

# HEARTWARE LIMITED

ABN 34 111 970 257



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Manager of Company Announcements  
ASX Limited  
Level 6  
20 Bridge Street  
SYDNEY NSW 2000

3 January 2007  
**BY E-LODGE MENT**

Dear Sir / Madam

## **Letter to Shareholders**

Please find attached a copy of a letter that is presently being distributed to HeartWare shareholders.

Yours faithfully

**David McIntyre  
Chief Financial Officer &  
Company Secretary**

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Dear Shareholder,

I would like to wish you a happy and healthy new year and to take this opportunity to reflect briefly on the year just passed - a year of significant progress for HeartWare.

## **Our Pump Works**

In early 2006, the Company knew only that the HVAD<sup>TM</sup> worked in laboratory and pre-clinical settings. We now have six patients in whom the pump is performing extraordinarily well. The most recent implant was conducted at Vienna General Hospital on the 19<sup>th</sup> of December. As with the previous five patients, the sixth implant was completed quickly and without incident. Two weeks out from the procedure, the patient continues to make an excellent recovery.

Over coming months HeartWare will progressively introduce new hospitals to the trial and will accelerate the rate of implants. A further 14 patients must be enrolled to satisfy our trial requirements. However, with over 750 days of cumulative support across six patients, we feel that the pump's exceptional clinical performance has already been well demonstrated.

## **Our Production Issues are Resolved**

When I first came on board, I had the task of explaining to our shareholders that the company had been unable to reliably produce pumps for some months. While there was never any major manufacturing problem, a series of minor production setbacks indicated clearly that system modifications were required. Over the last four months we have significantly upgraded our quality systems and dramatically improved our production capabilities. While we'll never be done seeking improvements, we have already achieved a significant turnaround in production efficiencies, pump output and manufacturing yields.

Over the month of December, we produced five HVAD<sup>TM</sup> pumps without any production during the holiday period. In January we expect to produce eight pumps. This current rate of production is clearly adequate to comfortably supply the needs of our CE mark clinical trial. Through 2007, our output will be progressively increased as we move towards our US clinical trials and European commercial launch.

Our third and fourth clinical sites, Hannover Medical Centre in Germany and Harefield Hospital in the UK, have both been trained. Hannover has received complete systems and is now screening for suitable implant candidates. Harefield will receive complete systems by mid January. A fifth centre is likely to begin enrolling patients towards the end of the first quarter of this year.



### **Our Team is First Rate**

HeartWare has in place an exceptionally strong team, with a depth of operational, technical, clinical and management talent unusual in a company of our size. Our management ranks were enhanced through the year with the appointments of Dozier Rowe as Chief Operating Officer and Jennifer Foley as Vice President of Clinical and Regulatory Affairs. Both bring to the company a great deal of valuable experience.

We were also pleased to announce the appointment of Bob Stockman to the HeartWare Board of Directors. Bob has a long and successful track record in the medical device arena, having founded, led and financed a number of successful medical companies. His experience and contacts within the US medical device and financial communities are already proving invaluable.

### **Our Pipeline is Compelling**

We have focused almost all of our recent attention on our HVAD™ program but have found creative ways to continue moving forward on each of our key platforms for the future: pump initialization, implantable electronics and software enhancements.

Many industry veterans have told us that we have a decided and sustainable advantage with our existing product due to its extremely small size, wearless design which should translate into better durability, and superb clinical performance to date. We are conscious, however, that product leadership in the long term will depend on our ongoing ability to innovate. We expect that our next-generation products will help expand the pool of potential patients dramatically by enabling physicians to implant our pumps with less invasive procedures, thereby offering a viable treatment option for patients at a much earlier stage in the progression of their disease.

Currently, HeartWare's primary focus is on ensuring the clinical and commercial success of our HVAD™. Over time, our market position will be reinforced by a cadence of product launches that will materially change the way Class III and IV heart failure patients are treated.

### **Our Market Opportunity is Exciting**

Despite the US healthcare system spending an estimated US\$30 billion per year on the management of heart failure, current treatment options are largely inadequate. The use of ventricular assist devices is beginning to attract widespread acceptance among clinicians. Prompted by the introduction of smaller, more reliable devices and increasingly positive data, the number of implants is growing every year.

The majority of implants are still conducted in a Bridge to Transplantation ("BTT") patient population. However, the Destination Therapy ("DT") indication, which represents the far greater long term market opportunity, is gaining increasing traction. DT patient enrolment is being driven largely by the HeartMate II, the second generation pump from Thoratec Corporation, currently in a pivotal US clinical trial and generating encouraging results.

Another potential market for VAD's that has garnered attention of late is known as Bridge to Recovery ('BTR'). An article was published in November 2006 in the New England Journal of Medicine which described the potential for the use of VAD's in a BTR indication. The study showed that for a subset of patients, the use of a VAD in conjunction with a particular drug regimen allowed the heart to recover to such an extent that the device was subsequently removed. The study was conducted at Harefield Hospital, one of HeartWare's investigational sites, and was co-authored by Dr Asghar Khaghani, a member of our Medical Advisory Board.



As the market moves towards an inflexion point in the adoption of VAD's, we believe HeartWare to be exceptionally well positioned. The advantages of our HVAD™ should ensure that we capture a meaningful share of a growing market. The introduction in time of our next generation miniature pumps should establish for HeartWare a sustainable competitive position over the long term.

### Summary

HeartWare has made great strides in 2006. We commenced our clinical trial, conducted six implants and have begun the process of proving the clinical value of the HVAD™. We resolved many manufacturing challenges, established sufficient production output to comfortably meet our clinical requirements and have in place a robust manufacturing platform from which to scale up volumes through 2007. We've also made a number of senior appointments at both executive and Board levels, ensuring that we have the necessary management depth across all key facets of the business.

Our market opportunity is real and expanding. We're seeing a healthy growth in implant numbers, but the number of heart failure patients who could potentially benefit from a device such as ours still vastly exceeds current implant rates. Based on the excellent early clinical data from our device, we expect to be both a beneficiary of and a catalyst for a significant acceleration in implant numbers over coming years.

We have a busy 12 months ahead as we work towards a series of key clinical, regulatory and product development objectives through 2007. We are acutely conscious of the slip in our timeline during 2006 and are absolutely committed to meeting milestones going forward.

We wish you all the best for a happy, prosperous and safe 2007. We appreciate your support and look forward to a year of significant accomplishments.

Yours sincerely

A handwritten signature in blue ink, appearing to read "Doug Godshall".

Doug Godshall  
Chief Executive Officer