HEARTWARE LIMITED

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Dear Shareholder

The third quarter of 2008 has proven to be one of the most significant in the history of the Company. We received full approval for our IDE, filed our design dossier for CE Mark, completed an ISO audit of our quality system, received Federal Court approval for redomiciliation to the United States, began actively manufacturing in our new facility and commenced our US clinical trial. We have also made significant progress with our next generation miniaturized pump (MVAD) program, about which we expect to release specific details over coming weeks.

I would be hard-pressed to develop a more meaningful list of achievements for the period. The effort and commitment demonstrated by our team to achieve these results have been extraordinary.

US Clinical Trial

On 21 August 2008 we announced that Dr Steven Boyce of Washington Hospital Center had conducted the first implant in the United States of the HeartWare® System. This marked the start of enrolment in HeartWare's US Bridge-to-Transplant clinical trial, during which 150 heart failure patients will be implanted with the HeartWare device at up to 28 participating centres.

Washington Hospital Center was the only US hospital to initiate implants on the basis of the FDA's "Conditional Approval" of HeartWare's Investigational Device Exemption (IDE). A number of additional centres were unable to advance their internal review processes until this IDE approval became "unconditional". On 23 September 2008 we announced that we had received full approval from the FDA, prompting a number of centres to accelerate their internal processes. Three additional centres have since received approval from their Institutional Review Boards (IRB's) and all are now finalizing the required contractual arrangements and supply agreements to begin implants. Several additional centres are in an advanced stage, with IRB approvals anticipated over coming weeks. A total of seven centres have now completed surgical training. It is our intention to announce the additional centres once they have commenced implants.

We are encouraged by the efforts of our investigators to expedite their internal review processes and expect momentum in the trial to begin building over coming weeks. We remain cautiously optimistic that by the end of the year at least five of our initial ten centres will have commenced implants.

First Revenue

The first implant at Washington Hospital Center marked not only the start of HeartWare's US clinical experience but also the first-ever receipt of revenue for the Company.

When the FDA approved HeartWare's IDE, the HeartWare system was given a "Category B2" designation, paving the way for the Company to be reimbursed for product used during the clinical trial.

Although reimbursement is determined on a hospital-by-hospital basis by local CMS Fiscal Intermediaries, there is very strong precedent to indicate that participating hospitals will be reimbursed for the vast majority of their HeartWare implants. Hospitals will be reimbursed at approximately US$140,000 for the procedure. The hospitals, in turn, will pay HeartWare for the implant kit and associated peripheral components.

International Clinical Trial

We continue to see very pleasing results from our international clinical trial. As at 31 October 2008, our sites have conducted 46 implants of the system. The cumulative support time now stands at 11,628 days, or approximately 32 years, and the average duration of support on the system is 253 days per patient. Of the 46 patients, 5 patients have unfortunately died, including 4 patients within 180 days of their implant and one patient beyond the 180 day endpoint. Of the remaining 41 patients, 12 have received heart transplants (after an average of 266 days on LVAD support prior to transplant), 3 patients have had their devices explanted due to recovery of their hearts, and 26 patients remain on LVAD support. Fourteen patients have been supported by the system for over 12 months. Our longest supported patient has lived with the device for some 21 months, having received the implant in February 2007.

The first formal clinical presentation of our data occurred in April 2008 when Dr Georg Wieselthaler presented data from our first 23 patients. It is encouraging that the survival rate of approximately 90% reported at that time continues to hold true over our expanded patient group and that our rate of complications such as bleeding, neurologic events and pump exchanges appears to have remained constant over the larger number of patients. We reiterate that our sample size remains small, however the apparent patterns of device reliability and high patient survival rates are extremely promising early indicators.

ISO Certification

On 20 October 2008 we announced that HeartWare had undertaken and passed a quality system audit and that the company had received ISO certification. The ISO standard is recognized internationally as a universal measure of quality and is a critical prerequisite to securing CE Mark and other regulatory approvals.

The receipt of ISO certification signifies an important maturation of the business, demonstrating that we have in place the systems, processes and the associated management discipline that is required of a commercial medical device enterprise. It is a tremendous credit to the HeartWare team, particularly those within our Quality Assurance group, that ISO was achieved on time, despite a facility move mid-stream and despite the heavy demand on resources necessitated by our concurrent IDE and CE Mark regulatory submissions.

