HEARTWARE LIMITED

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ASX Limited
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19 December 2007
BY E-LODGEMENT

Dear Sir / Madam

Shareholder Letter

Please see the attached shareholder letter that is presently being distributed to shareholders.

Yours faithfully

David McIntyre
Chief Financial Officer &
Company Secretary

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Dear Shareholder

As we head towards the end of the year, I thought it an opportune time to provide an update regarding our current status as well as to outline our key objectives for 2008.

Industry News

On 30th November, an independent panel of 15 clinicians convened by the US Food and Drug Administration ("FDA") recommended unanimously that Thoratec's HeartMate II Left Ventricular Assist System should be conditionally approved for use in the United States.

This is an extremely important milestone for the Ventricular Assist Device ("VAD") industry and great news for HeartWare. The unanimous panel recommendation will almost certainly lead to the HeartMate II being approved early in 2008. The HeartMate II will be the first rotary blood pump approved for use in the US. The device is significantly smaller and more reliable than its predecessor, the HeartMate XVE, which remains the only approved implantable VAD available to US clinicians. The approval of the HeartMate II is expected to increase the use of ventricular assist devices, because surgeons and referring cardiologists will have access for the first time to a relatively small and reliable pump. While estimates vary as to the impact HeartMate II will have, there appears to be unanimity among analysts that its approval will mark the first critical step towards the long anticipated expansion of the VAD market.

We congratulate Thoratec on achieving this important milestone.

HeartWare Regulatory Update

On 1st November we announced that we had filed our submission for an Investigational Device Exemption ("IDE") with the FDA. We advised also that we anticipated a period of communication with the FDA, a process which generally involves a series of questions and answers over several months.

As expected, on 30th November we received a response from the FDA seeking clarification of various elements of our submission. We are currently working through the process of addressing the FDA's questions.

We intend to complete our response to the FDA in January. This will initiate a second cycle of 30 days, at the end of which we expect to receive further feedback from the FDA. HeartWare's overriding priority is to expedite the regulatory process so as to commence our US clinical program as soon as possible. A number of US centres are lining up for our trial, with several already processing the documentation required to initiate implants.

The receipt of the first comments from the FDA on our HVAD™ IDE submission coincided with the FDA Advisory Panel meeting on Thoratec's HeartMate II. We learned a great deal about how the FDA and its independent advisors are thinking about VADs today and what they hope to see in the future. As a result of what we heard at the FDA Advisory Panel meeting, we have elected to make certain modifications to our proposed clinical trial design, which we expect will both optimize our ability to achieve a successful trial outcome in the current US regulatory environment. These proposed modifications will be included in our January response to the FDA letter on our HVAD™ IDE submission.

Completing our response to the FDA will require that we dedicate our executive team over the coming weeks. As a consequence, we will not complete our submission for CE Mark before the end of the year as previously described. We aim to complete our submission during the first quarter of 2008. This would then lead to a review cycle by our notified body in Europe which will be analogous to the process we are now undergoing in the US with the FDA. Our best estimate is that HeartWare will receive CE Mark during the second quarter of 2008. Following receipt of CE Mark, we intend to apply to the Therapeutic Goods Administration ("TGA") for approval to sell the HVAD™ device in Australia.

Clinical Update

As of 18th December, we have completed 25 implants. Our patients have been supported for a cumulative period of approximately 4,750 days, or almost 13 years. The average duration of support stands at 190 days. The range of support for currently implanted patients is 12 to 393 days. Thirteen patients have successfully passed the primary endpoint. Three patients are within approximately one month of reaching 180 days of support, which is one of the primary endpoints. Two patients currently on support have recently passed the one-year mark since being implanted with the HVAD™ device. Three patients have received heart transplants, after 425, 348 and 157 days of support respectively. One patient had his pump removed after 268 days of support because of myocardial recovery. We are very encouraged by these results.

Over recent months HeartWare's clinical results were presented at several high profile conferences. Dr. Georg Wieselthaler of Vienna General Hospital presented at the Heart Failure Meeting at the Cleveland Clinic in October and at the Japanese Society of Artificial Organs Meeting in November. Dr. Martin Strueber of Hannover Medical Center presented at the Berlin Symposium on Mechanical Circulatory Support in November. In addition, an abstract prepared by Dr. Wieselthaler has been accepted for the 2008 meeting of the International Society of Heart and Lung Transplantation ("ISHLT"), the key annual meeting of transplant surgeons.

It is through presentations such as these that clinicians learn of the HeartWare results. We are pleased by the level of interest and enthusiasm being expressed by several of the largest VAD centres in both the US and Europe.

