

HEARTWARE LIMITED

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Manager of Company Announcements
Australian Stock Exchange Limited
Level 6
20 Bridge Street
SYDNEY NSW 2000

11 October 2006
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,

As you know, I joined HeartWare as Chief Executive Officer on 18 September 2006. I am writing to introduce myself, to share my observations about the company after my first three weeks on the job and to provide an update regarding our near-term milestones.

A Quick Introduction

I have spent the past sixteen years with Boston Scientific Corporation, one of the largest medical device companies in the world. Immediately prior to joining HeartWare, I was President of the Vascular Surgery Division and a member of the Group Operating Committee.

Over the course of my career, I have spent a great deal of time analyzing medical device opportunities, comparing alternatives and optimizing business strategies. It's in this context that I took the decision to leave Boston Scientific and to take on the CEO role at HeartWare. My due diligence enquiries have been confirmed by my recent on-the-ground experience at HeartWare, and I am now more convinced than ever of this company's tremendous prospects.

Our Market Opportunity

HeartWare's technologies are aimed at addressing one of the largest unmet medical needs in the world. Heart failure is a terminal disease affecting millions, yet available treatment options remain largely inadequate. Growing clinical evidence demonstrates that mechanical assist devices, more specifically, ventricular assist devices or "VADs", are a compelling treatment option. There is increasing recognition that the introduction of advanced third-generation VADs, such as HeartWare's HVAD, will eliminate the barriers which have kept the LVAD market from expanding into a major medical device market.

The key criteria for success in the LVAD market are well accepted. The device must be gentle on the blood and must demonstrate long-term durability. In addition, the smaller the device, the less invasive the operating procedure and the lower the risk of operative or post-operative complications. Although it is still early in our clinical trial, the evidence from our first two patients continues to demonstrate that HeartWare's HVAD has the potential to satisfy the above criteria better than any other VAD in the clinic today. Our test data make us highly confident that our device durability will be second to none. Furthermore, the HVAD is the smallest of the third-generation devices and the only one that is implantable routinely above the diaphragm, two characteristics which should reduce operative time and complications.



An Update on our First Two Patients

I am pleased to report that, as of this writing, our first two patients have been supported by their HVADs cumulatively for over one year (378 days). Our first patient, implanted on 22 March, has passed the 180 day study endpoint. Our second patient is within a week of successfully reaching that endpoint. At the time of their HVAD implants, both patients were suffering from advanced heart failure and awaiting cardiac transplantation. Since their HVAD implants, both patients have seen a transformation in their quality of life. They both recovered quickly from the surgery and went home relatively soon after the procedure. No pump-related adverse events have been observed in either patient and the consistently low levels of plasma hemoglobin in both patients show that blood trauma is negligible.

Clearly, two successful patients do not constitute statistical “proof” of the clinical efficacy of the HVAD. These are, however, very strong early clinical results of the kind that, in my experience, bode well for the long-term clinical outcome of a new medical device. As we enroll more patients in the HVAD clinical trial over the coming months we hope to firmly establish the HVAD’s clinical credentials.

Our Focus over Recent Months

During the past few months, HeartWare has been transitioning from a research and development enterprise to a manufacturing operation. As a result, the company has not conducted additional clinical implants. The first stage of this transition is now largely complete.

Under the leadership of Dozier Rowe, Chief Operating Officer, we have refined our coating and polishing processes, installed and commissioned new laser welding equipment, implemented multiple improvements to our manufacturing fixtures and significantly upgraded our inspection and surface analysis capabilities. Our operations team also undertook a comprehensive review of the HVAD production process, identified and eliminated areas of risk or process variability and significantly reduced reliance on labour intensive processes. In addition, we have reviewed our third party supplier relationships and have implemented dual sourcing for certain critical components. These activities have resulted in a more robust, more consistent manufacturing capability, a substantial reduction in assembly time and improved product yields.

Also during the period, in response to patient and surgeon feedback, we have enhanced our controller and battery charger software and are introducing minor modifications to our surgical tools to even further improve their maneuverability.

Prior to my joining HeartWare as CEO, I conducted a review of the company’s manufacturing operations. My first three weeks as CEO have confirmed what my due diligence showed: HeartWare has successfully made the transition from a late-stage research and development company into an early-stage manufacturing operation. During its clinical trials and beyond, HeartWare will continue to monitor and upgrade all aspects of operations as part of our routine quality assurance program.

Resuming our Implant Program

The Vienna General Hospital has received HVAD product inventory. The surgical team in Vienna, led by Dr George Wieselthaler, is therefore now in a position to conduct a third HVAD implant as soon as a suitable patient is identified.

The Royal Perth Hospital will be our second center. Royal Perth will receive HVAD systems later this month, whereupon the cardiology and cardiac surgery teams will begin screening for suitable trial candidates.



Based on the operational improvements described above, a steady flow of clinical quality HVADs is now coming through HeartWare's Miramar manufacturing facility. We intend to open our third clinical trial center by year-end, with a fourth center coming on-line soon thereafter. During the first quarter of 2007 all four investigational centres should be actively enrolling patients in the HVAD clinical trial.

Looking Ahead

Since joining HeartWare I have completed a comprehensive review of our timelines. In light of the recent delays in our implant program, and assuming only modest enrollment rates at each center, we anticipate completing enrollment for our CE Mark study during the second quarter of 2007. This will allow for submission to the competent authority for CE marking during the third quarter of 2007. This represents a delay of approximately 3 to 6 months relative to the timelines indicated in our 2005 Annual Report.

In parallel we'll be initiating our US clinical trial. We expect to have sufficient bench and clinical data arising out of our European study to submit an Investigational Device Exemption to the US Food and Drug Administration (FDA) during the third quarter of 2007.

HeartWare will soon be in the position where the rate of enrolment into our clinical trial will depend not on our ability to supply product, but rather on the availability of suitable patients at each of our four clinical sites. Our priority in the short term remains to bring on-line all four participating non-US implant centers and to complete the enrollment of our twenty patient European and Australian study as quickly as possible.

A Final Word

Since joining HeartWare I have been struck by the depth of technical, operational and management talent within the company. I have been impressed also by the unrelenting commitment of the team to patient safety and product quality.

The foundation of what I believe will become a successful medical device company is already in place. I am excited by this opportunity and look forward to leading the company through its next stages of growth.

Thank you for your support.

Yours sincerely

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

Doug Godshall
Chief Executive Officer