000 | 241,000 | 225,000 |
| Rowe, Dozier | COO | 246,000 | 275,000 | 359,000 | 225,000 |
| Foley, Jennifer | VP. Clin & Reg | 171,000 | 203,000 | 224,000 | 220,000 |

The base salary of Ms. Reedy, our former Vice-President, Sales and Marketing, increased from $200,000 to $220,000 on January 2, 2007 in consideration of the change in Ms Reedy's responsibilities associated with Ms Reedy adopting the role of Vice-President, Sales & Marketing with effect from that date. Ms. Reedy's salary was not otherwise altered during 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 rarely pay sign-on bonuses. We would typically only pay a sign-on bonus when we believe that an upfront payment to an executive would significantly influence that individual's decision to join the Company. The decision to offer such bonuses generally evolves as part of the employment negotiation process and is dependent on the perceived importance of the relevant appointment, the availability of suitable candidates and the individual qualities and experience of the individual. A sign-on bonus is also beneficial where a potential executive becomes ineligible to receive a bonus at their existing employer if the executive decides to join HeartWare.

In 2007, we hired Ms. Jen Foley to be our new Vice-President, Clinical & Regulatory Affairs with effect from January 2, 2007. Ms. Foley was paid $30,000 as a sign-on bonus immediately following the commencement of her employment. Ms. Foley is a highly experienced and well-regarded clinical specialist who, prior to joining the Company, was one of the most senior executives within Boston Scientific Corporation's clinical affairs organization where she was responsible for overseeing the execution of clinical trials across nine of that company's divisions. We agreed to pay this bonus to Ms. Foley because we determined that it was imperative that we attract Ms. Foley to the Company given the Company's impending expansion of its human clinical trials and in consideration of her extensive experience in the field. The amount of the sign-on bonus was not set by reference to any benchmark or other external source and was determined at the discretion of the Chief Executive Officer and with the consent of the Chairman as being a sufficiently substantive enough inducement for Ms. Foley to join the Company.

The Compensation Committee and the Board of Directors also determined to pay a discretionary bonus on October 31, 2007 in recognition of the Company's completion of enrollment in its international clinical trial and the filing of its submission with the US Food & Drug Administration for an investigational device exemption for the commencement of human clinical trials in the United States and following due consideration of the overall progress made by the Company since it conducted its previous performance evaluation in June 2006. These accomplishments were achieved through an enormous contribution and personal sacrifice by the Company's employees and the Board determined that the payment of this bonus was appropriate in the circumstances. As the above bonus was both discretionary and retrospective in nature, there were no objectives established for any of the named executive officers in relation to this bonus.

All of our executives who were employed by us prior to January 1, 2007 and who did not have an established, pre-determined bonus were eligible to receive this discretionary bonus. Those individuals who had a pre-established bonus pursuant to their employment agreement were assessed based on their actual performance relative to the thresholds for that bonus (as set out in their respective employment agreements). For all others, the bonus of each individual executive was determined in conjunction with the benchmark data provided by the F W Cook review together with the outcome of the annual review process. Factors considered also included the employees' position and rank within the organization, their specific roles and responsibilities and their performance therein. The executives who received this bonus were:

- Doug Godshall, who received $71,250;
- David McIntyre, who received $45,000;
- Jeff LaRose, who received $45,000;
- Jennifer Foley, who received $30,000; and
- Dozier Rowe, who received $27,000.

The bonus for Mr. Godshall was determined by Mr. Rob Thomas, Chairman, following due consideration of Mr. Godshall's actual performance against the pre-agreed milestones as follows:

| Criteria | Target % | Maximum Bonus | Actual % | Actual Bonus |
|---|---|---|---|---|
| Completion of capital raise | 40% | $ 30,000 | 40% | $ 30,000 |
| Completion of CE Mark Enrollment | 20% | 15,000 | 20% | 15,000 |
| Submission of the HVAD IDE application | 15% | 11,250 | 15% | 11,250 |
| Development of a shareholder communication strategy | 15% | 11,250 | 10% | 7,500 |
| Overall leadership and development of the Company | 10% | 7,500 | 10% | 7,500 |
| | | $ 75,000 | | $ 71,250 |

Except for Ms. Foley, each of the bonuses paid to our executives was determined by the Chief Executive Officer in his discretion and after taking into account the benchmark data for the Peer Group (see below).

| | | Bonus as a Percentage of Base Salary Peer Group | | | | |
|---|---|---|---|---|---|---|
| | | 25th | | 75th | Actual Bonus | |
| Name | Title | Percentile | Average | Percentile | Percentage | $ |
| McIntyre, David | CFO | 12% | 21% | 31% | 20% | 45,000 |
| LaRose , Jeff | CSO | 0% | 17% | 28% | 20% | 45,000 |
| Rowe, Dozier | COO | 17% | 22% | 30% | 12% | 27,000 |

The Chief Executive Officer determined at his discretion that, after taking into account the Company's limited financial resources, the maximum bonus payable to any named executive would not exceed 20% of the relevant executive's base salary and notwithstanding that this amount was significantly less than the cash bonuses provided in all cases by the Peer Group.

Mr. McIntyre and Mr. LaRose received the maximum bonus of 20% of base salary in consideration of their exceptional service, performance and commitment to the Company. The bonuses for the remaining executives were then determined by the Chief Executive Officer on a reducing, sliding scale taking into account the relevant executive's performance and contributions in the preceding fifteen months.

Ms. Foley was paid a bonus of $30,000. The target amount of $30,000 was agreed between the Chief Executive Officer and Ms. Foley during the course of her employment negotiations in late 2006. The bonus was payable provided that the Company filed its investigational device exemption with the US Food & Drug Administration within ninety days of the completion of enrollment in the Company's international clinical trial. This target was successfully completed and the bonus was therefore paid in full.

No discretionary bonus was paid to Ms. Reedy as, at the time of payment of the bonus, Ms. Reedy had determined to cease her employment with the Company.

