

# HEARTWARE LIMITED

ABN 34 111 970 257



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

31 January 2006  
**BY E-LODGE MENT**

Dear Sir / Madam

## **Appendix 4C**

Please see the attached Appendix 4C for the quarter and year ended 31 December 2005.

Yours faithfully

A handwritten signature in black ink, appearing to read "Stuart McConchie".

**Stuart McConchie**  
**Chief Executive Officer**



**HEARTWARE LIMITED**  
**QUARTERLY & ANNUAL REPORT**  
**For the 12 months ended 31 December 2005**

The Board of Directors of HeartWare Limited (“HeartWare” or “the Company”) is pleased to advise of the Company’s key activities during 2005 and the achievements which have underpinned the Company’s progress through the year.

**Post Year-End Achievements**

*Regulatory Approval in Europe*

The culmination of HeartWare’s extensive pre-clinical work through 2005 was the receipt, in the final week of December, of regulatory approval to commence human clinical implants. The approval was received from the Austrian Ministry of Health, following receipt of Ethics Approval from the Vienna General Hospital. The Vienna General, associated with the University of Vienna, is among the world’s leading centres for device-based treatment of cardiac failure. The implant program in Austria will be led by Dr Georg Wieselthaler, the Clinical Director of Mechanical Circulatory Support at the Vienna General Hospital, and a member of HeartWare’s Medical Advisory Board.

HeartWare’s Ethics Committee submissions to hospitals in the UK and Germany will be reviewed in February and March. The Company anticipates receiving further regulatory approvals in these countries before the end of the current quarter. HeartWare remains confident of conducting its first human implant before the end of March 2006.



### *Surgical Training*

During the week commencing 16 January 2006, HeartWare conducted a formal training program for surgeons participating in the first phase of the Company's human clinical trial. The training was conducted at the Texas Heart Institute, recognised as one of the premiere cardiac surgery centres in the USA. The training was led by Professor O. Howard "Bud" Frazier, Chief of Transplant Services, who is also Chairman of HeartWare's Medical Advisory Board.

The training sessions were attended by the surgical teams from four participating hospitals – Royal Perth Hospital (Australia), the Vienna General Hospital (Austria), Hannover Medical School (Germany) and Harefield Hospital (UK). Subject to the relevant country regulatory approvals, these four centres will be the first to begin enrolling patients in HeartWare's CE mark trial for the HVAD. Through the course of the trial, these hospitals may be joined by additional centres.

### **Highlights of 2005**

#### *Capital Raising and Initial Public Offer*

On 31 January 2005, HeartWare began trading on the ASX, having raised A\$32.4 million (excluding issue costs) in its first ever issue of public stock.

Prior to the Company's Australian IPO, HeartWare had been funded by venture capital and private equity, with approximately A\$46 million invested over a period of some 8 years. Apple Tree Partners, the majority shareholder at the time of the listing, increased its investment at the time of the IPO and remains the cornerstone shareholder in the Company.

#### *Start of Animal Trials for the MVAD*

HeartWare's lead device, the HVAD, is the smallest "third generation" pump in development. Size is recognised as an important determinant of the clinical performance of an LVAD. Smaller pumps facilitate significantly less complex and less invasive operating procedures.



HeartWare's "next generation" device, the MVAD (or miniaturised VAD), is a full cardiac output axial flow pump with a fully suspended impeller system and a volume approximately one tenth that of the HVAD. With the possibility of human implantation by less invasive surgical techniques, the MVAD represents significant long term commercial potential for the Company.

During 2005, HeartWare accelerated its MVAD development program and successfully commenced animal studies for the device. Early testing of MVAD prototypes is yielding positive results, and a series of longer term chronic animal implants is planned for 2006. First human implants are expected within approximately two years.

#### *Resolution of Legal Dispute with Ventracor*

On 21 December 2004, within a week of HeartWare lodging its prospectus, Ventracor initiated a legal action against HeartWare's US subsidiary, alleging infringement of two of Ventracor's US patents.

Subsequently, in August 2005, HeartWare filed a comprehensive defence to the action along with a series of counterclaims. Relatively soon thereafter, on 19 October 2005, HeartWare and Ventracor jointly announced that negotiations were underway and, on 10 November 2005, the two companies announced that they had settled the dispute between their respective entities. The settlement took the form of a "covenant not to sue", with no royalty or monetary consideration payable.

The dispute was settled without excessive cost and, more importantly, without compromising HeartWare's timelines.

#### *Consolidation of Medical Advisory Board*

HeartWare draws on the expertise of a highly qualified group of eight clinicians, including both cardiac surgeons and heart failure cardiologists. This Medical Advisory Board is chaired by Professor O. Howard "Bud" Frazier, Chief of Transplant Services at the Texas Heart Institute, who is credited with having performed more VAD implants than any other surgeon.



In September HeartWare announced the appointment to the Advisory Board of Professor Gerry O’Driscoll, Medical Head of West Australian Advanced Heart Failure and Cardiac Transplant Services. With Australia expected to play an important role in HeartWare’s forthcoming clinical trial, Professor O’Driscoll’s appointment brings to HeartWare an important “local” clinical perspective.

