



HEARTWARE LIMITED

ABN 34 111 970 257

Half-Year Report for the period ended 30 June 2008 provided pursuant to ASX Listing Rule 4.2A.

This is the Half-Year Report and Interim Financial Report for the HeartWare Group. The HeartWare Group includes HeartWare Limited (ASX : HTW) and its subsidiary, HeartWare, Inc..

This Half-Year Report does not include all of the commentary, notes and information that are typically found in an annual financial report. Accordingly, this Half-Year Report should be read in conjunction with any public announcements made by the Company during the half-year in accordance with any continuous disclosure obligations arising under the *Corporations Act 2001*.

This Half-Year Report provides information as required by Appendix 4D of the ASX Listing Rules.



HeartWare Limited (ABN 34 111 970 257)

Results for Announcement to the Market

Important information concerning the financial results for the half-year ended 30 June 2008

The financial results set out in this Half-Year Report and the attached Interim Financial Report are the consolidated financial results for the HeartWare Group, being HeartWare Limited (“HeartWare” or “the Company”) and its subsidiary, HeartWare, Inc.

The Interim Financial Report has been prepared under Australian Accounting Standards. All figures (“\$”) referred to in this Half-Year Report and the Interim Financial Report are denominated in Australian dollars.

Review of Operations and Earnings Results for the Half-Year Ended 30 June 2008

The net loss of the HeartWare Group for the half-year ended 30 June 2008 after providing for income tax was \$16,405,289 (2007: \$13,633,357). The result reflects increased expenditure by the Company relating to the expansion of the Company’s clinical trial and in connection with the commercialisation of its range of circulatory assist devices or “heart pumps”, which are used for the treatment of congestive heart failure.

	Half-Year Ended 30 June 2008 \$	Half-Year Ended 30 June 2007 \$	Percentage Increase / (Decrease) %
Sales revenues	-	-	-
Profit / (Loss) before interest, tax, depreciation and amortisation (“EBITDA”)	(16,609,529)	(13,602,471)	22%
Profit / (Loss) before interest and tax (“EBIT”)	(17,016,695)	(14,033,052)	21%
Income tax benefit	-	-	-
Net Profit / (Loss) attributable to members (“NPAT”)	(16,405,289)	(13,633,357)	20%
Net tangible assets per ordinary share (cents per share)	6.65	4.98	34%



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Results for Announcement to the Market (Continued)

A summary of significant achievements for the half-year ended 30 June 2008 is set out below:

(a) Clinical Trial Update

Completion of Enrolment for International Clinical Trial

HeartWare continued its international human clinical trial during 2008 for its lead product, the HeartWare® LVAD System and has been approved to extend enrolment in the trial to 50 patients. As at 12 August 2008, 41 patients have been implanted with the HeartWare® Left Ventricular Assist System (“LVAS”). On a cumulative basis the HeartWare patients have now been supported by the device for over 9,700 days. Twenty six patients have passed the primary clinical endpoint for the trial. Our two longest supported patients to date both exceed 550 days.

Presentation of Initial Clinical Results

On 14 April 2008, Dr Georg Wieselthaler, cardiothoracic surgeon at Vienna General Hospital, presented the initial results from our international clinical trial of the HeartWare® LVAS at the annual meeting of the International Society for Heart and Lung Transplantation (“ISHLT”) held in the United States. The data presented showed a 6-month survival rate of 91% among the first 23 patients implanted with the HeartWare® device. Of the 23 patients, 21 met the primary end point of the trial, defined as survival to 180 days or transplantation. These included 19 patients who were supported by the HeartWare® LVAS at 180 days and 2 patients that received transplants after 157 days and 176 days respectively.

(b) Regulatory Update

HeartWare continues to pursue two parallel regulatory tracks. The first relates to our international (non US) opportunity and the pursuit of CE marking. The immediate major milestone in relation to our international regulatory timeline is the submission of our technical dossier to our Notified Body in Europe which is expected during the current quarter.

Subject to the time required for the regulatory authorities to process our application, we remain confident of being awarded CE marking for the HeartWare® LVAS towards the end of 2008. Following receipt of CE marking, HeartWare will be able to market and sell the device throughout Europe and in certain other jurisdictions where CE marking is recognized.

The more extensive regulatory process is that relating to our US clinical trial. HeartWare has allocated significant resources in 2008 to our US Investigational Device Exemption (“IDE”) submission and on 5 May 2008 we received conditional approval of our application. We continue to work towards resolving the few remaining conditions so that we can achieve full IDE approval.