***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, and the benchmark data from the Peer Group confirms, 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 "refresher" awards being given at the sole discretion of the Board of Directors. We have offered our Chief Executive Officer an option package roughly equal to 3% of our then-outstanding equity. Other executive officers are granted an initial option package that ranges from 0.75% to 1.5% of our then-outstanding equity, however, specific grants are negotiated on a case-by-case basis that considers a range of employment factors, including specific roles and responsibilities, historical compensation and market information. Compensation packages are often determined and negotiated with the assistance of an independent executive recruiter if one is utilized or, in the absence of the Company using such a recruiter, by reference to salary data sourced from the American Society of Human Resource Management.

In the interest of promoting long-term shareholder value, we have historically granted options that progressively vest in four annual tranches, commencing on the first anniversary of the date of grant. Further, all options granted under the ESOP prior to February, 2007 were granted at a premium to the then-current or fair market value of the underlying security but the Board has discontinued this practice following confirmation from F W Cook that it is common practice in the United States for options to be priced "at market".

See "—Equity Awards" below for further information on our option awards.

***Performance Rights Awards***

During 2007, we adopted the HeartWare Limited Performance Rights Plan ("PRP"). The Company adopted the PRP in light of recommendations arising from F W Cook's compensation review and after taking account of the total carried-interest ownership of our executives compared with the Peer Group.

The PRP is utilized, in conjunction with the ESOP, for the purpose of retaining and incentivizing the Company's "key employees", being those employees who the Board of Directors or management considers must be retained by the Company in the medium to long-term. For this reason, the use of the PRP has been selective and has therefore only been made available to 14 employees to date.

See "—Equity Grants" below for further information on our grants of performance rights.

***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 have not provided matching funds through December 31, 2007 and do not expect to do so for the foreseeable future.

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.

***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. We also maintain a non-matching, 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.

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. No such relocation occurred during 2007.

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.

**Equity Grants**

We have adopted the ESOP and the PRP that allow us to grant equity 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. The PRP, which was adopted on November 13, 2007, is designed to provide a distinctive financial incentive for a limited pool of employees who have been identified as key individuals the Company must strive to retain in the medium to long-term. We believe that the use of both the ESOP and the PRP is an important component of executive retention and central to our long-term development.

Each option issued under the ESOP and each performance right granted under the PRP 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 5 days (or such other period as our Board may determine) prior to the issue of the ESOP option. Distinct from the ESOP, performance rights granted under the PRP may entitle the holder to acquire one of our ordinary shares with a zero exercise price, provided that relevant performance hurdles are satisfied.

Options and performance rights 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.

Exercise conditions or performance hurdles, if any, are determined by the Board. Except as set out below, 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 and performance rights 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 or the PRP including, for example, where a performance hurdle is not satisfied or where a participant ceases to be an employee or director, 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 and performance rights granted under the PRP are not listed for quotation on the ASX or any other exchange or market. Options issued under the ESOP and performance rights granted under the PRP are not transferable, except on the death of an employee or during a takeover.

In connection with the benchmark exercise which considered, among other things, the carried-interest ownership of our executives as compared to the Peer Group, F W Cook determined that our top 10 executives have aggregated carried-interest ownership that is below the 25th percentile of the Peer Group. Further, due to the Company's historical practice of granting premium priced options, this carried-interest ownership was determined to be less valuable than that made available to the Peer Group. The carried-interest ownership of the 10 most senior executives was 6.55% while the Peer Group had carried-interest ownership of 7.20% (25th percentile), 9.12% (median) or 13.02% (75th percentile).

Further, F W Cook considered the quantum of "refresher" grants of options that a Peer Group executive received based on the relevant tenure of each executive. Following this review, F W Cook recommended that the Company utilize performance rights so as to bring the Company's executives in line with the carried-interest ownership of executives of the Peer Group and as a means to correct the previous practice of granting premium-priced options. Specifically, F W Cook recommended that the Company grant approximately 3.7 million performance rights to the Company's top 10 executives with no provision or recommendation for wider grants of performance rights to other employees.

Following due consideration, the Compensation Committee and the Board of Directors exercised their discretion and reduced the quantum of performance rights recommended by F W Cook by approximately 15% with the result that the Company determined to grant not more than 3.15 million performance rights to its "key" employees. The Compensation Committee, based on recommendations of the Chief Executive Officer, allocated the 3.15 million performance rights to 14 key employees, including our named executive officers.

We made the following grants of options during 2007 to our named executive officers:

- In connection with the appointment of Ms. Foley as Vice-President, Clinical and Regulatory Affairs with effect from January 2, 2007, Ms. Foley was granted 1,000,000 options on commencement of her employment with us and otherwise in accordance with the terms of her employment agreement. The exercise price of these options was AU$1.10, which constituted a 57% premium to the share price at the date of grant, which was AU$0.70.

- On November 13, 2007, we approved of the grant of up to an aggregate of 1.1 million performance rights under the PRP to our named executive officers. Accordingly, on November 16, 2007, Mr. McIntyre received 400,000 performance rights, Mr. LaRose received 300,000 performance rights and each of Mr. Rowe and Ms. Foley received 200,000 performance rights. Mr. Godshall has been allocated, but not issued, 1.1 million performance rights, and these will only be issued to Mr. Godshall provided shareholders approve such grant (as required by the ASX Listing Rules). The exercise price for the performance rights is zero and the performance rights lapse if they have not vested within 5 years of the grant date. Vesting of the performance rights is subject to the performance hurdles set out below. The share price at the date of grant was AU$0.75.

Vesting of each of the performance rights approved on November 13, 2007 is subject to satisfaction of the following performance hurdles:

- Vesting for the first tranche, representing 25% of each allotment, occurs on the last to occur of the first anniversary of the grant date, the Company receiving CE mark in Europe, the Company filing its application for Therapeutic Goods Association approval in Australia and the commencement of the Company's Bridge-to-Transplant trial in the United States.

- Vesting for the second tranche, representing 25% of each allotment, occurs on the last to occur of the second anniversary of the grant date and the completion of enrollment under the Company's Bridge-to-Transplant trial in the United States.

