

# HEARTWARE LIMITED

ABN 34 111 970 257



## QUARTERLY UPDATE 31 December 2006

Over the quarter ended 31st December, HeartWare made substantial progress across all facets of the business. Most importantly, we resolved the manufacturing challenges that had disrupted our clinical trial progress through mid 2006, enabling us to re-initiate our international HVAD™ implant program. In this period, we also opened two additional centres and completed five additional implants. We now have inventory in-house and at all participating centres and anticipate a continued acceleration in implant numbers over coming months.

### **HVAD Clinical Trial Update**

HeartWare has conducted seven implants of its HVAD™ left ventricular assist device. These include four patients at Vienna General Hospital, two at Royal Perth Hospital and one at Hanover Medical Centre. As at 31 January, these patients have been supported for a cumulative period of 948 days, or approximately 2.5 years. The first two patients are now well beyond the 180 day primary endpoint of the clinical trial, with our first patient being only weeks away from having being supported for an entire year. Patients three and four are out beyond 100 days. In all cases the procedure was completed quickly and without incident and the patients continue to experience dramatic improvements to their quality of life. In all cases the device appears to be performing exceptionally well.

As previously advised, Harefield Hospital in the UK will be the fourth centre to implant HeartWare's device. Surgical training and site initiation activities have been completed and the centre now has pump inventory on site. The Harefield cardiology team are currently screening patients and we anticipate implants to begin shortly.

Our clinical trial protocol allows up to five hospitals to participate in the trial. Discussions with our fifth centre are well advanced. Subject to a positive outcome at the forthcoming meeting of the centre's Ethics Committee, we plan to conduct surgical training and a site initiation visit in late February. This should allow implants to commence in March.

The clinical trial currently underway is aimed at achieving CE mark for the HVAD™. CE marking will allow the commercial sale of the device across various European countries. The trial requires the HVAD™ to be implanted in 20 patients, all suffering advanced heart failure and eligible for heart transplantation. The primary endpoint of the trial is patient survival, either to 180 days or to the point of receiving a heart transplant. As previously advised, HeartWare aims to complete enrolment in the trial by 30 June 2007. This will enable the Company to complete its European regulatory submissions during the third quarter of this year. With seven patients now enrolled and two additional centres expected to open this quarter, we remain confident of achieving this objective.

### **Manufacturing Update**

The Company's key priority during the quarter was continuing to upgrade its quality systems and manufacturing capabilities. These upgrades are essential for HeartWare to reliably meet the product demands of its international clinical trial, now underway. More importantly, the operational upgrades have established a robust manufacturing platform from which to scale-up production as the Company moves



towards European commercial launch and the start of a US clinical trial at the end of 2007.

The above operational activities have already led to significant improvements in manufacturing yields and product throughput. A comprehensive operational plan is in place to progressively scale production to meet clinical requirements over time. Further, the Company is no longer supply constrained in meeting the requirements of its current international trial. All participating centres have inventory on site and pump inventory at HeartWare's facility continues to build.

### **Executive Appointment**

During the quarter, Jennifer Foley accepted the position of Vice-President, Clinical and Regulatory Affairs at HeartWare. Prior to joining HeartWare, Jennifer was one of the most senior executives within Boston Scientific Corporation's clinical affairs organisation. At Boston Scientific she had overall responsibility for the execution of clinical trials across 9 of the company's divisions, with aggregate revenues of approximately US\$6 billion per year.

As HeartWare heads towards regulatory submissions and the start of a US clinical trial program, Jennifer's wealth of clinical and regulatory experience will be of enormous value to the Company. Her appointment will also allow Jane Reedy, previously responsible for both clinical affairs and marketing, to transition towards an exclusive focus on marketing activities in the lead up to the Company's European commercial launch, anticipated within approximately 12 months.

