

# HEARTWARE LIMITED

ABN 34 111 970 257



## QUARTERLY UPDATE 31 March 2007

Dear Shareholder,

I am writing to provide a brief update on some key events at HeartWare and in the broader LVAD industry over the past two months.

### **Clinical Update**

When I last wrote to you on March 13, we had completed 8 implants at 3 centers. We have now completed 13 implants at 5 centers. Since my last letter we have initiated implants at both Harefield Hospital in the United Kingdom and St. Vincent's Hospital in Sydney. Our international clinical trial protocol allows a maximum of 5 investigational centers so we will not be expanding to additional sites until we begin our US clinical trial later this year.

Given the deep ties that HeartWare has in Australia, it was particularly pleasing to welcome St Vincent's into our clinical trial. Dr's Paul Jansz and Phillip Spratt are already proving to be exceptional additions to our trial group. We look forward to a long-term close association with them and the entire staff at St. Vincent's.

St Vincent's have conducted only one implant of the HVAD™ pump to date. Some three weeks after the procedure, the patient continues to make an excellent recovery. Following his first experience with the HeartWare device on 4<sup>th</sup> April, Dr Jansz commented that the pump "marks a significant step forward in the treatment of heart failure." This remains consistently the view of all the clinicians who have implanted the HVAD™ pump.

### **Advisory Board Meeting**

During the week of 25<sup>th</sup> April, the International Society for Heart and Lung Transplantation ("ISHLT") held its annual meeting in San Francisco. The ISHLT includes over 2,200 members from 45 countries dedicated to advancing the treatment of end-stage heart and lung disease. The Society is instrumental in developing and promoting new therapeutic strategies and has been at the forefront of the rapidly evolving interest in the use of mechanical circulatory assist systems.

During the ISHLT meeting, we took the opportunity to hold a combined meeting of members of HeartWare's Medical Advisory Board and several of our clinical investigators. It was encouraging to hear the enthusiasm our investigators have for our device.

### **Regulatory Update**

As we have previously advised, HeartWare now has more than sufficient inventory of sterile pumps to complete our international clinical study. We continue to manufacture devices that we will use to support our FDA and CE submissions later this year. We have allocated some of our R&D group to testing and submission support activities. These members of our technical team are working closely with our regulatory group, together with external regulatory consultants where required



One of the core requirements for the FDA submissions is the provision of life cycle test data, demonstrating the operation of the devices in a controlled simulated environment over a period of time. We have recently successfully completed a critical 6 month test cycle involving 8 pumps during which all parameters of the devices were continually monitored and recorded. Despite now having met the FDA's life cycle test requirements, we have decided to let the test run indefinitely and to accumulate long-term data. There is no apparent reason why the pumps will ever stop running.

The balance of the testing that is required for our submission is also moving along without incident so we remain comfortable with our existing schedules.

### **LVAD Industry**

One of the most important events of the past month was the presentation of data from Thoratec's Heartmate II trial in the US. This is the first major study of a continuous flow pump and the data was extremely well received.

The primary end point of the HeartMate II study, as with the HeartWare HVAD™ study, is survival to 6 months or transplant. Thoratec reported that 75% of patients in the study successfully reached the primary end point. This is the expected approximate survival rate in this extremely sick population of patients and it is against survival data such as these that the HeartWare results will ultimately be benchmarked. Clearly it is too early in our clinical trial and we have too few patients enrolled thus far for us to make any predictions concerning survival data.

What made physicians most enthusiastic about the HeartMate II data is that the rate of complications was substantially reduced relative to Thoratec's first generation device, the HeartMate XVE. This is an extremely important development for the industry since the greatest restriction to industry growth has been the high device failure and the high complication rates associated with the first generation devices.

Some day, Thoratec will be HeartWare's competitor. Today, Thoratec is single-handedly building the market for LVAD's. We are delighted to see their success and we encourage and acknowledge their continued market development activities. Clearly, by the time HeartWare's HVAD™ device launches, in the US, the bigger the market is, the greater will be the commercial opportunity and the return for HeartWare and our shareholders. Thoratec expects to receive FDA approval for the Heartmate II by the end of 2007 so there will be a full 2 years for the market to become comfortable with a continuous flow system before we introduce our much smaller HVAD™ device.

