

# HEARTWARE LIMITED

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Dear Shareholders

While it has been only a little over 2 months since our last quarterly review, in anticipation of my upcoming visit to Australia to meet with investors, I thought it would be appropriate to provide an update sooner than the end of the current quarter. Following is a brief review of our key activities.

## **Clinical Trial**

The new year has started out in a superb fashion in almost all respects. Most importantly, our 8 patients are all alive and none have been transplanted. We have collective experience of over 1200 implant days and the system continues to perform well.

Our projection that our third and fourth centers would be opened, trained and ready to enrol patients in January proved to be accurate. Both Hannover and Harefield Hospitals received site training in January and both were equipped with inventory. Hannover conducted their first implant in early January. Harefield continues to actively screen for patients but has yet to implant.

We indicated also that we were in discussions with a fifth investigational center. We have now received conditional ethics approval from this fifth site and have completed all site training and initiation activities. The center is now ready to begin implants, subject only to receipt of full approval by the Ethics Committee, expected later in March. We will provide specific details regarding this center once the full approval is received.

Our internal model had predicted that by this time we would have ten patients enrolled in the study rather than the eight we currently have. Although this expectation was based on a relatively conservative assumed rate of patient enrolment, our participating centers have all seen an unusually small number of patients over January and February. These lulls in patient numbers often precede a burst in activity so we do expect our rate of implants to accelerate. It is encouraging that none of the centers appear to be implanting other devices in preference to ours.



With the addition of a fifth site and the passion our centers continue to show for the HVAD™, we are still anticipating that our 20<sup>th</sup> patient will be enrolled in June.

We already have more than sufficient inventory to complete the entire 20 patient international study and we are therefore stockpiling additional units to conduct characterization studies for regulatory submissions.

### **US Regulatory Activities**

During January, Jennifer Foley took the reigns of our clinical and regulatory activities. Under her guidance, we are currently finalizing the implementation of a new database which will enable us more effectively to generate a range of detailed clinical reports required by the regulatory bodies.

By early in April, we expect to have a package in the hands of the FDA for them to review. This package will include engineering data, clinical data from our current study and a proposal for our US trial design. We will then review this proposal with the FDA during a “pre-IDE” meeting at which we will lock our US trial design. We expect that the FDA will meet with us during the second quarter, enabling us to make our IDE submission during the third quarter, which is in line with forecast.

Predicting when we will then be authorized to commence US clinical trials is more difficult since that start date depends upon FDA review times and the number of questions they have for us. However, our projection of a fourth quarter start continues to appear realistic. Our additional manufacturing capacity and the availability of multiple test devices should also help ensure that we hit our target dates.

### **Quality Systems**

We have just completed a mock audit of our quality system using a consulting group that conducts audits on behalf of European Notified bodies. We were given very high marks for both our level of preparedness and of our plan to complete the work we still need to do. Our Director of Quality, Ramon Paz, has done an exceptional job of pulling the organization forward over the past 5 months and it is encouraging to get such a positive assessment at this stage of the process. We expect to be prepared for our ISO audit before the fourth quarter of 2007 and will likely elect to have the audit performed in the third quarter.

### **Expenditure**

As at the end of December, we had \$21.1M cash on hand. We continue to scrutinize our spending and are seeking creative ways to reduce our expenses in areas which do not set us back on our development timeline. Much of our spending in the fourth quarter of 2006 was for one time activities such as training clinical sites in Harefield and Hannover and adding manufacturing



equipment. We expect that there will be fewer non-recurring expenses for the next several months leading up to the commencement of our US trial.

Lastly, we are pleased to advise that Jeff LaRose, our Chief Scientific Officer, was invited to speak at the Herz Thorax Symposium in Basel, Switzerland on the 15<sup>th</sup> of March. This is an important conference that brings together several hundred key opinion leaders in Europe, including many of our future customers. It provides a unique opportunity for us to showcase the HVAD<sup>TM</sup> system and is a testament to the great work Jeff has done over the past several years.

We thank you for your continued support of HeartWare and will continue to keep you informed of progress.

Yours sincerely

A handwritten signature in cursive script, appearing to read "D. Godshall".

Doug Godshall  
Chief Executive Officer