### **Product Development Activities**

The Company continues to make important advances in its next generation technologies. In January, the Company initiated a series of animal studies aimed at determining the viability of certain minimally invasive surgical implantation techniques which, if successful, may allow HeartWare's next generation miniature pump (or "MVAD") to be implanted without open-chest surgery. Previous animal studies have provided early confirmation of the viability and haemocompatibility of the pump itself. The R&D focus has therefore turned towards the development of novel implantation tools and techniques with the potential to significantly enhance the potential clinical and market advantages of the device.

The Company has also continued to focus on its Transcutaneous Energy Transfer ("TETS") technology, aimed at the development of fully implantable battery, controller and electronics systems. The TETS platform will be largely device-independent, and will be compatible with HeartWare's full product suite. Although highly prospective, this remains a relatively early stage development program.

### **Cash Reserves**

As at 31 December 2006, the Company had cash reserves of approximately A\$21.6 million.

Expenditure during the quarter rose by almost A\$1.2 million over the preceding quarter due to increased costs and expenditure associated with the recommencement of implanting in late September, our first implants at each of Royal Perth Hospital and Hanover Medical Centre and the opening of Harefield Hospital.

Further, during the quarter the Company expended almost A\$700,000 on plant and equipment related to the manufacturing activities outlined above. This is equivalent to one third of the entire year's expenditure on plant and equipment being incurred in the October to December timeframe. This expenditure is not expected to be recurring.

Further details of the Company's cash flow are set out in the attached Appendix 4C.



## Summary

We believe that the Company is now well placed to proceed expeditiously through our international clinical trial. We expect to complete enrolment in the trial by midyear and to file our European regulatory submissions during the third quarter. In addition we expect to submit our IDE to the US FDA during the third quarter and anticipate a start to our US clinical trial late this year or in early 2008.

We are fortunate to be establishing our clinical momentum at a time when the use of mechanical assist devices is gaining increasing acceptance as a viable treatment option for patients suffering advanced heart failure. Our strong clinical outcomes and our inherent size, output and implant advantages continue to reinforce the Company's potential to play a leading part in the sector as overall implant numbers begin to accelerate.

Sincerely

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

**Doug Godshall**  
**Chief Executive Officer**  
**HeartWare Limited**

# Appendix 4C

## Quarterly report for entities admitted on the basis of commitments

Introduced 31/3/2000. Amended 30/9/2001

Name of entity

**HEARTWARE LIMITED**

ABN

**34 111 970 257**

Quarter ended ("current quarter")

**31 December 2006**

### Consolidated statement of cash flows

Cash flows related to operating activities	Current quarter \$A'000	Year to date (12 months) \$A'000
1.1 Receipts from customers		
1.2 Payments for		
(a) staff costs	(2,393)	(9,631)
(b) advertising and marketing		
(c) research and development	(419)	(1,352)
(d) leased assets	(203)	(657)
(e) other working capital	(3,448)	(10,129)
1.3 Dividends received		
1.4 Interest and other items of a similar nature received	267	1,158
1.5 Interest and other costs of finance paid		
1.6 Income taxes paid		
1.7 Other (provide details if material)		
<b>Net operating cash flows</b>	<b>(6,196)</b>	<b>(20,611)</b>

+ See chapter 19 for defined terms.