MVAD™ Device Update

During the first week of November we attended the annual meeting of the International Society of Rotary Blood Pumps ("ISRBP"), held in Sydney. The ISRBP is a multidisciplinary industry group which brings together a wide range of companies and individuals who share a common interest in advancing the use of rotary blood pumps.

During the conference Michael Ashenuga, one of HeartWare's Product Development Engineers, delivered a presentation on the status of HeartWare's next-generation miniaturized pump, the MVAD™ Left Ventricular Assist Device. While we have previously described the MVAD™ in general terms, we used the opportunity of the ISRBP conference to provide a detailed description of the technology and our concept for implanting it via a minimally invasive approach. Michael's presentation generated a great deal of interest. A copy is available for download from our website at http://www.heartware.com.au/IRM/content/usa/investor_corporatepresent.html

The MVAD™ device is approximately one third the size of our lead device, the HVAD™ pump, which is already substantially smaller than competing VADs. The small size of the MVAD™ device will allow it to be implanted via minimally invasive surgical techniques, avoiding the need for a sternotomy (opening the chest), which is the standard procedure by which current-generation pumps are implanted. We believe that reducing the invasiveness of the surgery required will be an important factor driving the increased adoption of VADs generally and of the HeartWare MVAD™ device in particular.

In partnership with Dr. Wieselthaler, we recently initiated a series of chronic animal studies using the MVAD™ device. Through these studies we continue to evaluate the performance characteristics of the device and to refine our minimally-invasive implant technique.

Operations

We are fortunate to have recently hired Mr. John Starkey for the position Director, Operations Engineering. John brings to HeartWare a broad range of experience including manufacturing engineering, product development and general management. He has worked in the medical device field for more than two decades, most recently at Johnson and Johnson, where he was responsible for a 70 person advanced technology development team. Our Manufacturing Engineering, Manufacturing Process Development and Process Technology Engineering groups all now report directly to him.

John has already had a significant and positive impact on our operations. As we prepare to increase our manufacturing output several-fold over the coming 12 months, his experience and manufacturing expertise will play an important part in ensuring a smooth manufacturing scale-up.

Corporate Update

For a pre-commercial medical device company, HeartWare enjoys an unusual depth of support from private and institutional investors in both Australia and the United States. HeartWare's cornerstone shareholder, Apple Tree Partners, holds approximately 37% of HeartWare's shares. Of the balance, US investors account for approximately 40% and Australian investors account for approximately 60%.

The above strong US institutional presence on our share register coupled with the fact that we already comply with US SEC reporting requirements presents HeartWare with a great degree of flexibility with regards future listing opportunities for the Company.

In the past we have raised the possibility of listing on a US stock exchange using American Depository Receipts ("ADRs"). However, the strong participation by US funds in HeartWare's ASX-listed stock during our most recent financing confirms that the ADR approach is not necessary in order to attract US investors to our stock. We are therefore unlikely at this time to initiate an ADR program and instead

presently favor re-domiciling to the United States with a view to pursuing a full Initial Public Offering on the NASDAQ Exchange at the appropriate time. This approach has a number of benefits and, importantly, would enable HeartWare to retain its ASX listing while gaining direct access to the US capital markets. We will continue to evaluate all of our options and will update shareholders as matters progress in this regard.

Looking Ahead

While it is always difficult to predict the dates on which regulatory processes will conclude, it is clear that we have an exciting year ahead. Over the coming 12 months, HeartWare expects to commence and to expand a pivotal US clinical trial, during which several of the world's highest-volume cardiac transplant centres will begin using the HVAD™ device. We expect to gain regulatory approval in Europe and to initiate commercial sales activities in key European markets. We expect to generate revenues both for pumps implanted in the US clinical trial and for those sold outside the US following our receipt of CE Mark. At the same time, we will continue to advance the MVAD™ device.

We also anticipate that, following approval of the Thoratec HeartMate II, the market for VADs will undergo significant growth, which will likely stimulate increased interest from both the clinical and the financial communities.

I continue to be impressed by the scope of the opportunity we have before us and by the compelling nature of our technology position. The exceptional depth of talent that we have assembled within a relatively small medical device company remains critical to attaining our goals. We have much work ahead of us, but with our strong team and powerful technology we look forward to a successful 2008.

I'd like to take this opportunity to wish you and your families a healthy and happy holiday season and the very best for the New Year.

As always, thank you for your continued support of HeartWare.

Yours sincerely

Doug Godshall
Chief Executive Officer