Other companies have also announced the commencement of US trials or plans to commence US trials in the near term. We remain on track to start our US study in the fourth quarter assuming the normal regulatory review process at the FDA. Fortunately, physicians in the US appear to share the same high interest level in our product that our current investigators have shown so we expect a very positive reception when we begin our trial.

### **Corporate Update**

We have described in previous communications our intention to pursue a listing on a US stock exchange. Virtually all of our operating activities are in the US and, in time, the US will be the most important market for our products. Clearly, the US also represents by far the greatest depth of investment capital for medical technologies such as ours. It has therefore long been the Company's strategic intent at the appropriate time to issue securities in the US so as to begin to tap the vast investment potential of that market.

Early in 2007 HeartWare lost its "Foreign Private Issuer" status under US securities law and became, in all material respects, a US company with US reporting and compliance obligations. We have also



implemented the necessary additional requirements to initiate a Level II ADR program. In particular we will soon be filing our registration statement in the United States ("Form 10"), one of our key SEC documents required as a precursor to a listing of securities on a US exchange. We have also appointed Citigroup to act as Depository Bank and we will over the next 3 months implement the necessary steps to list HeartWare on the Nasdaq Exchange via a Level II ADR program.

We expect to file our Form 10 in the short term and will at that time provide our shareholders with an outline of the process and timeline towards our US listing. We see this as an important step towards accessing the US capital markets and towards establishing meaningful liquidity in the US for the benefit of all our shareholders.

Attached is our ASX Appendix 4C for the 3 months ended 31 March 2007.

Yours sincerely

A handwritten signature in black ink, appearing to read "D. 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 March 2007**

### Consolidated statement of cash flows

Cash flows related to operating activities	Current quarter \$A'000	Year to date (3 months) \$A'000
1.1 Receipts from customers		
1.2 Payments for		
(a) staff costs	(2,389)	(2,389)
(b) advertising and marketing		
(c) research and development	(245)	(245)
(d) leased assets	(269)	(269)
(e) other working capital	(2,873)	(2,873)
1.3 Dividends received		
1.4 Interest and other items of a similar nature received	322	322
1.5 Interest and other costs of finance paid	(7)	(7)
1.6 Income taxes paid		
1.7 Other (provide details if material)		
<b>Net operating cash flows</b>	<b>(5,461)</b>	<b>(5,461)</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 (3 months) \$A'000
1.8 Net operating cash flows (carried forward)	<b>(5,461)</b>	<b>(5,461)</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	(177)	(177)
(d) physical non-current assets	(408)	(408)
(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		
(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>(585)</b>	<b>(585)</b>
<b>1.14 Total operating and investing cash flows</b>	<b>(6,046)</b>	<b>(6,046)</b>
<b>Cash flows related to financing activities</b>		
1.15 Proceeds from issues of shares, options, etc.	8	8
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	-	-
<b>Net financing cash flows</b>	<b>8</b>	<b>8</b>
<b>Net increase (decrease) in cash held</b>	<b>(6,038)</b>	<b>(6,038)</b>
1.21 Cash at beginning of quarter/year to date	21,101	21,101
1.22 Exchange rate adjustments to item 1.20	(16)	(16)
<b>1.23 Cash at end of quarter</b>	<b>15,047</b>	<b>15,047</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	210,286
1.25	Aggregate amount of loans to the parties included in item 1.11	
1.26	<p>Explanation necessary for an understanding of the transactions</p> <div style="border: 1px solid black; padding: 5px;"> <p>Costs referred to at item 1.24 include directors' fees and employment costs for the Chief Executive Officer (Douglas Godshall).</p> </div>	

**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		

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**Appendix 4C**  
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**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	464	915
4.2 Deposits at call	14,583	20,186
4.3 Bank overdraft		
4.4 Other (provide details)		
<b>Total: cash at end of quarter</b> (item 1.22)	15,047	21,101

**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		

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+ 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: ....

(Director)

Date: ..30 April 2007

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

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