We have also received confirmation that Mr. Asghar Khaghani, Consultant Cardiac Surgeon at the Royal Brompton and Harefield Hospital Trust in the United Kingdom, will join the HeartWare Medical Advisory Board. Mr. Khaghani is in charge of the cardiac transplantation and mechanical circulatory assist programs at Harefield Hospital and has extensive experience in LVAD implantations. He has participated in a number of clinical studies for a range of circulatory assist devices. HeartWare is very pleased to have Mr. Khaghani as a member of the Medical Advisory Board.

#### *Completion of GLP Animal Studies*

In early 2005 HeartWare commenced its final series of animal studies for the HVAD, conducted at the Texas Heart Institute under “Good Laboratory Practice” (or “GLP”) conditions. The study required the implanting of the device in a minimum of 6 sheep, each for a period of 90 days. Data from the GLP study forms the core component of submissions made to various regulatory authorities around the world for HeartWare to commence human implants.

HeartWare successfully completed the study in October 2005. Pathological analysis conducted by the Texas Heart Institute confirmed that the device performed as expected during the period of implantation. Levels of haemolysis (blood damage) were minimal, and there was no evidence of pump related thrombogenesis (blood clotting). The study was conducted without the use of anti-coagulants other than at the time of surgery, making the performance of the HVAD all the more encouraging.

Upon completion of the study, HeartWare convened a “formal” meeting of the Medical Advisory Board to review the GLP data. Following this review, the Medical Advisory Board provided a strong endorsement of the Company’s decision to progress the HVAD to the clinic in early 2006.



## *Summary*

HeartWare has met or exceeded all objectives set out in the Company's prospectus of 17 December 2004. This has been achieved within budget, and expenditure for the period has been well within the proposed Use of Funds as detailed in that document.

With the completion of all pre-clinical activity for its lead device, HeartWare is now on the verge of the most important milestone in its history – the first human implant of the HVAD. We remain confident of a successful start to our implant program and look forward in 2006 to another year of significant progress and growth.

## **Cash Reserves**

HeartWare had cash reserves of approximately A\$13.8 million as at 31 December 2005.

During the reporting period ended 31 December 2005, HeartWare took further steps towards its goal of commercializing its range of heart pumps and, to this end, expended funds in the areas of product development and testing, pre-production, life cycle testing and development of the physiological control algorithm and external accessories.

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

A handwritten signature in black ink, appearing to read "Stuart McConchie".

**Stuart McConchie**  
**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 2005**

### 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	(1,544)	(5,180)
(b) advertising and marketing		
(c) research and development	(80)	(282)
(d) leased assets		
(e) other working capital	(1,219)	(6,646)
1.3 Dividends received		
1.4 Interest and other items of a similar nature received	222	832
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>(2,621)</b>	<b>(11,276)</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>(2,621)</b>	<b>(11,276)</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	(117)	(274)
(d) physical non-current assets	(438)	(1,865)
(e) research and development	(649)	(2,730)
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	-	163
<b>Net investing cash flows</b>	<b>(1,204)</b>	<b>(4,706)</b>
<b>1.14 Total operating and investing cash flows</b>	<b>(3,825)</b>	<b>(15,982)</b>
<b>Cash flows related to financing activities</b>		
1.15 Proceeds from issues of shares, options, etc.	51	32,500
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		(2,680)
<b>Net financing cash flows</b>	<b>51</b>	<b>29,820</b>
<b>Net increase (decrease) in cash held</b>	<b>(3,774)</b>	<b>13,838</b>
1.21 Cash at beginning of quarter/year to date	17,612	-
1.22 Exchange rate adjustments to item 1.20	-	-
<b>1.23 Cash at end of quarter</b>	<b>13,838</b>	<b>13,838</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	233
1.25	Aggregate amount of loans to the parties included in item 1.11	
1.26	<p><u>Explanation necessary for an understanding of the transactions</u>            Costs referred to at item 1.24 include directors' fees, together with employment costs in relation to the Chief Executive Officer.</p>	

**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

HeartWare Limited acquired HeartWare, Inc. on 24 January 2005. The consideration for the acquisition was A\$44 million which was payable by way of the issue of 88 million ordinary shares in HeartWare Limited, together with a convertible note to the value of A\$1.42 million.

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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+ See chapter 19 for defined terms.

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

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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	11,106	671
4.2	Deposits at call	2,732	16,941
4.3	Bank overdraft		
4.4	Other (provide details)		
<b>Total: cash at end of quarter</b> (item 1.22)		13,838	17,612

**Acquisitions and disposals of business entities**

		Acquisitions (Item 1.9(a))	Disposals (Item 1.10(a))
5.1	Name of entity	HeartWare, Inc.	
5.2	Place of incorporation or registration	Delaware, United States of America	
5.3	Consideration for acquisition or disposal	A\$44 million, payable by the issue of 88 million ordinary shares in HeartWare Limited, together with a convertible note to the value of A\$1.42 million.	
5.4	Total net assets	A\$9.9 million	
5.5	Nature of business	Development of circulatory assist devices ("heart pumps")	

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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)

31 January 2006  
Date: .....

Print name: Stuart McConchie.....

**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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+ See chapter 19 for defined terms.