

# HEARTWARE LIMITED

ABN 34 111 970 257



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31 January 2008

Dear Shareholder

In accordance with the ASX Listing Rules, attached is HeartWare's Cash Flow Statement for the 3 and 12 months ended 31 December 2007 (see attached ASX Appendix 4C).

HeartWare's primary focus of late has been the preparation, submission and follow-up with the US Food and Drug Administration ("FDA") regarding our application for an Investigational Device Exemption ("IDE"). As previously advised, HeartWare filed its submission with the FDA late in 2007 and we received a response from the FDA soon thereafter, including a series of questions relating to our application. Since then, we have had multiple productive and detailed communications with the FDA that led us to modify our US clinical trial protocol in a manner which we believe will be an appreciable upgrade in comparison to the way Bridge-to-Transplant trials have historically been structured in the United States. We also expect that investigator interest in the study design itself will be very high and that this will complement the extraordinarily high level of interest they continue to express for the HeartWare<sup>®</sup> LVAD.

A first quarter approval of our IDE remains our expectation but we are reluctant to forecast when the FDA will "approve" our IDE since it is difficult to predict exactly when their questions will be fully addressed. That said, we are very impressed by the collaborative, thorough approach the FDA has been taking with our submissions and live discussions which we believe bodes well for the near and long term prospects for the Company.

In anticipation of a start to our US clinical trial, we have selected and are close to finalizing our initial US investigators. We are also building product inventory designated specifically for US implants such that, upon receipt of the IDE, we will be in a position to begin the trial and to scale up implant numbers relatively quickly. Our current pump production has been ramping very nicely and this will enable us to open each trial site whenever they receive their approvals to start implanting. We look forward to providing details regarding our centers and clinical trial design following receipt of our IDE.

We have previously advised that we expect to receive CE Marking for the HeartWare<sup>®</sup> device during the second quarter of this year. We remain confident that this timing is realistic.

Finally, our international clinical trial continues to progress well. The objective of the international trial is for 70% of patients to reach the primary endpoint - heart transplantation or survival to 180 days supported by the HeartWare<sup>®</sup> LVAD. To date, 27 patients have been implanted with the HeartWare<sup>®</sup> LVAD. Of these, 16 have now passed the primary endpoint. Six patients have received transplants (at 425, 348, 157, 402, 195 and 176 days respectively) and one has had his device successfully explanted after 268 days of support. Two patients died within the first 180 days. The cumulative



period of support on the device is approximately 5,550 days, equating to over 15 years. The average duration of support stands at 206 days per patient.

I look forward to providing updates regarding both the IDE and CE Marking processes in the near term.

Yours sincerely

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

**Doug Godshall**  
Chief Executive Officer

# 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 2007**

### 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	(3,048)	(10,026)
	(b) advertising and marketing		
	(c) research and development	(92)	(583)
	(d) leased assets	(214)	(919)
	(e) other working capital	(2,454)	(12,308)
1.3	Dividends received		
1.4	Interest and other items of a similar nature received	300	1,085
1.5	Interest and other costs of finance paid	(1)	(1)
1.6	Income taxes paid		
1.7	Other (provide details if material)		
	<b>Net operating cash flows</b>	<b>(5,509)</b>	<b>(22,752)</b>

+ See chapter 19 for defined terms.

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**Quarterly report for entities**  
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	Current quarter \$A'000	Year to date (12 months) \$A'000
1.8 Net operating cash flows (carried forward)	<b>(5,509)</b>	<b>(22,752)</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	(73)	(265)
(d) physical non-current assets	(277)	(909)
(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	10	10
(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>(340)</b>	<b>(1,164)</b>
<b>1.14 Total operating and investing cash flows</b>	<b>(5,849)</b>	<b>(23,916)</b>
<b>Cash flows related to financing activities</b>		
1.15 Proceeds from issues of shares, options, etc.	17	37,051
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		(2,077)
<b>Net financing cash flows</b>	<b>17</b>	<b>34,974</b>
<b>Net increase (decrease) in cash held</b>	<b>(5,832)</b>	<b>11,058</b>
1.21 Cash at beginning of quarter/year to date	37,905	21,102
1.22 Exchange rate adjustments to item 1.20	2	(85)
<b>1.23 Cash at end of quarter</b>	<b>32,075</b>	<b>32,075</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	\$280
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 Chief Executive Officer (Douglas 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

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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	1,159	20,487
4.2	Deposits at call	30,916	17,417
4.3	Bank overdraft		
4.4	Other (provide details)		1
<b>Total: cash at end of quarter</b> (item 1.22)		32,075	37,905

**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: ..31 January 2008

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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