

# HEARTWARE LIMITED

ABN 34 111 970 257



## QUARTERLY UPDATE 31 October 2006

### Clinical trial progress

As at the 31st of October, the Company has now successfully implanted 4 patients with its HeartWare's HVAD™ left ventricular assist device. Details are as follows:

- On the 23<sup>rd</sup> of October, the cardiothoracic team at Royal Perth Hospital, led by cardiac surgeon Dr Rob Larbalestier, implanted a HVAD™ in a 37 year old male patient suffering advanced heart failure, marking its 2<sup>nd</sup> implant in less than 4 days.
- On the 19<sup>th</sup> of October and as previously advised, a 35 year old female patient suffering advanced heart failure was implanted with a HVAD™ at Royal Perth Hospital.

In each of the above cases, the procedure was completed quickly and without incident. Each of the patients has been discharged from intensive care and is recovering well from the surgery. These patients were suffering from advanced heart failure and had several other co-morbidities, making it all the more encouraging that they are doing well to date.

With 438 days of cumulative support for its 4 patients including 2 patients having passed the 180-day primary endpoint of the clinical trial, the Company is well placed as it looks to proceed expeditiously through the 20 patient requirement for CE mark approval for the HVAD™ left ventricular assist device.

HeartWare expects Hannover Medical Centre to be the 3<sup>rd</sup> site to initiate implants of the HVAD™ and Harefield Hospital in the United Kingdom is scheduled to be the 4<sup>th</sup> center. The Company has scheduled onsite training for the clinical and support staff at both Hannover and Harefield during the first week of December.

Another important development is that the Company is now contemplating opening a 5<sup>th</sup> site during the 1<sup>st</sup> quarter of 2007. This is because the Company has received significant interest from physicians following positive feedback on the Company's HVAD™ at recent scientific symposiums conducted by the Cardiovascular Research Foundation and the Cleveland Clinic. In addition, the operational improvements described in our prior letter and updated below have also provided us with sufficient product availability to support an additional site.

### Operational update

As previously advised, a large proportion of the Company's efforts over the last 6 months have been focussed on improving the Company's internal manufacturing processes and its supply chain management.



Considerable time and effort has been spent across a variety of areas within our manufacturing flow with particular attention being directed towards re-engineering long-lead time processes, building manufacturing fixtures, second-sourcing key product components and establishing more consistent production methodologies. The goal in this regard has been for the Company to transition away from a “batch process” (which is typical for a development stage company) to a “flow process” which delivers consistent and continuous product from the manufacturing line.

A secondary, but nonetheless important, focus has also been to reduce the “art” associated with making the HVAD<sup>TM</sup>. By establishing leaner, standardised processes which require significantly less “operator involvement” this is expected to generate more consistent work practices, better manufacturing outcomes and higher yields. Ultimately, this will translate into a lower cost device.

Lastly, the Company has undertaken a series of detailed collaborative reviews with several of its primary suppliers. The purpose of these reviews has been to ensure that the Company receives components and product within required specifications on a timely basis. This review has already begun to decrease product variation, improve quality and increase yield. This aspect is of fundamental importance as the Company seeks to tightly managed its inventory whilst still maintaining a continuous supply of its product. In some cases, we have elected to hold more inventory on items for which long lead times could cause us to suffer a supply shortfall.

The above is an on-going effort as part of the Company’s process improvement but the results are best evidenced by the Company’s recent successful restart to its implant program. We believe that these efforts are of the utmost importance to the Company, the real benefits of which will be felt across all elements of HeartWare’s business for some time to come.

### **Cash Reserves**

As at 30 September 2006, the Company had cash reserves of approximately \$28.5 million.

Expenditure during the quarter was approximately \$600,000 less than the preceding quarter and is well within internal expenditure forecasts on a year-to-date basis. Notably, expenditure in both the current and preceding quarter were characterised by a variety of non-recurring expenditure that was incurred for the primary purpose of improving manufacturing outputs and yields.

During the quarter, the Company acquired plant and equipment exceeding \$600,000, including purchasing a laser welder so as to assist with expediting a number of key manufacturing processes. The Company also expended additional working capital by purchasing supplementary inventory so as to “back-fill” stock in order to establish a “process flow” as discussed above. This period has also seen a small growth in headcount with the appointment of six engineers or specialists in the manufacturing and quality areas.

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



## Summary

We believe that the considerable efforts to improve the consistency of our manufacturing processes are best represented by our return to the clinic in October. What has been more encouraging than manufacturing yield improvements, cost reductions, stronger external partnerships and the like is the extremely positive feedback we are receiving from the surgeons who have implanted the HVAD<sup>TM</sup>. Both Perth and Vienna have seen our pump implanted in very ill patients who have collectively had very encouraging recoveries. By way of example, our 1<sup>st</sup> patient could hardly walk across the room before receiving the HVAD<sup>TM</sup> and now he rides his bicycle to his appointments at the clinic. This is what compels us to do everything we can to get this remarkably small pump into the hands of our physicians.

As noted above, this Quarterly Update marks the first of our forthcoming quarterly releases that are primarily focussed on keeping you informed of developments that your Company is making.

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")

**30 September 2006**

### Consolidated statement of cash flows

Cash flows related to operating activities		Current quarter \$A'000	Year to date (9 months) \$A'000
1.1	Receipts from customers		
1.2	Payments for		
	(a) staff costs	(2,863)	(7,238)
	(b) advertising and marketing		
	(c) research and development	(54)	(933)
	(d) leased assets	(170)	(454)
	(e) other working capital	(2,535)	(6,681)
1.3	Dividends received		
1.4	Interest and other items of a similar nature received	515	891
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>(5,107)</b>	<b>(14,415)</b>

+ See chapter 19 for defined terms.

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

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	Current quarter \$A'000	Year to date (9 months) \$A'000
1.8 Net operating cash flows (carried forward)	<b>(5,107)</b>	<b>(14,415)</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	(37)	(37)
(d) physical non-current assets	(617)	(1,515)
(e) research and development	(1)	(1)
1.10 Proceeds from disposal of:		
(a) businesses (item 5)		
(b) equity investments		
(c) intellectual property		
(d) physical non-current assets	-	4
(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>(655)</b>	<b>(1,549)</b>
<b>1.14 Total operating and investing cash flows</b>	<b>(5,762)</b>	<b>(15,964)</b>
<b>Cash flows related to financing activities</b>		
1.15 Proceeds from issues of shares, options, etc.	44	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>44</b>	<b>30,849</b>
<b>Net increase (decrease) in cash held</b>	<b>(5,718)</b>	<b>14,885</b>
1.21 Cash at beginning of quarter/year to date	34,279	13,680
1.22 Exchange rate adjustments to item 1.20	(1)	(5)
<b>1.23 Cash at end of quarter</b>	<b>28,560</b>	<b>28,560</b>

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+ 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	787
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 and employment costs for the former Chief Executive Officer (Stuart McConchie), together with separation costs for Mr McConchie of approximately \$470,000.	

**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

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- 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

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**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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**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	6,061	7,372
4.2	Deposits at call	22,499	26,907
4.3	Bank overdraft		
4.4	Other (provide details)		
<b>Total: cash at end of quarter</b> (item 1.22)		28,560	34,279

**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:

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(Director)

Date: ..31 October 2006

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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