



HEARTWARE INTERNATIONAL, INC.
ARBN 132 897 762

RESULTS FOR ANNOUNCEMENT TO THE MARKET

**ASX Appendix 4E
Preliminary Final Report
For the 12 Months Ended
31 December 2008**

This is the Preliminary Final Report for the HeartWare Group.
The HeartWare Group includes HeartWare International, Inc. (ASX:HIN) and its subsidiaries
HeartWare Limited and 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 HeartWare Group relies on relief available under ASIC Class Order 98/1418, and as such, will lodge its audited Annual Financial Report, for the year ended 31 December 2008, in the form of United States Securities and Exchange Commission Form 10-K, prepared in accordance with United States Generally Accepted Accounting Principles, on or before 27 February 2009.

All amounts in this report are denominated in United States dollars unless otherwise indicated.

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 INTERNATIONAL, INC. (ARBN 132 897 762)
& CONTROLLED ENTITIES
FINANCIAL RESULTS FOR YEAR ENDED 31 DECEMBER 2008

RESULTS FOR ANNOUNCEMENT TO THE MARKET

	Year Ended 31 December 2008 US\$	Year Ended 31 December 2007 US\$	% Increase / (Decrease)
Revenues from ordinary activities	331,799	-	-
Profit / (Loss) before interest, tax, depreciation and amortisation attributable to members ("EBITDA")	(24,417,136)	(22,350,628)	9%
Profit / (Loss) before interest and tax attributable to members ("EBIT")	(25,008,761)	(22,889,674)	9%
Income Tax Benefit	-	-	-
Profit / (Loss) after tax attributable to members ("NPAT")	(23,763,621)	(21,938,999)	8%
Net tangible assets per ordinary share (cents)	290.46	450.81	(36)%

The Directors do not recommend that a dividend relating to the year ended 31 December 2008 be paid. As such, there is no franking or applicable record date.

Effective 13 November 2008, the Company redomiciled from Australia to the United States. Pursuant to a court approved scheme of arrangement under Australian law, all ordinary shares of HeartWare Limited, a company incorporated in Australia, were transferred by court order to HeartWare International, Inc., a Delaware corporation, in exchange for shares of common stock of HeartWare International, Inc. Shareholders received common stock in a ratio of 35 HeartWare Limited ordinary shares to 1 share of HeartWare International, Inc. common stock. In addition, all outstanding equity awards of HeartWare Limited were exchanged for equivalent interests in HeartWare International, Inc (on the same 35:1 ratio).

On 16 December 2008, HeartWare International, Inc. HeartWare Limited and HeartWare Inc. entered into a Deed of Cross Guarantee (the "Deed") pursuant to which each of these companies have agreed to cross-guarantee each other's liabilities. The Deed was established as a condition to obtaining financial reporting relief under ASIC Class Order 98/1418 which provides relief for the Company from the requirement to prepare and lodge audited accounts for HeartWare Limited in Australia (and instead permits the HeartWare Group to file financials statements that comply with US accounting and legal requirements).

As such, HeartWare will lodge its audited Annual Financial Report, for the year ended 31 December 2008, in the form of United States Securities and Exchange Commission Form 10-K, prepared in accordance with United States Generally Accepted Accounting Principles, on or before 27 February 2009. All amounts in this report are denominated in United States dollars unless otherwise indicated.



HEARTWARE INTERNATIONAL, INC. (ARBN 132 897 762)
& CONTROLLED ENTITIES
FINANCIAL RESULTS FOR YEAR ENDED 31 DECEMBER 2008

HeartWare International, Inc. is the ultimate parent entity, HeartWare, Inc. is the alternative Trustee and HeartWare Limited is a member of the Closed Group for purposes of the Class Order.

COMMENTARY TO THE EARNINGS RESULT

In 2008, HeartWare made tremendous strides towards its goal of commercialising the HeartWare® Ventricular Assist System ("HeartWare System"). In 2008, we completed enrolment of our combined European and Australian clinical trial, commenced our U.S. bridge-to-transplant clinical trial and recorded first product revenue related to sales of the HeartWare System through this trial, received ISO certification, transitioned from an Australian to a U.S. headquartered company and continued research and development activities for our next generation product, the MVAD.

In January 2009 we announced receipt of CE Marking which represents the culmination of years of work and represents an important transition for the Company as the HeartWare System will now be available for sale throughout Europe.

On 12 February 2009, we entered into an Agreement and Plan of Merger with Thoratec Corporation ("Merger") for a cash consideration of US\$282 million, payable 50% in cash and 50% in Thoratec common stock. Consummation of the Merger is subject to customary conditions, including adoption of the Merger Agreement by HeartWare's shareholders and the expiration or termination of the required waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 ("HSR Approval"). Approval by Thoratec's shareholders is not required in order to implement the Merger.

Thoratec and HeartWare may terminate the Merger Agreement under certain limited circumstances specified in the Merger Agreement (a copy of which may be downloaded from the Company's website). Upon the termination of the Merger Agreement in these limited circumstances (e.g. pursuant to a super merger offer), HeartWare may be required to pay Thoratec a termination fee equal to \$11.3 million, and in other specified circumstances, HeartWare may be obligated to pay Thoratec a termination fee equal to \$5.0 million.