- Vesting for the third tranche, representing 25% of the each allotment, occurs on the last to occur of the third anniversary of the grant date, the Company filing an application for Pre-Market Approval with the United States Food and Drug Administration as a Bridge-to-Transplant therapy and the completion of enrollment under the Company's Destination Therapy clinical trial in the United States.

- Vesting for the fourth tranche, representing 25% of the each allotment, occurs on the last to occur of the fourth anniversary of the grant date and the Company completing a human feasibility study for its next generation device, the MVAD.

The Board considers potential options grants to executives upon commencement of employment and as part of our annual employee performance review process with the next contemplated review expected to occur at the end of the 2008 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 Mr. Godshall, Mr. McIntyre, Mr. Rowe and Ms. Reedy contain provisions that 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**

Since December 31, 2007, and except as described herein, there has been no material change to the compensation arrangements of the named executive officers.

**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 2 fiscal years with regard to (i) our Chief Executive Officer, (ii) our Chief Financial Officer, (iii) our other 3 most highly compensated executive officers during fiscal 2007 and (iv) one additional individual for whom disclosure would have been provided but for the fact that the individual was not serving as an executive officer at the end of fiscal 2007, to whom we refer collectively as the "named executive officers."

## SUMMARY COMPENSATION TABLE
## For the Years Ended December 31, 2007 and 2006

| Name and Principal Position | Year | Salary ($) | Bonus (1) ($) | Stock Awards (2) ($) | Option Awards (3) ($) | Non-Equity Incentive Plan Compensation (4) ($) | Change in Pension Value and Nonqualified Deferred Compensation Earnings (5) ($) | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|---|---|---|---|---|
| Douglas Godshall | 2007 | 350,000 | — | — | — | 71,250 | — | — | 421,250 |
| Chief Executive Officer (6) | 2006 | 87,500 | 75,000 (7) | — | 2,217,984 | — | — | — | 2,380,484 |
| David McIntyre | 2007 | 225,000 | 45,000 | 262,717 | — | — | — | 108,000 (10) | 640,717 |
| Chief Financial Officer | 2006 | 186,834 | 35,000 | — | 79,367 | — | 5,003 | 111,127 (11) | 417,331 |
| Dozier Rowe | 2007 | 225,000 | 27,000 | 131,358 | — | — | — | — | 383,358 |
| Chief Operating Officer | 2006 | 147,212 | — | — | 79,367 | — | — | — | 226,579 |
| Jeffrey LaRose | 2007 | 225,000 | 45,000 | 197,038 | — | — | — | — | 467,038 |
| Chief Scientific Officer | 2006 | 211,539 | 45,000 | — | 79,367 | — | — | — | 335,906 |
| Jennifer Foley | 2007 | 211,539 | 30,000 | 131,358 | 376,736 | 30,000 (12) | — | — | 779,633 |
| Vice-President, Clinical and Regulatory | 2006 | — | — | — | — | — | — | — | — |
| Jane Reedy | 2007 | 439,231 (13) | — | — | — | — | — | — | 439,231 |
| Former Vice President, Sales and Marketing | 2006 | 200,000 | 25,000 | — | 79,367 | — | — | — | 304,367 |

(1) Unless otherwise stated, the amount specified represents a cash bonus paid on October 31, 2007 as part of a Company-wide discretionary bonus in recognition of the completion of enrolment in the Company's international clinical trials, the filing of an investigational device exemption, or IDE, with the US Food & Drug Administration and the Company's overall progress since June 2006.

(2) All performance rights, or stock awards, are issued with an exercise price of nil. The amount referenced is calculated by multiplying the number of stock awards granted by the closing market price of the Company's stock on the relevant grant date as published by the Australian Securities Exchange. The stock awards were granted on November 16, 2007 when the closing market price was AU$0.745 and was converted using the exchange rate at December 31, 2007 of AU$1.00 = US$0.8816. The amount referenced could also have been calculated, and generated the same grant date fair value, using the Black-Scholes valuation model adopting the assumptions described in Note 3 and Note 12 of the Notes to Consolidated Financial Statements included in our audited Consolidated Financial Statements for the fiscal years ended December 31, 2007, 2006 and 2005 appearing elsewhere in this document.

(3) All option awards are issued with an exercise price in AU$. All 2006 amounts were converted using the exchange rate at December 31, 2006 of AU$1.00 = US$0.7913. All 2007 amounts were converted using the exchange rate at December 31, 2007 of AU$1.00 = US$0.8816. In each case, the amount referenced is calculated at the relevant grant date using the Black-Scholes valuation model adopting the assumptions described in Note 3 and Note 12 of the Notes to Consolidated Financial Statements included in our audited Consolidated Financial Statements for the fiscal years ended December 31, 2007, 2006 and 2005 appearing elsewhere in this document.

(4) The amounts reported were all paid on October 31, 2007. Further details of these payments are set out under the heading "-Bonus" under the "-Elements of Compensation" above.

(5) Statutory payments for superannuation (i.e., pension) fund equal to 9% of annual salary. This only applied for the period during 2006 in which Mr. McIntyre was employed in Australia and the amount was converted into US$ using the average exchange rate during the 2006 fiscal year of AU$1.00 = US$0.7580.

(6) Mr. Godshall commenced employment as Chief Executive Officer of the Company on September 18, 2006 and became director a director of the Company on October 28, 2006. Mr. Godshall does not receive any compensation for his services as a director.

(7) Represents a sign-on bonus on commencement of employment on September 18, 2006.

(8) The Board of Directors has determined to grant 1.1 million performance rights to Mr. Godshall with an exercise price of zero. However, the ASX Listing Rules require that all equity grants to Mr. Godshall be first approved by the Company's shareholders and this approval has not yet been obtained. The Company expects to seek shareholder approval to grant these performance rights to Mr. Godshall on or before May 31, 2008.

(9) Mr. McIntyre's base salary includes AU$73,333 paid in Australian dollars while Mr. McIntyre resided in Australia. Amounts were converted into US$ using the average exchange rate during the 2006 fiscal year of AU$1.00 = US$0.7580.