CE Mark Update

HeartWare remains on track to receive CE Mark by the end of the year.

The Company's receipt of ISO certification satisfied the first critical requirement of the CE Mark application process. The second key component was the submission of a Design Dossier, as announced on 11 September 2008.

HeartWare's Design Dossier included a detailed clinical report based on data from our first 25 patients. Of these 25 patients, 23 patients (92%) successfully met the primary endpoint of the trial, namely survival to 180 days or heart transplantation.

The submission is currently the subject of review by BSI Management Systems, the independent Notified Body appointed to assess HeartWare's application, as well as an independent clinician appointed by BSI to conduct a detailed review of our clinical data. We remain confident that the review process is on track.

Following receipt of CE Mark we plan to pursue a controlled commercial rollout. Our first priority will be to effectively transition our existing sites from clinical trial centres into cornerstone commercial customers. Having established these as "hub" sites in key geographies, we plan to then expand into a number of additional high profile transplant centres. We have been pleased by the enthusiasm expressed for our product by key opinion leaders in Europe and we expect to see a steady, measured growth in market penetration following our commercial launch.

Redomiciliation

HeartWare held a series of shareholder meetings on 22 October 2008 to vote on a proposed corporate restructure, which will lead to a US incorporated company, HeartWare International, Inc., replacing HeartWare Limited as the ultimate parent company in the HeartWare Group. Details of the restructure were set out in a detailed Information Memorandum which you would have received in mid September.

HeartWare shareholders voted overwhelmingly in favor of the restructure, which was unanimously endorsed by HeartWare's Board of Directors. With final Federal Court approval received on 30 October 2008, the restructure will take effect in early November. Shareholders in HeartWare Limited will be issued with Chess Depository Interests (CDI's) in HeartWare International in exchange for their shares in HeartWare Limited. Trading in HeartWare shares will be suspended on 31 October 2008 and HeartWare CDI's will begin trading (on a deferred settlement basis) on 3 November 2008. New holding statements will be dispatched to shareholders on approximately 14 November 2008.

Following these changes, HeartWare shareholders will have the same economic interest in the HeartWare Group as they had prior to the restructure, the key difference being that such economic interest will be in the newly incorporated US parent company, HeartWare International, Inc.

While we have not committed to a timeframe for listing on a US exchange, we have previously flagged the possibility of a US listing, subject both to internal priorities and to external market considerations. The redomiciliation of the HeartWare Group buys us significant flexibility in this regard. While our shareholders retain liquidity on the ASX, we now have the ability to list on a US exchange such as NASDAQ with relatively short lead time provided that we continue to meet the listing requirements of the exchange.

Financials

Today we also released our cash flows for the quarter ended 30 September 2008. During the quarter, our operating activities associated with the achievement of the previously mentioned milestones consumed A$6.9 million. The Company's cash balance at 30 September 2008 was A$39.3 million.

We had indicated previously that the third quarter would be our highest spend given that we incurred significant non-recurring expenses for redomiciliation and also due to our need to carry the expansion costs of our US clinical trial infrastructure without the trial revenue yet flowing in earnest. As always, we will endeavor to manage our cash position judiciously and will seek to balance the expansion of our exciting pipeline of projects such as MVAD with the ramp in revenue we expect to see with US clinicals and our international launch.

Closing Comments

While HeartWare continues to make encouraging progress, external events have provided material validation of the market opportunity. In particular, Thoratec Corporation has enjoyed impressive early success with the Heartmate II following its approval in the US in April this year. Over the quarter ending 28 June 2008 and 27 September 2008, Thoratec successfully opened 43 new sites and reported a staggering 44% growth in sales in each of those quarters (as against prior year comparatives), almost entirely due to Heartmate II uptake. Our expectation has always been that the introduction of a smaller, reliable, continuous flow device that demonstrates solid clinical outcomes would lead to a significant shift in cardiologist referral patterns and sustained growth in the VAD market. Early indications are that the Heartmate II will underpin significant growth in implant numbers, both in the US and internationally. We congratulate Thoratec on their successful launch and applaud their continued market development efforts.

Our team has worked diligently over recent months as evidenced by the achievement of key regulatory, clinical and corporate objectives. We have never been as encouraged as we are today both by the results we are seeing in the clinic and by our expanding market opportunity. As always, we thank you for your continued interest in the HeartWare story.

Yours sincerely

Doug Godshall
Chief Executive Officer