

# HEARTWARE LIMITED

ABN 34 111 970 257



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Manager of Company Announcements  
ASX Limited  
Level 6  
20 Bridge Street  
SYDNEY NSW 2000

29 February 2008  
**BY E-LODGEMENT**

Dear Sir / Madam

## **ASX Appendix 4E**

Please see the attached ASX Appendix 4E.

The 2007 Annual Financial Report & Directors' Report will also be filed with the ASX today.

Yours faithfully

**David McIntyre**  
**Chief Financial Officer &**  
**Company Secretary**



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## **RESULTS FOR ANNOUNCEMENT TO THE MARKET**

### **ASX Appendix 4E Preliminary Final Report For the 12 Months Ended 31 December 2007**

This is the Preliminary Final Report for the HeartWare Group.  
The HeartWare Group includes HeartWare Limited (ASX: HTW) and its subsidiary, HeartWare, Inc..

This Preliminary Final Report does not include all of the commentary, notes and information that are typically found in an annual financial report. The Annual Financial Report for the HeartWare Group for the year ended 31 December 2007 has been audited and will be lodged with ASX on or before 29 February 2008.

This Preliminary Final Report is provided to ASX pursuant to ASX Listing Rules 4.3A. It provides information as required by Appendix 4E of the ASX Listing Rules.



**HEARTWARE LIMITED (ABN 34 111 970 257)  
& CONTROLLED ENTITIES  
FINANCIAL RESULTS FOR YEAR ENDED 31 DECEMBER 2007**

***Results for Announcement to the Market***

	Year Ended 31 December 2007 \$	Year Ended 31 December 2006 \$	Percentage Change %
<b>Revenues from ordinary activities</b>	1,150,040	1,143,912	Up 0.5%
<b>Profit / (Loss) before interest, tax, depreciation and amortisation attributable to members ("EBITDA")</b>	(26,685,336)	(23,618,065)	Up 13.0%
<b>Profit / (Loss) before interest and tax attributable to members ("EBIT")</b>	(27,496,217)	(24,364,886)	Up 12.9%
<b>Income Tax Benefit</b>	-	-	-
<b>Profit / (Loss) after tax attributable to members ("NPAT")</b>	(26,376,647)	(23,250,653)	Up 13.4%
<b>Net Profit / (Loss) for the year attributable to members</b>	(26,376,647)	(23,250,653)	Up 13.4%
<b>Net tangible assets per ordinary share (cents)</b>	14.52	13.43	Up 8.1%

The Directors do not recommend that a dividend relating to the year ended 31 December 2007 be paid. As such, there is no franking or applicable record date.

***Commentary to the Earnings Result***

During the year the HeartWare Group continued to commercialise the HeartWare® LVAD System, the first of its range of circulatory assist devices or "heart pumps", which are used for the treatment of congestive heart failure. 2007 was also a pivotal year for the Company as it completed enrolment of its 20-patient clinical trial, lodged an application with the United States Food & Drug Administration with a view to commencing its bridge-to-transplant clinical trials in the United States, conducted additional research and development on its future range of products including ongoing cannulation studies for its miniaturised ventricular assist device or "MVAD", as well as further development work on the intravascular pump or "IV VAD" and the fully implantable electronics system (i.e. transcutaneous energy transfer system ("TETS")).

Accordingly, the net loss of the HeartWare Group for the year ended 31 December 2007 after providing for income tax was \$26,113,807 (2006: \$23,250,653). The increase in the loss over the preceding year reflects the expansion of the Company's international clinical trials, progress towards the commencement of its US clinical trials and early-stage manufacturing development.



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& CONTROLLED ENTITIES  
FINANCIAL RESULTS FOR YEAR ENDED 31 DECEMBER 2007**

***Commentary to the Earnings Result (Continued)***

Total revenue for the year was \$1,150,040 (2006: \$1,143,912). Revenue comprises interest revenue only. The Company has no sales revenue as it has not received regulatory approval that permits sales of its heart pumps. Sales of the HeartWare® LVAD System are expected to commence during the first half of 2008.