**Appendix 4C**  
**Quarterly report for entities**  
**admitted on the basis of commitments**

	Current quarter \$A'000	Year to date (12 months) \$A'000
1.8 Net operating cash flows (carried forward)	<b>(6,196)</b>	<b>(20,611)</b>
<b>Cash flows related to investing activities</b>		
1.9 Payment for acquisition of:		
(a) businesses (item 5)		
(b) equity investments		
(c) intellectual property	(7)	(44)
(d) physical non-current assets	(684)	(2,199)
(e) research and development		
1.10 Proceeds from disposal of:		
(a) businesses (item 5)		
(b) equity investments		
(c) intellectual property		
(d) physical non-current assets		3
(e) other non-current assets		
1.11 Loans to other entities		
1.12 Loans repaid by other entities		
1.13 Other – cash assets acquired on acquisition of business		
<b>Net investing cash flows</b>	<b>(691)</b>	<b>(2,240)</b>
<b>1.14 Total operating and investing cash flows</b>	<b>(6,887)</b>	<b>(22,851)</b>
<b>Cash flows related to financing activities</b>		
1.15 Proceeds from issues of shares, options, etc.		32,870
1.16 Proceeds from sale of forfeited shares		
1.17 Proceeds from borrowings		
1.18 Repayment of borrowings		
1.19 Dividends paid		
1.20 Other – expenses of the issue of shares		(2,021)
<b>Net financing cash flows</b>		<b>30,849</b>
<b>Net increase (decrease) in cash held</b>	<b>(6,887)</b>	<b>7,998</b>
1.21 Cash at beginning of quarter/year to date	28,560	13,680
1.22 Exchange rate adjustments to item 1.20	(18)	(23)
<b>1.23 Cash at end of quarter</b>	<b>21,655</b>	<b>21,655</b>

+ See chapter 19 for defined terms.

**Payments to directors of the entity and associates of the directors**

**Payments to related entities of the entity and associates of the related entities**

		Current quarter \$A'000
1.24	Aggregate amount of payments to the parties included in item 1.2	197
1.25	Aggregate amount of loans to the parties included in item 1.11	
1.26	Explanation necessary for an understanding of the transactions Costs referred to at item 1.24 include directors' fees for the Board of Directors together with employment costs for the Chief Executive Officer, Mr D Godshall.	

**Non-cash financing and investing activities**

- 2.1 Details of financing and investing transactions which have had a material effect on consolidated assets and liabilities but did not involve cash flows

--

- 2.2 Details of outlays made by other entities to establish or increase their share in businesses in which the reporting entity has an interest

--

**Financing facilities available**

*Add notes as necessary for an understanding of the position. (See AASB 1026 paragraph 12.2).*

	Amount available \$A'000	Amount used \$A'000
3.1	Loan facilities	
3.2	Credit standby arrangements	

---

+ See chapter 19 for defined terms.

**Appendix 4C**  
**Quarterly report for entities**  
**admitted on the basis of commitments**

---

**Reconciliation of cash**

Reconciliation of cash at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows.		Current quarter \$A'000	Previous quarter \$A'000
4.1	Cash on hand and at bank	3,723	6,061
4.2	Deposits at call	17,932	22,499
4.3	Bank overdraft		
4.4	Other (provide details)		
<b>Total: cash at end of quarter</b> (item 1.22)		21,655	28,560

**Acquisitions and disposals of business entities**

	Acquisitions (Item 1.9(a))	Disposals (Item 1.10(a))
5.1	Name of entity	
5.2	Place of incorporation or registration	
5.3	Consideration for acquisition or disposal	
5.4	Total net assets	
5.5	Nature of business	

---

+ See chapter 19 for defined terms.

### **Compliance statement**

- 1 This statement has been prepared under accounting policies which comply with accounting standards as defined in the Corporations Act.
- 2 This statement does give a true and fair view of the matters disclosed.



Sign here: ..... Date: ..31 January 2007.....  
(Director)

Print name: Douglas Godshall.....

### **Notes**

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity wanting to disclose additional information is encouraged to do so, in a note or notes attached to this report.
2. The definitions in, and provisions of, *AASB 1026: Statement of Cash Flows* apply to this report except for the paragraphs of the Standard set out below.
  - 6.2 - reconciliation of cash flows arising from operating activities to operating profit or loss
  - 9.2 - itemised disclosure relating to acquisitions
  - 9.4 - itemised disclosure relating to disposals
  - 12.1(a) - policy for classification of cash items
  - 12.3 - disclosure of restrictions on use of cash
  - 13.1 - comparative information

---

+ See chapter 19 for defined terms.