(10) Includes twelve 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 the United States.

(11) Includes a one-time pre-tax 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 the United States. As at December 31, 2006, a pre-tax amount of US$80,077 (AU$105,647) has been paid to Mr. McIntyre in this regard. The 2006 amount also includes $3,300 related to the cost of providing a maintained motor vehicle and car parking space during his employment in Australia.

(12) This amount represents a sign-on bonus on commencement of employment in September 2006.

(13) Ms. Reedy was our Vice President, Sales and Marketing until September 12, 2007 and resigned all positions with the Company with effect from December 31, 2007.The 2007 compensation includes an accrual for severance recorded in the fiscal year ended December 31,2 007 that will be paid to Ms. Reedy in 2008.

The following table lists all plan-based awards to named executive officers during 2007:

GRANTS OF PLAN-BASED AWARDS
For the Year Ended December 31, 2007

| Name and Position | Action Date (1) | Grant Date (2) | Estimated Future Payouts Under Non-Equity Incentive Plan Awards (3) Threshold ($) | Target ($) | Maximum ($) | Estimated Future Payouts Under Equity Incentive Plan Awards (4) Threshold (#) | Target (#) | Maximum (#) | All Other Option Awards: Number of Securities Underlying Options (5) (#) | Exercise or Base Price of Option Awards (6) ($/sh) | Grant Date Fair Value of Stock and Option Awards (7) ($) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Douglas Godshall | | | | | | | | | | | |
| Chief Executive Officer | — | — | — | 75,000 | 75,000 | — | —(8) | — | — | — | — |
| David McIntyre | | | | | | | | | | | |
| Chief Financial Officer | 11/13/07 | 11/16/07 | — | — | — | — | 400,000 | 400,000 | — | — | 262,717 |
| Dozier Rowe | | | | | | | | | | | |
| Chief Operating Officer | 11/13/07 | 11/16/07 | — | — | — | — | 200,000 | 200,000 | — | — | 131,358 |
| Jeffrey LaRose | | | | | | | | | | | |
| Chief Scientific Officer | 11/13/07 | 11/16/07 | — | — | — | — | 300,000 | 300,000 | — | — | 197,038 |
| Jennifer Foley | | | | | | | | | | | |
| Vice-President, | 12/21/06 | 01/02/07(9) | — | — | — | — | — | — | 1,000,000 | 0.97 (10) | 376,736 (11) |
| Clinical and Regulatory | 11/13/07 | 11/16/07 | — | — | — | — | 200,000 | 200,000 | — | — | 131,358 |
| Jane Reedy | | | | | | | | | | | |
| Former Vice-President, Sales and Marketing | — | — | — | — | — | — | — | — | — | — | — |

(1) This date represents the date on which the Board of Directors resolved to issue the option or stock award.

(2) This date represents the date on which the option or stock award was entered into the Company's register of option holders.

(3) Details of this payment to Mr. Godshall are set out under the heading "-Bonus" under the "-Elements of Compensation" section above.

(4) The amounts represent the number of shares in the Company expected to be issued to the relevant named executive officer under the Company's Performance Rights Plan. These stock awards vesting in four equal tranches on satisfaction of various performance hurdles, details of which are set out under the heading "-Equity Grants" above.

(5) These option awards vest in four equal annual tranches commencing on the first anniversary of the grant date.

(6) All option awards are issued with an exercise price in AU$ and are converted into US$ using the exchange rate at December 31, 2007 of AU$1.00 = US$0.8816.

(7) With the exception of the option awards granted to Ms. Foley on January 2, 2007, all amounts refer to a grant of performance rights, or stock awards, with an exercise price of nil. The amount referenced in the table is calculated by multiplying the number of stock awards granted by the closing market price of the Company's stock on the relevant grant date as published by the Australian Securities Exchange. The stock awards were granted on November 16, 2007 when the closing market price was AU$0.745 and was converted using the exchange rate at December 31, 2007 of AU$1.00 = US$0.8816. In each case, the amount referenced could also have been calculated, and generated the same grant date fair value, using the Black-Scholes valuation model and adopting the assumptions described in Note 3 and Note 12 of the Notes to Consolidated Financial Statements included in our audited Consolidated Financial Statements for the fiscal years ended December 31, 2007, 2006 and 2005 appearing elsewhere in this document.

(8) The Board of Directors has determined to grant 1.1 million performance rights to Mr. Godshall with an exercise price of zero. However, the ASX Listing Rules require that all equity grants to Mr. Godshall be first approved by the Company's shareholders and this approval has not yet been obtained. The Company expects to seek shareholder approval to grant these performance rights to Mr. Godshall on or before May 31, 2008.

(9) In accordance with Ms. Foley's employment agreement, these options were granted following the commencement of Ms. Foley's employment with the Company on January 2, 2007.

(10) The exercise price of these options is AU$1.10 which was converted into US$ using the exchange rate at December 31, 2007 of AU$1.00 = US$0.8816.

(11) Ms. Foley was granted 1,000,000 options with an exercise price of AU$1.10, being the same issue price for the Company's capital raising that was completed in May 2006. The exercise price was converted into US$ using the exchange rate at December 31, 2007 of AU$1.00 = US$0.8816. The amount referenced in the table is calculated at the relevant grant date using the Black-Scholes valuation model using the assumptions described in Note 3 and Note 12 of the Notes to Consolidated Financial Statements included in our audited Consolidated Financial Statements for the fiscal years ended December 31, 2007, 2006 and 2005 appearing elsewhere in this document.

Options are granted with exercise prices in Australian dollars (i.e., AUS) and otherwise in accordance with the terms of the Company's ESOP rules. Performance rights are granted with an exercise price of zero and otherwise in accordance with the terms of the Company's PRP rules. The exercise price per share (if any) and the calculated Black-Scholes value at grant date per share in the table above has been converted to US dollars using the exchange rate at December 31, 2007 of AU$1.00 = US$.8816. 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 5 days (or such other period as our Board may determine) prior to the time of the issuance of the option.