Our US study is a pivotal trial, and therefore does not include a feasibility or pilot phase, requires the enrolment of 150 patients across a maximum of 28 centres. The primary endpoint is survival to 180 days and is defined to include patients who have received a heart transplant, patients who remain alive and supported by the device at 180 days, and recovery patients who have survived for a minimum of 60 days following the explants of their device. Patients are not required to be listed for transplant at 180 days in order to be considered a success.

In anticipation of final approval of our IDE we have 5 sites trained and expect additional sites to be trained over the ensuing months. We expect to begin US implants shortly.



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Results for Announcement to the Market (Continued)

We believe the HeartWare LVAS will be eligible for US Centers for Medicare & Medicaid Services ("CMS") reimbursement and as a result the US clinical trial will generate initial revenue for HeartWare.

(c) Manufacturing Update

We anticipate a significant increase in demand once we begin our US clinical trial and once we initiate European commercial sales. Our operations team has been steadily scaling our production capability throughout this year so as to be prepared for this expected increased volume within the next 6 or so months.

In April 2008 we secured a new manufacturing facility in Miami Lakes, Florida in the US. The new facility has ample manufacturing capability for our current and projected needs and should serve us well for the foreseeable future. The new facility includes three clean rooms all of which are ISO Class 100,000 compliant.

The relocation to the new facility is expected to be completed soon.

(d) Capital Raising

The Company is presently in a strong financial position having completed a significant equity financing in July 2008, raising approximately \$31.1 million from institutional and sophisticated investors in the United States and Australia.

The proceeds of the capital raising are to be used to fund the further development and commercialisation of the HeartWare® LVAS and to advance the Company's MVAD™ pump program. The funds will allow HeartWare to complete its current European clinical trial and to make significant inroads into its US clinical trial program. The funding will also be applied to scaling up HeartWare's manufacturing capability in order to meet the clinical demand anticipated for the HeartWare® LVAS throughout 2008.

Financial Statements

The Company's Interim Financial Report for the period ended 30 June 2008 is attached.

Cash Flow

As at the end of the half-year, the Company has cash reserves of approximately \$16,069,977.

The attached Interim Financial Results do not include the funds held by our third party escrow agent in relation to the above mentioned capital raising as of 30 June 2008. This is because the Company did not have control over the initial funds received and the capital raising required shareholder approval which was not obtained until 11 July 2008, which was after the 30 June 2008 reporting date for the Interim Financial Report. Following the receipt of shareholder approval, the Company has cash reserves of approximately \$42.6 million (as at 31 July 2008).

During the half-year, HeartWare took further steps towards its goals of commercialisation of its range of circulatory assist devices and, to this end, expended funds in a variety of areas including clinical trial costs, product development and testing, pre-production, research and development. Expenditure increased significantly during the half-year, in large part due to significant increased costs associated with progress towards the receipt of various regulatory approvals in the United States and Europe.



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Results for Announcement to the Market (Continued)

Dividends

The *Corporations Act 2001* prohibits the Company from declaring a dividend until such time as it has achieved sufficient profits to support such a dividend. The Directors are therefore unable to, and do not, recommend that a dividend relating to the half-year ended 30 June 2008 be declared or paid by the Company.

Earnings Per Share (EPS)

	30 June 2008	30 June 2007
	Cents	Cents
Basic and diluted earnings/(loss) per share (cents per share)	(0.07)	(0.07)
Weighted average number of ordinary shares used in the calculation of basic earnings per share	248,100,277	186,299,282

The amount used as the numerator in calculating basic and diluted EPS (for 30 June 2008) is the NPAT figure reported in the section entitled "Review of Operations and Earnings Result for the Half-Year Ended 30 June 2008" above.



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Results for Announcement to the Market (Continued)

Segment Reporting

The consolidated entity operates in the medical devices sector and conducts integrated operations in the United States of America and Australia. The HeartWare Group is developing and commercialising its range of circulatory assist devices or “heart pumps” which are used for the treatment of congestive heart failure. The Company does not yet have regulatory approvals so as to permit it to sell its products into the global market. Segment results are set out in the attached Interim Financial Report.

Compliance Statement

The attached Interim Financial Report is not subject to dispute or qualification. This Half-Year Report is based on the Interim Financial Report that has been subject to review. HeartWare has a formally constituted audit committee.

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

**Rob Thomas
Chairman
HeartWare Limited**

Date: 13 August 2008