In connection with the Agreement and Plan of Merger, the Company has entered into a loan agreement with Thoratec in order to fund the ongoing operations of HeartWare through the closing of the transaction. Under this loan agreement (and subject to various conditions), Thoratec has agreed to make US\$20 million available to HeartWare with US\$12 million being available on 1 May 2009 and the remaining US\$8 million being available from 31 July 2009. Thoratec may unilaterally elect to extend the "end date" for securing HSR Approval through 31 January 2010 but must provide HeartWare with an additional US\$8 million in loaned funds on making such election (bringing the total loaned amount to US\$28 million).

The terms of the agreements are more fully described in materials filed with the U.S. Securities and Exchange Commission and the ASX and as described in our Annual Report on Form 10-K.

Finally, we also listed our common stock on NASDAQ with effect from 24 February 2009.

The net loss of the HeartWare Group for the year ended 31 December 2008 after providing for income tax was \$23,763,621 (2007: \$21,938,999). The increase in the loss over the preceding year reflects the above achievements with the bulk of expenditure pertaining to expansion of the Company's clinical trials, expenses related to regulatory activities, transitioning to a Company headquartered in the U.S. and on-going research and development activities.



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& CONTROLLED ENTITIES
FINANCIAL RESULTS FOR YEAR ENDED 31 DECEMBER 2008

MANAGEMENT DISCUSSION AND ANALYSIS

Overview

The 2008 calendar year has seen HeartWare achieve remarkable results, including:

- Receipt of ISO certification.
- Transitioned from an Australian to a U.S. headquartered company.
- Commenced our U.S. IDE clinical trial.
- Recorded first product revenue.
- Completed enrolment of our 50 patient European and Australian clinical trial.
- Refined two new MVAD concepts and conducted preclinical studies on both.

Undoubtedly, the key event for 2008 was receipt of IDE approval from the U.S. FDA and began enrolling centres for a U.S. bridge-to-transplant clinical trial under which 150 patients awaiting heart transplantation will be enrolled at up to 28 participating centres. In August 2008, our first patient in this trial received the HeartWare System at Washington D.C. Commencement of this clinical trial in the U.S. resulted in the Company recording initial revenue from product sales.

We also completed a combined European and Australian human clinical trial for the HeartWare System in 2008. This international trial began in March 2006 and called for the implantation of 20 patients. The trial had been expanded to permit enrolment of 50 patients so as to provide increased depth of clinical data. Enrolment in this trial was the basis for application for and subsequent receipt of approval of CE Marking of the HeartWare System. CE Marking means the HeartWare System will now be available for commercial sale throughout Europe.

In 2008 we received an IDE from the US FDA and began enrolling centres for a US bridge-to-transplant clinical study. In August 2008, our first patient in the United States received the HeartWare System at Washington Hospital Center in Washington, DC. This marked the start of our US bridge-to-transplant clinical trial, under which 150 patients awaiting heart transplantation will be enrolled at up to 28 participating centres.

Beyond the HeartWare System, we are also evaluating our next generation device, the Miniaturized Ventricular Assist Device, or MVAD. The MVAD is based on the same technology platform as the HeartWare System but adopts an axial flow, rather than a centrifugal flow, configuration. The MVAD, which is currently at the development stage and undergoing animal studies focused on minimally invasive implantation techniques, is approximately one-third the size of the HVAD Pump.

The Company has opened 2009 with CE Marking in Europe, sufficient quantities of its products, a significantly stronger manufacturing environment, and strong clinical results providing an excellent foundation for the Company as it looks forward.

FINANCIALS

Balance Sheet

HeartWare's cash reserves as at 31 December 2008 and 2007 were \$20.8 million (AU\$30.0) and \$28.3 million (AU\$32.1), respectively.

HeartWare recognized inventory for the first time in 2008. Prior to 1 September 2008, all costs associated with manufacturing the HeartWare System and related surgical products were expensed as research and development costs. Upon receipt of full IDE approval in the U.S. of the HeartWare System the Company deemed commercialisation and future economic benefit was probable and as a result we adopted a policy of capitalizing inventory and recognizing cost of sales as of 1 September 2008.



HEARTWARE INTERNATIONAL, INC. (ARBN 132 897 762)
& CONTROLLED ENTITIES
FINANCIAL RESULTS FOR YEAR ENDED 31 DECEMBER 2008

Until we sell the inventory for which costs were previously expensed, the carrying value of our reported inventories and our cost of sales will reflect only incremental costs incurred subsequent to the commencement of capitalization of inventory on 1 September 2008. As such, as we sell that portion of our existing inventory there will be a period of time where we will recognize manufacturing revenue with little or no corresponding cost. Therefore we anticipate our gross margin on sales of our product will fluctuate and will not be comparative from quarter to quarter.

