



HEARTWARE LIMITED

ABN 34 111 970 257

Half-Year Report for the period ended 30 June 2007 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 2007

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 2007

The net loss of the HeartWare Group for the half-year ended 30 June 2007 after providing for income tax was \$13,633,357 (2006: \$9,474,879). 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 2007 \$	Half-Year Ended 30 June 2006 \$	Percentage Increase / (Decrease) %
Sales revenues	-	-	-
Profit / (Loss) before interest, tax, depreciation and amortisation (“EBITDA”)	(13,602,471)	(9,485,473)	43%
Profit / (Loss) before interest and tax (“EBIT”)	(14,033,052)	(9,836,615)	43%
Income tax benefit	-	-	-
Net Profit / (Loss) attributable to members (“NPAT”)	(13,633,357)	(9,474,879)	44%
Net tangible assets per ordinary share (cents per share)	4.98	11.56	(57%)

A summary of significant achievements for the half-year ended 30 June 2007 is set out below:

(a) Clinical Trial Update

Completion of Enrolment for International Clinical Trial

HeartWare continued its human clinical trials during 2007 for its lead product, the HVAD™ Left Ventricular Assist Device (“HVAD™ pump”). As at 29 August 2007, 19 patients have been implanted



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Results for Announcement to the Market (Continued)

with the HVAD™ pump. On a cumulative basis the HeartWare patients have now been supported by the device for over 3,000 days. 8 patients have passed the primary clinical endpoint for the trial and the average days of support per patient on the HVAD™ pump exceeds 150 days.

HeartWare expects to complete enrolment of its international clinical trial within days.

First “Bridge to Recovery” Patient

In July, Royal Perth Hospital became our first centre to demonstrate the potential of the HVAD™ pump to be used as a “bridge to recovery” device. On 18 July, the surgical team at Royal Perth Hospital successfully removed the HVAD™ pump from one of their patients. The 38-year-old male patient was implanted with his HVAD™ pump on 23 October 2006. After 268 days, or approximately 9 months, of support by the device, the patient’s heart function had improved to such an extent that the cardiology and cardiac surgery teams at Royal Perth Hospital decided to explant the HVAD™ pump.

HeartWare’s primary focus is on the use of the HVAD™ pump as either a bridge to transplantation or as a destination therapy device. However, as our implant numbers grow, it is likely that some meaningful proportion of our patients will respond so well to the therapy that a complete recovery becomes possible. The prospect of pumps being used as a “bridge-to-recovery” may expand the market for these devices and confirmatory studies are being conducted by various institutions.

First-ever HVAD™ Pump Patient Receives a Transplant

To date, three HVAD™ pump patients have received heart transplants, all after extended periods of support on their respective pumps. Included in this group is HeartWare’s first ever patient, who received his HVAD™ pump implant on 22 March 2006 at the Vienna General Hospital. This patient underwent successful transplantation on 23 May 2007, having been supported by his pump for 427 days.

Our technical team was particularly excited to receive the explanted pump back into the HeartWare facility for inspection. After 427 days of continuous operation, the impeller and all internal surfaces appeared to be in a very similar condition as they were when first released from our manufacturing facility. The pump’s internal geometry and wear-less impeller suspension mechanism have been designed specifically to enable long term use – potentially for many years.

(b) Regulatory Update

HeartWare is pursuing two parallel regulatory tracks. The first relates to our international (non US) opportunity. The major milestone in relation to our international regulatory timeline is the completion of enrolment in our current international clinical trial and this is expected to occur within the next few days. When we have enrolled 20 patients in the trial, we can continue preparing and ultimately submit our technical dossier to our Notified Body in Europe. We remain on track to make these submissions during the fourth quarter of this year. Subject to the time required for the regulatory authorities to process our application, we remain confident of being awarded CE marking for the HVAD™ pump during the first quarter 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. Given the proximity to our commercial launch, HeartWare is now actively developing its marketing and distribution plans for Europe.

The more extensive regulatory process is that relating to our US clinical trial. HeartWare has allocated significant resources over recent months to preparing for our US Investigational Device Exemption



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Results for Announcement to the Market (Continued)

("IDE") submission. To this end, we have a pre-IDE meeting with the FDR during September and aim to submit our regulatory filings by mid November.