Except as stated below, all options granted under the Company's ESOP rules to-date, including options granted to named executive officers, vest in four equal annual tranches commencing on the first anniversary of the grant date subject to satisfaction of performance hurdles (if any). The vesting schedule was determined following consultation with the Company's lawyers, Corrs Chambers Westgarth, and the Company's corporate advisers, Inteq Limited, in late 2004.

Options granted in November 2007 under the Company's PRP to the named executive officers vest in four tranches subject to the satisfaction of certain performance hurdles (if any). For further details on these performance hurdles, please see the section titled "-Equity Grants".

There were no option exercises during 2007 by named executive officers.

The following table summarizes all outstanding equity awards for the named executive officers as of December 31, 2007:

## OUTSTANDING EQUITY AWARDS AT DECEMBER 31, 2007

| | Option Awards | | | | Stock Awards | | | |
|---|---|---|---|---|---|---|---|---|
| | Number of Securities Underlying Unexercised Options (# Exercisable) | Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#) | Option Exercise Price (1) ($) | Option Expiration Date | Number of Shares or Units of Stock That Have Not Vested (#) | Market Value of Shares of Units of Stock That Have Not Vested ($) | Equity Incentive Plan Awards: Number of Unearned Shares, Units or other Rights That Have Not Vested (#) | Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (2) (#) |
| Douglas Godshall (3) Chief Executive Officer) | 1,395,316 | | 0.97 | 09/04/16 | | | | |
| | | | 0.97 | 09/04/16 | | | | |
| David McIntyre Chief Financial Officer | 191,051 | | 0.53 | 01/31/10 | | | 400,000 | 193,952 |
| | 191,051 | | 0.66 | 01/31/10 | | | | |
| | | | 0.88 | 01/31/10 | | | | |
| | | | 1.32 | 01/31/10 | | | | |
| | 382,102 | | 0.66 | 11/30/12 | | | | |
| | 50,000 | | 0.97 | 10/18/16 | | | | |
| Dozier Rowe Chief Operating Officer | 250,000 | | 1.24 | 04/20/16 | | | 200,000 | 96,976 |
| | | | 0.97 | 10/18/16 | | | | |
| | 50,000 | | 0.97 | 10/18/16 | | | | |
| Jeffrey LaRose Chief Scientific Officer | 1,540,000 | | 0.18 | 01/31/10 | | | 300,000 | 145,464 |
| | 382,102 | | 0.44 | 04/27/15 | | | | |
| | | | 0.44 | 04/27/15 | | | | |
| | 50,000 | | 0.97 | 10/18/16 | | | | |
| Jennifer Foley Vice President, Clinical and Regulatory Affairs | | | 0.97 | 01/02/17 | | | 200,000 | 96,967 |
| | 50,000 | | 0.97 | 10/18/16 | | | | |
| Jane Reedy Former Vice-President, Sales and Marketing | | | 0.44 | 04/27/15 | | | | |
| | 50,000 | | 0.97 | 10/18/16 | | | | |

(1) All option awards are issued with an exercise price in AU$ and are converted into US$ using the exchange rate at December 31, 2007 of AU$1.00 = US$0.8816.

(2) Represents the closing market price of the Company's shares on December 31, 2007 as published by the Australian Securities Exchange (and converted into US$ using the exchange rate at December 31, 2007 of AU$1.00 = US$0.8816) multiplied by the number of stock awards.

(3) The Board of Directors has determined to grant 1.1 million performance rights to Mr. Godshall with an exercise price of zero. However, the ASX Listing Rules require that all equity grants to Mr. Godshall be first approved by the Company's shareholders and this approval has not yet been obtained. The Company expects to seek shareholder approval to grant these performance rights to Mr. Godshall on or before May 31, 2008.

### 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, Ms. Reedy and Mr. LaRose, their employment contracts 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. Mr. Godshall's employment agreement was determined and negotiated with the assistance of an executive recruiter, Russell Reynolds Associates, during which process the role and responsibilities, available market data and Mr. Godshall's previous compensation were considered.

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 (the sign-on bonus was used as an incentive to persuade Mr. Godshall to join HeartWare as he considered multiple employment offers).
- An annual performance bonus of $75,000 subject to satisfaction of agreed annual performance criteria (the criteria and quantitative components of such bonus, by percentage, are set forth below).
- 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 (the number of options equals approximately 3% of the then-outstanding shares of the Company and was based on the Company's understanding of comparable executive equity packages as confirmed by the Company's recruitment consultant, Russell Reynolds Associates, and the exercise price per share was equal to the per share price of the Company's most recent capital raise at the time of grant). Consistent with all our options granted under the ESOP rules, these options vest in four equal annual tranches commencing on the first anniversary of the grant date. This vesting schedule was established following consultation with the Company's lawyers, Corrs Chambers Westgarth, and the Company's corporate advisers, Inteq Limited, in late 2004.

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.

Mr. Godshall's annual performance bonus, targeted at $75,000, for the year ending December 31, 2008, will be determined based on whether and to the extent the following criteria have been satisfied:

| Criteria | % of Bonus |
|---|---|
| • Successful completion of initial phase of USE IDE clinical trial. | 25% |
| • Receipt of CE Marking in Europe. | 15% |
| • Advance MVAD to next development milestone. | 10% |
| • Implement branding and product differentiation strategy. | 5% |
| • Train and stock 20 sites in the United States. | 10% |
| • Develop corporate financing opportunities. | 25% |
| • Develop global marketing strategy. | 10% |

The above objectives for Mr. Godshall were discussed, negotiated and agreed by Mr. Godshall and Mr. Robert Thomas, Chairman of the Company. Mr. Thomas provided his initial suggestions on the objectives to Mr. Godshall and then the appropriateness of these objectives, and their respective weightings, were agreed by Mr. Thomas and Mr. Godshall following a series of discussions and communications. The objectives and their respective weightings were then approved by the Board of Directors.

