



**HEARTWARE INTERNATIONAL REPORTS  
FIRST QUARTER 2011 REVENUES OF \$18.0 MILLION;  
68% INCREASE FROM \$10.7 MILLION IN FIRST QUARTER 2010**

– Conference call today at 5:00 p.m. U.S. ET –

**Framingham, Mass. and Sydney, Australia, May 6, 2011** - HeartWare International, Inc. (NASDAQ: HTWR; ASX: HIN), a leading innovator of less invasive, miniaturized circulatory support technologies that are revolutionizing the treatment of advanced heart failure, today announced revenues of \$18.0 million for the first quarter ended March 31, 2011. This represents a 68 percent increase from \$10.7 million in revenues for the first quarter of 2010.

“During the first quarter, we generated our second highest international sales results for the HeartWare<sup>®</sup> Ventricular Assist System. We are appreciative of the strong support of our 56 customers in 18 countries, as 134 pumps were sold outside of the U.S.,” explained Doug Godshall, President and Chief Executive Officer. “The international markets accounted for 65 percent of our revenues, or approximately \$11.7 million for the 2011 first quarter, up from \$8.0 million in the first quarter of 2010.”

“In the U.S., where first quarter revenues more than doubled to \$6.3 million compared to \$2.7 million in the first quarter of 2010, we now have 46 of the planned 50 U.S. sites approved for implantation in our 450-patient destination therapy study, and 121 patients have been randomized and enrolled,” added Mr. Godshall. “In the first quarter, we also received our largest allotment – 94 patients – granted by the Food and Drug Administration (FDA) in January under the Continued Access Protocol (CAP) for our bridge-to-transplant clinical study. Participating hospital sites began the re-initiation process and have enrolled 28 patients in this third CAP cohort.”

Total operating expenses for the first quarter of 2011 were \$18.0 million, compared to \$9.3 million in the prior year period. Research and development expense was \$9.3 million for the first quarter of 2011, primarily attributable to expanded clinical trial activity and increased expenditure on HeartWare’s pipeline technologies, including the commencement of final preclinical testing for the next generation MVAD platform. Selling, general and administrative expenses were \$8.7 million in the first quarter of 2011. These expenses reflect recruitment for key positions to meet rising demand for the Company’s products and the need to support clinicians in a larger number of centers, as well as ongoing expansion of commercialization activities in Europe and other countries outside the U.S.

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Net loss for the first quarter of 2011 was \$9.4 million, or a \$0.68 loss per basic and diluted share, compared to a \$4.5 million net loss, or a loss of \$0.35 per basic and diluted share, in the first quarter of 2010.

At March 31, 2011, the Company's balance sheet showed \$214.1 million in cash, cash equivalents and investments. This compares to approximately \$217.5 million in cash, cash equivalents and investments at December 31, 2010.

During the first quarter, the FDA notified HeartWare that it had accepted for filing the Company's Pre-Market Approval (PMA) application, which was submitted to the FDA for a bridge-to-transplant indication in late December 2010. Today, more than 1,000 advanced heart failure patients globally have received the HVAD<sup>®</sup> pump.

HeartWare will host a conference call on Thursday, May 5, 2011 at 5:00 p.m. U.S. Eastern Standard Time (being 7:00 a.m. Australian Eastern Daylight Time, Friday, May 6, 2011) to discuss the Company's financial results, highlights from the quarter and business outlook. The call may be accessed by dialing 1-888-846-5003 five minutes prior to the scheduled start time and referencing "HeartWare." For callers outside the U.S., please dial + 1-480-629-9809. Doug Godshall, President and Chief Executive Officer and David McIntyre, Chief Financial Officer and Chief Operating Officer, will host the conference call.

A live webcast of the call will also be available at the Company's website ([www.heartware.com](http://www.heartware.com)) by selecting "HeartWare First Quarter 2011 Conference Call" under the section titled "Corporate Presentations" on the Home Page. A replay of the conference call will be available through the above weblink immediately following completion of the call.

### **About HeartWare International**

HeartWare International develops and manufactures miniaturized implantable heart pumps, or ventricular assist devices, to treat Class IIIB / IV patients suffering from advanced heart failure. The HeartWare<sup>®</sup> Ventricular Assist System features the HVAD<sup>®</sup> pump, a small full-output circulatory support device (up to 10L/min flow) designed to be implanted next to the heart, avoiding the abdominal surgery generally required to implant competing devices. HeartWare has received CE Marking for the HeartWare System in the European Union and TGA approval in Australia. The device is currently the subject of United States clinical trials for two indications: bridge-to-transplant and destination therapy. For additional information, please visit [www.heartware.com](http://www.heartware.com).

*HeartWare International, Inc. is a member of the Russell 2000<sup>®</sup> and its securities are publicly traded on The NASDAQ Stock Market and the Australian Securities Exchange.*

*HEARTWARE, HVAD, MVAD and HeartWare logos are registered trademarks of HeartWare, Inc.*

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## **Forward-Looking Statements**

*This announcement contains forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to the timing and progress of, and presentation of data related to, clinical trials, expected timing of FDA regulatory filings, FDA acceptance of our filings, and research and development activities. Management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on forward-looking statements because they speak only as of the date when made. HeartWare does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. HeartWare may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including without limitation, the possibility the FDA does not accept our PMA application or approve the marketing of the HeartWare® Ventricular Assist System in the U.S., and those described in "Item 1A. Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission. We may update our risk factors from time to time in "Part II, Item 1A "Risk Factors" in our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, or other filings with the Securities and Exchange Commission.*

### **For further information:**

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- Tables to Follow-

**HEARTWARE INTERNATIONAL, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except share and per share data)  
(unaudited)

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
Revenues, net	\$ 17,975	\$ 10,703
Cost of revenues	7,596	5,680
Gross profit	10,379	5,023
Operating expenses:		
Selling, general and administrative	8,664	4,556
Research and development	9,300	4,756
Total operating expenses	17,964	9,312
Loss from operations	(7,585)	(4,289)
Other income (expense):		
Foreign exchange gain (loss)	592	(367)
Interest expense	(2,605)	—
Interest income, net	167	112
Loss before income taxes	(9,431)	(4,544)
Provision for income taxes	—	—
Net loss	<u>\$ (9,431)</u>	<u>\$ (4,544)</u>
Net loss per common share — basic and diluted	<u>\$ (0.68)</u>	<u>\$ (0.35)</u>
Weighted average shares outstanding — basic and diluted	<u>13,900,602</u>	<u>12,958,326</u>

**HEARTWARE INTERNATIONAL, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(in thousands)  
(unaudited)

	<u>March 31, 2011</u>	<u>December 31, 2010</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 156,077	\$ 192,148
Short-term investments, net	57,976	21,330
Accounts receivable, net	14,116	19,053
Inventories, net	17,342	15,077
Prepaid expenses and other current assets	2,808	2,406
Total current assets	248,319	250,014
Property, plant and equipment, net	8,336	7,484
Other intangible assets, net	1,704	1,596
Long-term investments, net	-	4,006
Deferred financing costs, net	2,871	2,939
Restricted cash	1,538	1,538
Total assets	<u>\$ 262,768</u>	<u>\$ 267,577</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,544	\$ 3,890
Accrued expenses and other current liabilities	8,225	7,001
Total current liabilities	10,769	10,891
Convertible senior notes, net	90,200	88,922
Stockholders' equity	161,799	167,764
Total liabilities and stockholders' equity	<u>\$ 262,768</u>	<u>\$ 267,577</u>

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