Subject to successfully completing our IDE application process within the next 3 months, we hope to begin our US implants by the first quarter of 2008. We expect first to conduct a pilot trial involving ten patients at up to five investigational centres and subsequently to initiate our pivotal Bridge to Transplant and Destination Therapy trials involving up to 40 hospitals. We expect to be reimbursed for the HVAD™ pumps implanted during our US clinical trials.

(c) Manufacturing Update

The HeartWare HVAD™ pump is manufactured to very tight tolerances. Approximately two months ago at our Annual General Meeting we described a finding by our technical team which indicated that HVAD™ pumps manufactured within a narrow "window" within our then broader range of specifications appeared to produce superior bench test data than those manufactured outside of this range. As a consequence we decided to tighten our acceptance criteria such that only HVAD™ pumps manufactured within this tighter range of tolerances would be released for clinical use. We are seeing very steady progress in creating new processes that can produce HVAD™ pumps within this tight range. This is best evidenced by the fact that we have recently conducted five implants over a five week period, reflecting our highest implant rate to date.

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 in place a clear plan by which to scale our production capability through the balance of this year so as to be prepared for this expected increased volume within the next 6 or so months.

(d) Capital Raising

The Company is presently in a strong financial position having completed a significant equity financing in July 2007, raising approximately \$37 million from institutional and sophisticated investors in the United States, Europe and Australia.

The capital raising, which was oversubscribed, was well supported both by existing HeartWare shareholders and by several new institutional investors from both Australia, Europe and the United States.

The proceeds of the capital raising are to be used to fund the further development and commercialisation of HeartWare's HVAD™ pump and to advance the Company's MVAD™ pump program. The funds will allow HeartWare to continue its current European clinical trial and to make significant inroads in its planned 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 HVAD™ pump through 2007.

Financial Statements

The Company's Interim Financial Report for the period ended 30 June 2007 is attached.

In reviewing the Interim Financial Report, shareholders should note that the Company has changed its Australian accounting policy in relation to business combinations between entities under common control. This change affects the way in which the Company accounts for the acquisition of HeartWare, Inc. by HeartWare Limited (which occurred on 24 January 2005) in its Australian financial statements.



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Results for Announcement to the Market (Continued)

Previously at 31 December 2006, the Company had adopted two different accounting policy for business combinations in Australia (as it applies to the Company's Australian financial statements) and in the United States (as it applies to the Company's US financial statements).

In order to avoid any confusion and to more closely align the Company's Australian and US financial statements and accounting policies, the Company has changed its Australian accounting policy, as permitted by Australian Accounting Standards, in order to mirror the approach that it has adopted in the United States.

Further details of the change in accounting policy, including a description of the aggregate effect on the financial statements, is set out in Note 2 to the Interim Financial Statements.

Cash Flow

As at the end of the half-year, the Company has cash reserves of approximately \$29,979,273.

The attached Interim Financial Results record the funds held by the Company in relation to the abovementioned capital raising as a "liability" instead of equity at 30 June 2007. This is because the capital raising required shareholder approval which was not obtained until 26 July 2007, which was after the 30 June 2007 reporting date for the Interim Financial Report. As a result, the funds received and held by the Company as at 30 June 2007 in relation to the capital raising are initially recorded as a liability in accordance with relevant accounting principles. Following the receipt of shareholder approval, the Company has cash reserves of approximately \$41 million (as at 31 August 2007).

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.

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 2007 be declared or paid by the Company.

Earnings Per Share (EPS)

	30 June 2007	30 June 2006
	Cents	Cents
Basic and diluted earnings/(loss) per share (cents per share)	(0.07)	(0.06)
Weighted average number of ordinary shares used in the calculation of basic earnings per share	186,299,282	162,983,281

The amount used as the numerator in calculating basic and diluted EPS (for 30 June 2007) is the NPAT figure reported in the section entitled "Review of Operations and Earnings Result for the Half-Year Ended 30 June 2007" 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 audit dispute or qualification. This Half-Year Report is based on the Interim Financial Report that has been subject to an audit 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: 31 August 2007