***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), legal 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 Australian 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. The number of options granted in this regard was approximately equal to 0.75% of the Company's issued capital at the relevant time and was negotiated and agreed with Mr. McIntyre prior to the commencement of his employment. Consistent with all our options granted under the ESOP rules, these options vest in four equal annual tranches commencing on the first anniversary of the grant date. This vesting schedule was established following consultation with the Company's lawyers, Corrs Chambers Westgarth, and the Company's corporate advisers, Inteq Limited, in late 2004.

Mr. McIntyre's employment agreement does not contain a fixed term and may be terminated by either party on 3 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:

  A one-time pre-tax relocation allowance of $27,750 upon commencement of assignment in the United States in April 2006. The allowance is provided to assist Mr. McIntyre with meeting out-of-pocket

expenses that were 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).

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. The number of options granted to Mr. Rowe was negotiated with him following recommendations made to the Company by its recruitment consultant, Russell Reynolds Associates. Consistent with all our options granted under the ESOP rules, these options vest in four equal annual tranches commencing on the first anniversary of the grant date. This vesting schedule was established following consultation with the Company's lawyers, Corrs Chambers Westgarth, and the Company's corporate advisers, Inteq Limited, in late 2004.

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.

*Jennifer Foley, Vice-President, Clinical & Regulatory Affairs*

As Vice-President, Clinical & Regulatory Affairs, Ms. Foley is primarily responsible for the conduct of the Company's clinical trials.

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

- Annual salary of $220,000.
- A sign-on bonus of $30,000 paid upon commencement of employment (the sign-on bonus was used as an incentive to persuade Ms. Foley to join HeartWare and in light of the limited availability of senior executives with extensive clinical experience).
- A one-off bonus of $30,000 subject to the Company filing an investigational device exemption with the US Food and Drug Administration within ninety days of the completion of enrolment of our international clinical trial.
- Full participation in our employee benefits program, including life and disability insurance (short and long term), health and group dental.

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

*Jane Reedy, Former Vice President, Clinical and Marketing*

Ms. Reedy was our Vice President, Sales and Marketing until September 12, 2007, in which position she was responsible for global sales and marketing and for managing reimbursement systems in domestic and international markets.

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

- Annual salary of $220,000.
- 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. The number of options granted to Ms. Reedy was agreed following protracted negotiations between Ms. Reedy and the Company. Ms. Reedy had been acting as a consultant to the Company for an extended period of time and was able to negotiate a higher number of options as a result. Consistent with all our options granted under the ESOP rules, these options vest in four equal annual tranches commencing on the first anniversary of the grant date. This vesting schedule was established following consultation with the Company's lawyers, Corrs Chambers Westgarth, and the Company's corporate advisers, Inteq Limited, in late 2004.

For more information, see "—Non-Continuing Named Executive Officers" below.

**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, 2007 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 6 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 3 months notice in writing of such termination or payment of 3 months' salary in lieu of notice;
- the continuation of all benefits provided to him and his family for 6 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 payment for 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.

***Termination for Good Reason***

If either of Mr. Godshall or Mr. McIntyre terminates his employment for "good reason" (as defined in his 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 6 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, 2007.

**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 |

(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 at the grant date using the assumptions described in Note 3 and Note 12 of the Notes to Consolidated Financial Statements included in our audited Consolidated Financial Statements for the fiscal years ended December 31, 2007, 2006 and 2005 appearing elsewhere in this document.

(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 Florida to Australia.

***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 3 consecutive months or 3 months in aggregate in any twelve month period, then Mr. Godshall shall be entitled to receive his salary and health insurance benefits for 3 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, 2007.

| | Death | | | | | Disability | | | |
|---|---|---|---|---|---|---|---|---|---|
| Name | Severance Payment ($) | Payment in Lieu of Notice ($) | Share Options (1) ($) | Benefits (2) ($) | Total ($) | Severance Payment ($) | Share Option (3) ($) | Benefits (4) ($) | Total ($) |
| Douglas Godshall | 175,000 | 87,500 | 119,406 | 5,342 | 387,248 | 87,500 | 119,406 | 2,671 | 209,577 |

(1) Represents the Black-Scholes value of share options calculated as at the grant date using the assumptions described in Note 3 and Note 12 of the Notes to Consolidated Financial Statements included in our audited Consolidated Financial Statements for the fiscal years ended December 31, 2007, 2006 and 2005 appearing elsewhere in this document.

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

(3) Represents the Black-Scholes value of share options calculated as at the grant date using the assumptions described in Note 3 and Note 12 of the Notes to Consolidated Financial Statements included in our audited Consolidated Financial Statements for the fiscal years ended December 31, 2007, 2006 and 2005 appearing elsewhere in this document..

(4) 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 and Mr. Rowe 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 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 3 months notice of the termination, then he shall be entitled to a payment equal to an additional 3 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, if his employment is terminated by the Company without cause or if he terminates his employment for good reason, and if such termination occurs within twelve months following the change in control, then all his 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 and Mr. Rowe if his 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, 2007.

**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 |

(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 using the assumptions described in Note 3 and Note 12 of the Notes to Consolidated Financial Statements included in our audited Consolidated Financial Statements for the fiscal years ended December 31, 2007, 2006 and 2005 appearing elsewhere in this document.

***Non-Continuing Named Executive Officers***

Our former Vice-President, Sales & Marketing, Ms. Reedy ceased her role as Vice-President, Sales & Marketing in September 2007 but remained employed by the Company until December 31, 2007.

The Company and Ms. Reedy entered into an agreement on September 12, 2007 under which Ms Reedy would continue to be employed by the Company until December 31, 2007 at which time Ms. Reedy would resign all positions with the Company. Under this agreement, we agreed to pay Ms. Reedy a severance payment equal to twelve months salary, or $220,000, plus applicable payroll taxes.

## DIRECTOR COMPENSATION

The following table sets out total compensation for the year ended December 31, 2007 to our non-executive directors. Executive directors do not receive compensation for their service as directors.