Components of selected captions in the consolidated balance sheets at 31 December 2008 are as follows:

Inventories, net

Raw material	\$ 813,276
Work-in-process	1,690,852
Finished goods	1,003,937
	<u>\$ 3,508,065</u>

Statement of Operations

Revenue

HeartWare reported total revenue of \$331,799 from product sales in the year ended 31 December 2008 related to sales through our U.S. clinical trial. We had no revenue from product sales in the years prior to 2008. We have completed enrolment for our combined European and Australian clinical trial for the HeartWare System and received CE Marking approval in January 2009. As a consequence of recently receiving CE Marking, the commencement of commercial revenue from the sale of the HeartWare System outside of the United States is imminent.

Cost of Goods Sold

Cost of goods sold totalled \$77,632 during the year ended 31 December 2008. There was no cost of goods sold recognized during the year ended 31 December 2007 (as there were no sales in this period). As we had inventory on hand that had previously been expensed as research and development costs our cost of goods sold and related gross margin for the year ended 31 December 2008 is not be reflective of expected future margins. In addition, as we use a standard costing method for determining costs of inventory and have limited experience setting standards and manufacturing our products, actual results may differ from standards which, as noted above, could result in inconsistent gross margins from quarter to quarter.

Selling, General and Administrative

Selling, general and administrative expenses include office expenses associated with general corporate administration. These costs are primarily related to salaries and wages and related employee costs, depreciation of fixed assets, travel, external consultants and contractors, legal and accounting fees (including in relation to redomiciliation) and general infrastructure costs and include all operating costs not associated with or otherwise classified as research and development costs or cost of revenues.

During 2008, we experienced significant growth as we completed enrolment in our international clinical trial, initiated enrolment in our first human clinical trial in the United States, continued to manage dual reporting structures in the United States and Australia and raised additional capital. As a result, we experienced expansion of our staff, including senior management, and a related expansion in infrastructure costs.

In 2008, selling, general and administrative expenses were approximately \$11.0 million, or 37% of operating expenses, as compared to \$7.3 million, or 33% of operating expenses, in 2007. The increase was primarily a result of an increase in headcount and related employee costs, increased office costs and



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& CONTROLLED ENTITIES
FINANCIAL RESULTS FOR YEAR ENDED 31 DECEMBER 2008

professional fees associated with our redomiciliation to the US, travel and marketing activities in preparation for commercial activities.

Research and Development

Research and development expenses are the direct and indirect costs associated with developing our products prior to commercialisation. These expenses consist primarily of salaries and wages and related employee costs, external research and development costs, materials and expenses associated with clinical trials associated with our US clinical trial. Additional costs include travel, facilities and overhead allocations.

Though we approach commercialisation of the HeartWare System, we expect that research and development expenses will continue to represent a significant portion of our operating expenses for the foreseeable future related to new product development. In addition, we expect increased clinical costs that will be expensed to research and development relating to the HeartWare System for U.S. clinical trials.

As mentioned above, we achieved significant research and development milestones, completing enrolment of our international human clinical trial, beginning enrolment for our US clinical trial and the commencement of animal studies for less invasive implantable techniques for our next generation heart pump, the MVAD. In 2008, research and development expenses were \$18.6 million, or 63% of operating expenses, as compared to \$14.6 million, or 67% of operating expenses, in 2007. The increase of approximately \$4.0 million was primarily driven by increased headcount and related employee costs as well as increased clinical trial costs, professional fees and other research and development expenses related to existing research projects and expenses associated with regulatory activities associated with obtaining IDE, CE Marking and ISO certification.

Other Income

Other income consists primarily of interest income and foreign exchange income or loss.

Interest income is primarily derived from cash and short-term deposits accounts, denominated in both Australian and United States dollars, held in Australia. Interest income was approximately \$1.2 million in 2008 as compared to \$951,000 in 2007. The increase was primarily due to increased average cash balances in 2008 as a result of the completion of a private placement of shares in July 2008.

Foreign exchange income was approximately \$4.6 million in 2008 as compared to a loss of approximately \$851,000 in 2007. The difference was due to fluctuations in the value of our Australian and US dollar-based cash holdings as a result of movements in the exchange rate between the Australian dollar and the US dollar.

Cash Flow Statement

The net decrease in cash during the year ended 31 December 2008 was \$7.5 million as compared to an increase of \$11.6 million during the year ended 31 December 2008.

Cash used in operating activities, primarily related to the net loss for the period was \$24.1 million (2007:\$19 million). Cash used in financing activities, primarily related to purchasing fixed assets was \$2.3 million (2007:\$1 million). Cash provided by financing activities of \$28.0 million (2007:\$30.9 million) was comprised of capital raise proceeds of \$29.4 million offset by the repayment of the convertible note of \$1.3 million.

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& CONTROLLED ENTITIES
FINANCIAL RESULTS FOR YEAR ENDED 31 DECEMBER 2008

Please find attached the Company's 2008 Annual Financial Report on United States Securities and Exchange Commission Form 10-K for the year ended 31 December 2008, together with the Consolidated Balance Sheets, Statement of Operations and Statement of Cash Flows and other relevant commentary thereto.

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

Rob Thomas
Chairman
27 February 2009