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SHAREHOLDER UPDATE
22 July 2005

Highlights

During the second quarter of 2005, HeartWare has made significant progress. We remain on track to achieve our key short-term milestone – the first human implant of the HeartWare HVAD scheduled for the first quarter of 2006.

Significant achievements over the period include:

- completion of five "GLP" pre-clinical implants of the HeartWare HVAD. These are the final implants required prior to seeking regulatory approvals to commence human clinical trials;
- commencement of life-cycle-testing for the HeartWare HVAD, a critical requirement for regulatory submissions;
- confirmation, following meetings with principal investigators at several European hospitals, of the high level of interest in participating in the HeartWare HVAD clinical trial;
- appointment of key new executives, completing our executive recruitment program; and
- further refinement of the MVAD, HeartWare's miniaturised VAD, with an expectation that pre-clinical trials will begin within the current quarter.

Over 12 Months Cumulative "GLP" Experience

In our Shareholder Update of March 2005 we indicated our intention to commence GLP studies for the HeartWare HVAD. These studies involve the implantation of a number of our heart pumps in sheep under strictly regulated Good Laboratory Practice (GLP) conditions, with each monitored closely for a period of up to 90 days following the procedure. These GLP studies are a formal requirement for human clinical trials and an important precursor to HeartWare's planned submissions to the Australian, European and US regulatory authorities.

We are pleased to advise that we have conducted five GLP studies with the HeartWare HVAD. A sixth GLP procedure will be performed next week. All procedures have been conducted at the Texas Heart Institute, one of the most prestigious cardiac research centres in the United States. We have now reached over one year of cumulative experience with the HeartWare HVAD under GLP conditions. The first two GLP studies have been electively terminated after completing the 90-day period. Early visual results indicate that the pumps performed according to design.

Extensive pathological examination will be performed at the Texas Heart Institute. Two further studies will each reach 90 days early next week.

Completion of the sixth and final GLP implant represents an important milestone in the development of the HeartWare HVAD. It is particularly gratifying that this milestone will be achieved on schedule, allowing us to maintain the overall HeartWare HVAD program. Following formal closure of the GLP study, HeartWare will make submissions to ethics committees and regulatory bodies to initiate a human clinical trial. We remain on track to commence this trial in the first quarter of 2006.

Commencement of Life Cycle Testing

We are pleased to report that life-cycle testing of the HeartWare HVAD is now underway.

In addition to the GLP study results, regulatory authorities require evidence of the long term reliability and robustness of the device. This data is demonstrated under long-term simulated real-world operating conditions. In preparation for regulatory submissions, HeartWare's engineers have developed and built a life-cycle-testing platform which runs a number of our heart pumps in parallel. The test platform is now operational and the test devices are performing well.

This is an important technical achievement and a key "critical path" component of the HeartWare HVAD development program.

Participation of European Clinical Trial Centres Confirmed

As detailed in our IPO prospectus, HeartWare plans to conduct its upcoming HVAD clinical trial with the participation of two Australian centres and up to five European centres.

During June 2005 Stuart McConchie and Jane Reedy held a series of meetings with investigators at hospitals in the UK, Germany, Austria and Italy. These meetings served to reinforce critical relationships and to reconfirm the high level of interest among leading European clinicians to take part in the trial. Five centres in Europe have committed in principle to participate.

Several LVAD companies have encountered difficulty with the rate at which trial patients can be recruited, and have suffered consequent delays in advancing their product through the clinic. The group of hospitals expected to participate in the HeartWare HVAD trials include some of the leading cardiac centres in Europe. These centres have well established LVAD implant programmes, drawing on large patient populations and have a demonstrated ability to enrol the necessary patient numbers efficiently. We remain confident that the parallel participation of these leading centres will significantly help to expedite the clinical trial process.

HeartWare has developed a trial protocol, which is currently being refined in collaboration with clinical advisers, investigators and HeartWare's Advisory Board. We expect to submit the protocol for approval by the ethics committees of participating European hospitals in the fourth quarter of 2005.

Details of the participating centres will be provided once the protocol has been adopted and formal agreements executed.

Appointment of New Executives

On 3 May 2005 HeartWare announced the appointment of Bill Rissman, Jane Reedy and Howard Leibman. With these appointments, HeartWare has completed its executive recruitment program and now has in place comprehensive management capability across all elements of the business.

Bill joins HeartWare's US Operations Centre in the role of Vice President, Manufacturing and Product Development. Bill has over 25 years of experience in medical device engineering roles, including senior operational and technical positions with market leaders Guidant, Medtronic and St Jude Medical. Bill's experience will help ensure the efficient implementation of the complex manufacturing processes required for the HeartWare devices.

Previously a consultant to HeartWare, Jane Reedy has now joined the Company full time in the role Vice President, Clinical and Marketing, also based in the US. With prior roles including Director of Clinical Services at Thoratec Corporation, Jane brings to HeartWare over 20 years of experience in clinical and regulatory affairs relating specifically to the circulatory assist industry.

Howard Leibman has joined HeartWare's Sydney office in the role Director, Corporate Development, with responsibility for HeartWare's investor relations and corporate affairs functions. Previously a corporate finance executive with eG Capital, Howard brings to HeartWare a depth of experience in the Australian capital markets.

Advances with the MVAD

HeartWare's current key focus is to finalise the pre-clinical development of the HVAD and to commence human clinical trials in the first quarter of 2006. In parallel, however, HeartWare engineers continue to advance the development of our next-generation device, the MVAD, or Miniaturised VAD. Refinement of the MVAD prototype has progressed to the point where pre-clinical testing is expected to commence within the current quarter.

The MVAD is a full-output miniaturised blood pump with the potential to be implantable by minimally invasive surgical techniques. While still at a relatively early stage of development, the device presents potentially very significant clinical and commercial opportunity by opening access to patients in an earlier stage of heart failure.

Legal Action Initiated by Ventracor

As we have advised previously, VentrAssist Pty Limited (a subsidiary of Ventracor Limited (ASX:VCR)) has filed a lawsuit in a United States District Court in Florida alleging patent infringement by HeartWare based upon HeartWare's pre-clinical activities in the United States.

HeartWare maintains that there is no basis for any such legal action in the United States at this time.

To the extent the lawsuit proceeds, HeartWare intends to vigorously defend itself and will seek a decision from the Court in Florida that Ventracor's patents are not infringed, are invalid and are unenforceable.

Summary

HeartWare continues to make significant advances towards its ultimate goal – securing a leading position in the rapidly evolving market for cardiac assist devices. The market opportunity remains compelling, with an estimated 100,000 "end stage" heart failure patients expected to be eligible for LVAD treatment each year and an attractive reimbursement regime established in the US.

HeartWare remains on track to achieve the key near term milestones outlined in our prospectus. Specifically, we continue to work towards our first clinical implant in the first quarter of 2006. With strong support from leading clinicians and hospitals around the world, we remain confident of achieving this goal.

We thank you for your support and will continue to keep you informed of developments.

Yours sincerely

Stuart McConchie
Chief Executive Officer