**DIRECTOR COMPENSATION (1)**

| 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 (2) ($) | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|---|---|---|---|
| Robert Thomas Chairman | 2007 | 100,608 | — | — | — | 9,055 | — | 109,663 |
| Seth Harrison, M.D. Deputy Chairman | 2007 | 83,840 | — | — | — | 7,546 | — | 91,386 |
| Dr. Christine Bennett Non-executive director | 2007 | 50,304 | — | — | — | 4,527 | — | 54,831 |
| Dr. Denis Wade Non-executive director | 2007 | — | — | — | — | 54,831 | — | 54,831 |
| Robert Stockman (3) Non-executive director | 2007 | — | — | 67,720 (4) | — | — | — | 67,720 |

(1) All amounts paid to directors are denominated in AU$ and are converted into US dollars using the average exchange rate for fiscal 2007 of AU$1.00 = US$0.8384.

(2) Statutory contributions of 9% of fees to a superannuation fund (i.e., pension) for Australian directors only. These amounts are paid in AU$ and are converted into US dollars using the average exchange rate for fiscal 2007 of AU$1.00 = US$0.8384.

(3) Mr. Stockman was appointed to the Board of Directors as of December 11, 2006 and has not received any director's fees during 2006 or 2007. Mr. Stockman will commence receiving directors' fees with effect from January 1, 2008 at the rate of $60,000 per annum.

(4) Mr. Stockman was granted 200,000 options on July 26, 2007 with an exercise price of AU$0.75. The amount in the table represents the Black-Scholes value of these share options calculated using the assumptions described in Note 3 and Note 12 of the Notes to Consolidated Financial Statements included in our audited Consolidated Financial Statements for the fiscal years ended December 31, 2007, 2006 and 2005 appearing elsewhere in this document.

**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 similar entities in the life sciences and/or biotechnology industries in Australia. Consideration was given to the size of companies, the stage of companies (i.e., whether such companies were pre- or post-revenue) and whether or not comparable companies were publicly held. The Company did not undertake a formal study or rely on specific benchmarking data in setting director compensation. 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 3 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 and except for an initial grant of options to Mr. Stockman on July 26, 2007, 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 or employee of the Company, except that (1) 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 and (2) 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. None of our executive officers serves as a member of the board of directors or compensation committee of any other entity that has one or more executive officers who serve on our board of directors or compensation committee.

## Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth, as of January 31, 2008, 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 January 31, 2008 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 January 31, 2008, there were 248,100,277 ordinary shares outstanding.

| Name and Address of Beneficial Owner | Number of Shares Beneficially Owned | Percent of Shares Outstanding |
|---|---|---|
| **5% Shareholders** | | |
| Apple Tree Partners I, L.P<br>501 Kings Highway East, E-1<br>Fairfield, Connecticut 08625 | 93,093,958 (1) | 38% |
| Muneer A. Satter<br>71 S. Wacker Drive, Suite 500<br>Chicago, IL 60606 | 20,350,000 | 8% |
| Pequot Capital Investors<br>c/o Pequot Capital Management, Inc.<br>500 Nyala Farm Road<br>Westport, CT 06880 | 12,662,135 | 5% |
| **Directors and Named Executive Officers** | | |
| Robert Thomas | 3,431,153 (2) | 1% |
| Dr. Seth Harrison | 93,093,958 (3) | 38% |
| Dr. Denis Wade | 1,258,333 (4) | 1% |
| Dr. Christine Bennett | 250,000 (5) | * |
| Robert Stockman | 500,000 | * |
| Douglas Godshall | 1,495,621 (6) | 1% |
| David McIntyre | 1,415,357 (7) | * |
| Jeffrey LaRose | 1,972,102 (8) | 1% |
| Dozier Rowe | 310,000 (9) | * |
| Jane Reedy | 623,152 (10) | * |
| Ramon Paz | 182,500 (11) | * |
| James Schuermann | — | * |
| Jennifer Foley | 250,000 (12) | * |
| Barry Yomtov | 75,000 (13) | * |
| All directors and executive officers as a group (14 persons) | 104,857,176 (14) | 42% |

* Indicates less than 1%

(1) Includes 1,505,176 shares issuable as of December 31, 2007 upon conversion of a convertible note.

(2) Includes 1,073,153 shares subject to options exercisable within 60 days of January 31, 2008 and 1,350,000 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 1,008,333 shares held by a family trust and 250,000 shares subject to options exercisable within 60 days of January 31, 2008.

(5) Represents shares subject to options exercisable within 60 days of January 31, 2008.

(6) Includes 1,395,316 shares subject to options exercisable within 60 days of January 31, 2008.

(7) Represents 1,387,357 shares subject to options exercisable within 60 days of January 31, 2008 and 28,000 shares held by Mr. McIntyre's spouse.

(8) Represents shares subject to options exercisable within 60 days of January 31, 2008.

(9) Includes 300,000 shares subject to options exercisable within 60 days of January 31, 2008.

(10) Represents shares subject to options exercisable within 60 days of January 31, 2008.

(11) Includes 167,500 shares subject to options exercisable within 60 days of January 31, 2008.

(12) Represents shares subject to options exercisable within 60 days of January 31, 2008.

(13) Represents shares subject to options exercisable within 60 days of January 31, 2008.

(14) Includes 8,751,913 shares subject to options exercisable within 60 days of January 31, 2008.

## Item 13. 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 $1.3 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: Mr. Rob Thomas, Dr. Seth Harrison, Mr. Douglas Godshall, Dr. Christine Bennett, Dr. Denis Wade and Mr. Bob 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 to being a member of our Board of Directors, Dr. Harrison is also the managing general partner of Apple Tree Partners I, L.P., which owned 37% of the outstanding voting shares of the Company as of December 31, 2007.

### Policies and Procedures for Review and Approval of Related Party Transactions

We have not adopted formal written policies and procedures for the review, approval or ratification of transactions, such as those described above, with our executive officers, directors and significant stockholders. However, we are subject to the Corporations Act and the listing requirements of the ASX. Chapter 10 of the ASX Listing Rules includes provisions related to acquisitions or disposals of substantial assets to related parties, purchases of securities by related parties, payments to directors and termination of benefits as they related to transactions with persons in a position of influence. Furthermore, Chapter 2E of the Corporations Act requires public companies to seek shareholder approval where a financial benefit is to be provided to a related party except for certain circumstances such as arm's lengths transactions, reasonable compensation and standard benefits.

## Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The Audit Committee of the Board of Directors has appointed Grant Thornton (Grant Thornton NSW in Australia and Grant Thornton LLP in the United States) as our independent auditors for its fiscal year ending December 31, 2007. The Audit Committee is directly responsible for the appointment, retention, compensation and oversight of the work of our independent auditors (including resolution of disagreements between management and the independent auditors regarding financial reporting) for the purpose of preparing or issuing an audit report or related work. In making its determination regarding whether to appoint or retain a particular firm of independent auditors the Audit Committee takes into account the views of management.

Fees billed by Grant Thornton in 2007 and 2006 are as follows:

| | 2007 | 2006 |
|---|---|---|
| Audit Fees [1] | $ 220,885 | $ 198,454 |
| Other Advisory Fees [2] | 24,164 | 4,548 |
| Tax Fees [3] | 16,402 | 5,685 |
| | $ 261,451 | $ 208,687 |

[1] Audit fees are fees on an accrual basis for professional services rendered in connection with our annual audit, interim reviews, statutory filings and registration statements.

[2] Other Advisory fees include services related to assistance with compliance with regulatory requirements and other services.

[3] Tax fees are fees for tax services related to tax compliance, tax planning and tax advice.

***Audit Committee's pre-approval policy***

It is the Audit Committee's policy to approve in advance the types and amounts of audit, audit-related, tax and any other services to be provided by our independent auditors. In situations where it is not possible to obtain full Audit Committee approval, the Committee has delegated authority to the Chairman of the Audit Committee to grant pre-approval of auditing, audit-related, tax and all other services. Any pre-approved decisions by the Chairman are required to be reviewed with the Audit Committee at its next scheduled meeting. The Audit Committee has approved all of Grant Thornton's services for 2007 and 2006 and, in doing so has considered whether the provision of such service is compatible with maintaining independence.

**Part IV**

**Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

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

1. Financial Statements:

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

2. Financial Statement Schedules:

   None.

3. Exhibits:

   See Exhibit Index

SIGNATURES

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

HeartWare Limited

Date: February 28, 2008

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

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

| Name | Title | Date |
|---|---|---|
| /s/ Douglas Godshall<br>Douglas Godshall | Chief Executive Officer and Director<br>(Principal Executive Officer) | February 28, 2008 |
| /s/ David McIntyre<br>David McIntyre | Chief Financial Officer and Secretary<br>(Principal Financial and Accounting Officer) | February 28, 2008 |
| /s/ Robert Thomas<br>Robert Thomas | Chairman | February 28, 2008 |
| /s/ Seth Harrison<br>Seth Harrison | Deputy Chairman | February 28, 2008 |
| /s/ Christine Bennett<br>Christine Bennett | Director | February 28, 2008 |
| /s/ Denis Wade<br>Denis Wade | Director | February 28, 2008 |
| /s/ Robert Stockman<br>Robert Stockman | Director | February 28, 2008 |

## Exhibit Index

| Exhibit No. | Description |
|---|---|
| 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. * |

| Exhibit No. | Description |
|---|---|
| 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 * + |
| 10.33 | HeartWare Limited Share Performance Rights Plan — Plan Rules *** + |
| 10.34 | Separation Agreement, dated September 12, 2007, between Jane Reedy, HeartWare, Inc. and, as to Sections 2, 6, 7, and 9 only, HeartWare Limited **** + |
| 10.35 | Incentive Option Agreement between HeartWare Limited and Dr Christine Bennett |
| 10.36 | Incentive Option Agreement between HeartWare Limited and Dr Denis Wade |
| 10.37 | Incentive Option Agreement between HeartWare Limited and Inteq Limited |
| 10.38 | Incentive Option Agreement between HeartWare Limited and Robert Thomas |
| 10.39 | Deed of Consent to Assignment of Sublease, between HeartWare Limited, ZCM Asia Holdings Pty Limited, Zurich Capital Markets Asia Pty Limited and Royal Bank of Canada, dated July 1, 2007 |
| 10.40 | Business Lease, dated December 27, 2006, between HeartWare, Inc. and Atlantic-Philadelphia Realty LLC |
| 21.1 | List of Subsidiaries * |
| 23.1 | Consent of Independent Registered Public Accounting Firm |
| 31.1 | Certificate pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 of Chief Executive Officer |
| 31.2 | Certificate pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 of Chief Financial Officer |

| Exhibit No. | Description |
|---|---|
| 32.1 | Certificate pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, of Chief Executive Officer |
| 32.2 | Certificate pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, of Chief Financial Officer |

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* Incorporated by reference to the respective exhibits filed with the Company's Registration Statement on Form 10 (File No. 000-52595) filed with the Securities and Exchange Commission on April 30, 2007.

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

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

**** Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 17, 2007

+ Management contract or compensatory plan or arrangement.

Exhibit 31.1

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO RULE 13A-14(a) OR RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934**

I, Douglas Godshall, certify that:

1. I have reviewed this Annual Report on Form 10-K of HeartWare Limited;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2008

/s/ Douglas Godshall
Douglas Godshall
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO RULE 13A-14(a) OR RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934**

I, David McIntyre, certify that:

1. I have reviewed this Annual Report on Form 10-K of HeartWare Limited;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2008

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

Exhibit 32.1

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350 AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of HeartWare Limited (the "Company") for the fiscal year ended December 31, 2007 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned Chief Executive Officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that based on his knowledge:

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

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

Date: February 28, 2008

/s/ Douglas Godshall
Douglas Godshall
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350 AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of HeartWare Limited (the "Company") for the fiscal year ended December 31, 2007 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned Chief Executive Officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that based on his knowledge:

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

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

Date: February 28, 2008

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

END