

HEARTWARE INTERNATIONAL REPORTS THIRD QUARTER 2010 REVENUES OF \$13.8 MILLION; COMPARED TO \$7.5 MILLION IN THIRD QUARTER OF 2009

 Nine months 2010 revenues of \$34.3 million compared to \$12.0 million in 2009 nine months –

- Conference call today at 8:00 a.m. U.S. ET -

Framingham, Mass. and Sydney, Australia, November 3, 2010 - 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 \$13.8 million for the third quarter ended September 30, 2010. This compares to \$7.5 million in revenues for the third quarter of 2009, and revenues of \$9.8 million in the second quarter of 2010. For the nine months ended September 30, 2010, the Company generated revenues of \$34.3 million, compared to \$12.0 million in the first nine months of 2009.

"Third quarter results reflect the largest number of implants of the HeartWare[®] Ventricular Assist System in any quarter to date, driven primarily by steady commercial expansion in markets outside of the United States, as well as increased U.S. clinical activities," explained Doug Godshall, President and Chief Executive Officer. "The international markets accounted for approximately 72 percent of our revenues for the quarter, as we increased our customer base to 36 hospitals, from 16 at the start of the year. In the U.S., the rate of implant procedures remains variable, as the first allotment of 54 patients under a Continued Access Protocol (CAP) for our bridge-to-transplant clinical study was depleted in August, and the Food and Drug Administration (FDA) granted a second 54-patient CAP in September, requiring re-initiation at sites. Site recruitment continues in our 450-patient destination therapy study, as we move toward our goal of 50 U.S. sites for that trial."

Total operating expenses for the third quarter of 2010 were \$16.3 million, compared to \$6.8 million in the prior year period. Research and development expense was \$9.3 million for the third quarter of 2010, attributable to heightened engineering, testing, document and related preparation costs associated with the planned bridge-to-transplant premarket approval application (PMA) submission to the FDA, together with increased expenditure on the Company's pipeline technologies. Selling, general and administrative expenses were \$7.0 million in the third quarter of 2010, with non-cash, share-based compensation charges contributing \$1.8 million. For the first nine months of 2010, total operating expenses were \$40.8 million compared to \$21.7 million for the same period of 2009. The increases described above also reflect ongoing expansion of commercialization activities in Europe and other countries



outside the U.S., additional investment in HeartWare's technology pipeline and increased recruitment for key positions to meet expected rising demand for the Company's products and the need to support clinicians in a larger number of centers.

Net loss for the third quarter of 2010 was \$7.8 million, or a \$0.57 loss per basic and diluted share, compared to a \$5.9 million net loss, or a loss of \$0.60 per basic and diluted share, in the third quarter of 2009. For the nine months ended September 30, 2010, the Company recorded a net loss of \$22.4 million, or a \$1.66 loss per basic and diluted share, compared to a \$19.0 million net loss, or a loss of \$2.07 per basic and diluted share, in the first nine months of 2009.

"Today, nearly 700 advanced heart failure patients globally have received the HVAD® pump," added Mr. Godshall. "Our current priorities include: preparation for the presentation of data from our U.S. bridge-to-transplant (BTT) study at the American Heart Association Scientific Sessions on November 14; compilation of preclinical, manufacturing and clinical data into a PMA submission to the FDA for BTT, which is targeted for year-end; initiation of all 50 sites in our destination therapy trial; and preparing the MVAD portfolio for Good Laboratory Practice (GLP) animal studies early next year."

At September 30, 2010, the Company's balance sheet showed \$93.0 million in cash, cash equivalents and investments. This compares to approximately \$50.8 million in cash and cash equivalents at December 31, 2009, and reflects incorporation of proceeds from the Company's public offering in February 2010.

HeartWare will host a conference call on Wednesday, November 3, 2010 at 8:00 a.m. U.S. Eastern Daylight Time (11:00 p.m. Australian Eastern Daylight Time) to discuss the Company's financial results, quarterly highlights and business outlook. The call may be accessed by dialing 1-877-407-4018 five minutes prior to the scheduled start time and referencing "HeartWare." For callers outside the United States, dial +1-201-689-8471. 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) by selecting "HeartWare Third Quarter 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[®] Ventricular Assist System features the HVAD[®] 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. The device is currently the subject of United States clinical trials for two indications: bridge-to-transplant under a continued access protocol and destination therapy. For additional information, please visit www.heartware.com.

HeartWare International, Inc. is a member of the Russell 2000[®] and its securities are publicly traded on The NASDAQ Stock Market and the Australian Securities Exchange.

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 progress of, and presentation of data related to, clinical trials, expected timing of FDA regulatory fillings 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 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, or other current reports, as filed 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)

	Three Months Ended September 30,			Nine Months Ended September 30,				
	- 2	2010		2009	- 2	2010		2009
Revenues, net	\$	13,817	\$	7,507	\$	34,277	\$	11,952
Cost of revenues		6,003		4,104		15,976		6,401
Gross profit		7,814		3,403		18,301		5,551
Operating expenses:								
Selling, general and administrative		6,993		3,149		19,238		11,721
Research and development		9,313		3,646		21,580		9,994
Total operating expenses		16,306		6,795		40,818		21,715
Loss from operations		(8,492)		(3,392)		(22,517)		(16,164)
Other income (expense), net		648		(2,482)		147		(2,834)
Net loss	\$	(7,844)	\$	(5,874)	\$	(22,370)	\$	(18,998)
Net loss per common share - basic and diluted	\$	(0.57)	\$	(0.60)	\$	(1.66)	\$	(2.07)
Weighted average shares outstanding - basic and diluted	1	3,752,829	9	,715,577	13.	,467,540		9,156,074



HEARTWARE INTERNATIONAL, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands) (unaudited)

	Sept	tember 30, 2010	December 31, 2009		
ASSETS					
Current assets:					
Cash and cash equivalents	\$	67,498	\$	50,835	
Short-term investments, net		21,495			
Accounts receivable, net		8,290		11,385	
Inventories, net		17,219		8,871	
Prepaid expenses and other current assets		2,265		1,663	
Total current assets		116,767		72,754	
Property, plant and equipment, net		6,842		3,719	
Other intangible assets, net		1,486		1,192	
Long-term investments, net		4,008		_	
Restricted cash		288		288	
Total assets	\$	129,391	\$	77,953	
LIABILITIES AND STOCKHOLDERS' EQUITY Current liabilities:					
Accounts payable	\$	3,143	\$	3,122	
Accrued expenses and other current liabilities	φ	7,089	φ	3,122	
Total current liabilities		10,232		6,970	
		10,232		0,970	
Commitments and contingencies		110 150		70.092	
Stockholders' equity	ф.	119,159	Φ.	70,983	
Total liabilities and stockholders' equity	\$	129,391	\$	77,953	

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