ASX ANNOUNCEMENT
3 September 2007

Completion of Enrolment in International Clinical Trial and Confirmation of International and US Regulatory Timelines

HeartWare is pleased to report the completion of patient enrolment in the Company's international clinical trial for the HVAD™ left ventricular assist device ("HVAD™ device"). This follows the successful implantation of the HVAD™ device in a 52 year old male patient at Vienna General Hospital in Austria on 31 August 2007. The completion of patient enrolment enables HeartWare to move forward with regulatory submissions during the fourth quarter of this year, with an expectation of commercial launch of the device in Europe early in 2008.

As previously advised, the international clinical trial for the HVAD™ device requires the HVAD™ device to be implanted in twenty patients, all suffering advanced heart failure and awaiting cardiac transplantation. Twenty patients have now been implanted with the HVAD™ device. On a cumulative basis these patients have been supported for over 3,000 days, or more than eight years. The average duration of support across the patient population exceeds 150 days per patient. Eight patients have so far passed the primary endpoint of the trial.

HeartWare remains on track to meeting key regulatory milestones both internationally and in the United States, in line with the projected timelines previously advised to the market. Having completed enrolment in the trial, we take this opportunity to reiterate our anticipated regulatory timeline and to provide further details regarding forthcoming milestones.

Regulatory Approval in Europe

Following completion of patient enrolment in the trial, the next step in the European regulatory process is a submission of our clinical trial data to a European Notified Body. The preparation of this submission, known as a "Technical Dossier", has been underway at HeartWare for some months. The submission will be progressively updated over coming weeks to incorporate data accumulated from our most recent patients. We expect to file the submission during the fourth quarter of this year.

Following the submission, we anticipate a period of dialogue between HeartWare and our notified body. On the basis of completing our submission during the fourth quarter, we anticipate being granted regulatory approval (CE marking) during the first quarter of 2008. Once CE marking is awarded, HeartWare will then be able to market and sell the HVAD™ device commercially throughout Europe and in other countries that recognize CE marking. Following receipt of CE marking, we intend also to make submissions to the Australian Therapeutic Goods Administration (TGA) for approval of the HVAD™ device in Australia.

Having completed enrolment of the required twenty patients, HeartWare does not plan to stop implants at the five centres participating in the trial. HeartWare has made a submission to the Ethics Committees at each of the five centres to increase to 30 the number of patients who can be implanted with the HVAD™ device under the clinical trial. While there is no requirement to conduct further implants, extending patient numbers and increasing the depth of clinical data will be beneficial, particularly to support our anticipated commercial release of the HVAD™ device early in 2008.

US Clinical Trial

The key milestone in HeartWare's US regulatory activities is the application to the United States Food and Drug Administration ("FDA") for an Investigational Device Exemption ("IDE"), to allow use of HeartWare's HVAD™ device in a US clinical trial.

HeartWare expects to file its IDE with the FDA in October. The FDA will ordinarily ask questions after the first submission and we anticipate there will be a round of questions prior to the granting of the IDE. We expect to gain approval from the FDA to commence our US clinical trial in late 2007 or, more likely, early 2008.

We expect to begin our US trial with the participation of five leading US cardiac transplant centres. Discussions with these centres are well advanced.

We will provide further detail regarding our US study and the participating hospitals once we have made our IDE submission in October.

Milestone Summary

The following table provides a summary of the Company's key milestones over the coming 12 months along with indicative timing for each.

Milestone	**Indicative Timing**
▪ Submission of Technical Dossier to Competent Authority	Q4 2007
▪ Extension of International Trial to allow additional implants	Q4 2007
▪ Submissions of IDE to US FDA	Q4 2007
▪ CE Marking	Q1 2008
▪ First commercial revenue (following CE marking)	Q1 / Q2 2008
▪ Commencement of US Trial	Q1 2008
▪ First US revenue (reimbursement during the clinical trial)	Q1 2008

About HeartWare

HeartWare is developing a family of proprietary circulatory assist devices to treat patients with heart failure. HeartWare's lead device, the HVAD™ device, is currently the subject of an international clinical trial. With a volume of 45cc, the HVAD™ device is a small "3rd generation" pump designed to be implanted within the thoracic cavity.

HeartWare's miniaturization platform enables the development of smaller devices, potentially implantable by minimally invasive surgical techniques. Pre-clinical studies are underway for HeartWare's MVAD™ pump, a pump one-third the size of the HVAD™ device. HeartWare's IV-VAD, a pump one-tenth the size of the HVAD™ device, is at early prototype stage.

For further information:

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