***Management Discussion & Analysis***

Overview

The 2007 calendar year has seen HeartWare achieve some of its most important milestones to date, namely the completion of enrolment in its 20-patient international clinical trial and the lodgement of an investigational device exemption (“IDE”) with the US Food and Drug Administration (“FDA”) to commence a bridge-to-transplant clinical trial in the United States.

Undoubtedly, the key event for 2007 was the Company lodging a submission with the United States Food & Drug Administration seeking an IDE for the proposed use of the HeartWare® LVAD System in a Bridge-to-Transplant indication in the United States on 1 November 2007. The purpose of the proposed study is to evaluate the safety and effectiveness of the HeartWare® LVAD System in the United States in patients eligible for cardiac transplantation with refractory, advanced heart failure. The proposed primary endpoint is survival to anaesthetic induction for heart transplantation or survival to 180 days on the device and listed for heart transplantation, whichever occurs first. The initial phase of the US clinical trial comprises thirty (30) patients implanted with the HeartWare® LVAD System at up to ten (10) clinical centres in the United States, the ultimate objective of which is for the Company to secure regulatory approval to sell its HeartWare® LVAD System in the United States of America. As at the date of this report, we have not yet received final approval from the FDA to commence our US clinical trial. Receipt of FDA approval in this regard is critical as it will mark the commencement of first revenues for the Company as the Company expects to be reimbursed during the course of its US clinical trial.

As at the date of this report, HeartWare has implanted thirty (30) patients across its five (5) international clinical centres, with more than 6,050 accumulative implant days, or approximately 16.5 years of patient data. Eighteen (18) of our first twenty (20) patients have reached successful completion of the 180-day primary endpoint, with sixteen (16) of these eighteen (18) patients also having been supported on the HeartWare® LVAD System for a period exceeding 180-days. Though early in the study, we have had encouraging clinical outcomes and very positive surgeon review.

The Company also further developed and stabilized its manufacturing processes, particularly towards the end of 2007 with the result that the Company is now in a position to easily meet the needs of the commencement of the US clinical trial.

The Company has opened 2008 with sufficient quantities of its products, a stable manufacturing environment and with strong clinical results. These are excellent foundations for the Company as it looks forward to the commencement of US clinical trials and, importantly, “first revenue”.

Financials

HeartWare’s cash reserves as at 31 December 2007 were \$32.1 million (2006: \$21.1 million).

Expenditure grew significantly during 2007 as the Company transformed itself from a focus on product development to one that is focussed on both clinical trials and developing more substantive manufacturing processes. The Company expanded its clinical trials in both Europe and Australia, further advanced its product pipeline through additional research and development, and expects to shortly commence clinical trials in the United States for the HeartWare® LVAD System.



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FINANCIAL RESULTS FOR YEAR ENDED 31 DECEMBER 2007**

***Management Discussion & Analysis (Continued)***

The growth of the Company is reflected in the increase in head count from 65 employees to 76 employees, with a parallel increase in annual employee entitlements costs to \$10.4 million (2006: \$10 million).

Other notable increases in costs include additional clinical and regulatory consulting costs totalling \$2.2 million (2006: \$1.6 million) incurred in consequence of the commencement of our international clinical trials. The Company also expends all product used for its international clinical trials. Product costs have not been capitalized in the Balance Sheet because this is not permitted under applicable Australian accounting standards as we do not have regulatory approval and therefore do not hold product "for sale". These costs are included in the Income Statement in the line item titled "Raw materials and consumables used". The Company expects to revisit this issue in early 2008 following the commencement of first revenue with the first US human implant and subject to satisfaction of relevant regulatory hurdles.

Other non-operating expenses included in this year's loss are the share-based payments expense of \$2.8 million (2006: \$1.2 million), together with amortization and depreciation expense of \$0.8 million (2006: \$0.8 million).

\* \* \* \* \*

Please find attached the Company's 2007 Annual Financial Report & Directors' Report for the year ended 31 December 2007, together with the Income Statement, Balance Sheet and Statement of Cash Flows and other relevant commentary thereto.

A handwritten signature in blue ink, appearing to read "Rob Thomas".

**Rob Thomas**  
**Chairman**  
29 February 2008