

HeartWare International Reports Fourth Quarter And Full-Year 2015 Financial Results

- Fourth Quarter 2015 Revenue of \$68.1 Million

- Full-Year 2015 Revenue of \$276.8 Million, an Increase of 6.3% Over Full-Year 2014 on Constant-Currency Basis

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

FRAMINGHAM, Mass., Feb. 25, 2016 /PRNewswire/ -- [HeartWare International, Inc.](#) (NASDAQ: HTWR), a leading innovator of less-invasive, miniaturized circulatory support technologies that are revolutionizing the treatment of advanced heart failure, today announced its financial results for the fourth quarter and full-year 2015.

The company reported revenue of \$68.1 million for the fourth quarter of 2015, a 7% decrease from revenue of \$73.2 million for the fourth quarter of 2014. Fourth quarter revenue reflected a decline of \$6.4 million relative to the same period in 2014 due to completion of patient enrollment in the company's ENDURANCE2 Destination Therapy (DT) clinical trial of the HVAD® System during the third quarter of 2015 and unfavorable currency changes of \$3.4 million. Fourth quarter 2015 revenue decreased 2.4 percentage points on a constant-currency basis compared to the fourth quarter of 2014. For fiscal-year 2015, the company generated revenue of \$276.8 million, which was a 1% decrease compared to revenue of \$278.4 million in 2014. Fiscal-year 2015 revenue increased 6.3 percentage points on a constant-currency basis compared to fiscal-year 2014.

During the fourth quarter, 720 HVAD Systems were sold globally, contributing to a total of 2,903 units sold in 2015, and representing a 5% increase compared to 2,751 units in 2014. U.S. revenue, generated through the sale of 376 units during the fourth quarter of 2015, was \$41.2 million, compared to \$41.5 million for the fourth quarter of 2014. Revenue from international markets, derived from the sale of 344 units sold during the fourth quarter of 2015, was \$26.9 million, compared to \$31.7 million for the fourth quarter of 2014, an increase of 4.3% after adjusting for foreign currency.

"We made substantial progress in expanding our commercial footprint in the past year, adding 55 new hospital centers globally. With a presence in 47 countries, and more than 300 commercial centers, we have an established network of customers from which to grow our business well into the future," said Doug Godshall, President and Chief Executive Officer. "In 2015, we initiated enrollment in LATERAL, our clinical trial to evaluate the thoracotomy implant technique, and we are working toward enrollment completion of this 145-patient study; we presented results from our first DT clinical trial, ENDURANCE, in which our HVAD System achieved the primary endpoint, and soon after, completed enrollment in our supplemental DT cohort, ENDURANCE2, setting the stage for us to submit for the DT indication in mid-2016; we initiated the first human implants of the MVAD® System; and we performed significant upgrades to our quality system.

"In 2016, our priorities include fortifying our HVAD System by working toward rollout of new, competitive enhancements and seeking an expanded DT indication; completing our remediation efforts related to the warning letter from FDA; and understanding and resolving the early clinical challenges experienced with our next-generation MVAD System," said Mr. Godshall.

Fourth Quarter and Full-Year 2015 Financial Results

Gross margin percentage was 66.2% in the fourth quarter of 2015, as compared to 68.1% in the fourth quarter of 2014. The decrease compared to the fourth quarter of 2014 was primarily due to the effect of foreign currency exchange rates during the quarter. For the year ended December 31, 2015, gross margin was 62.7%, compared to 66.9% for full-year 2014, primarily as a result of charges aggregating \$8.5 million for field actions during the third quarter of 2015.

Selling, general and administrative expenses were \$25.2 million for the fourth quarter of 2015, compared to \$21.4 million for the fourth quarter of 2014. The increase over the prior year comprised \$1.2 million in growth-related expenses, \$1.6

million of Valtech transaction expenses, and a \$1.0 million lease abandonment charge for the former headquarters of CircuLite, Inc., which HeartWare acquired in 2013.

Research and development expense was \$27.4 million for the fourth quarter of 2015, compared to \$30.8 million in the same period in 2014. The decrease from the prior year was primarily due to a reduction in aggregate project spending.

Net loss for the fourth quarter of 2015 was \$0.9 million, or \$0.05 per basic and diluted share, compared to a net loss of \$0.9 million, or \$0.05 per basic and diluted share, for the fourth quarter of 2014. For the year ended December 31, 2015, the company recorded a net loss of \$72.8 million, or a loss of \$4.21 per basic and diluted share, compared to a net loss of \$19.4 million, or a loss of \$1.14 per basic and diluted share, for fiscal-year 2014.

The increase in fiscal 2015 net loss, compared to the fiscal 2014 net loss, primarily included foreign currency effects of \$18.1 million, increased impairment and fair value accounting adjustments of \$16.0 million, debt extinguishment charges of \$16.6 million and \$3.4 million of various operating changes.

Non-GAAP net loss for the fourth quarter of 2015 was \$9.2 million, or \$0.53 per basic and diluted share, compared to a net loss of \$6.9 million, or \$0.41 per basic and diluted share, for the fourth quarter of 2014. Non-GAAP net loss for the year ended December 31, 2015 was \$49.8 million, or \$2.89 per basic and diluted share, compared to a net loss of \$34.6 million, or \$2.03 per basic and diluted share, for fiscal-year 2014. The increased non-GAAP net loss in the fourth quarter and fiscal-year 2015 periods, compared to their respective periods in 2014, was due primarily to the impact of foreign currency changes. See "Use of Non-GAAP Financial Measures" and "Reconciliation of GAAP to Non-GAAP Net Loss Per Common Share."

At December 31, 2015, HeartWare had approximately \$244 million of cash, cash equivalents and investments, compared to approximately \$249 million at September 30, 2015. Subsequent to the close of 2015, HeartWare extended to Valtech Cardio, Ltd. convertible loans of \$31 million, including \$30 million pursuant to the termination of the acquisition agreement between the two companies.

Conference Call and Webcast Information

HeartWare will host a conference call and live webcast on Thursday, February 25, 2016 at 8:00 a.m. ET to discuss its financial results and provide a business commentary. The conference call may be accessed by dialing 1-877-407-0789 five minutes prior to the scheduled start time and referencing "HeartWare." Callers outside the U.S. should dial +1-201-689-8562.

The live webcast will be available in the Investors section of the company's website (<http://ir.heartware.com/>). A replay of the conference call will be available through the above link immediately following completion of the call.

About HeartWare International

HeartWare International develops and manufactures miniaturized implantable heart pumps, or ventricular assist devices, to treat patients suffering from advanced heart failure. The HeartWare® Ventricular Assist System features the HVAD® pump, a small full-support circulatory assist device designed to be implanted next to the heart, avoiding the abdominal surgery generally required to implant competing devices. The HeartWare System is approved in the United States for the intended use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure, has received CE Marking in the European Union and has been used to treat patients in 47 countries. The device is also currently the subject of a U.S. clinical trial for 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.

Use of Non-GAAP Financial Measures

HeartWare management supplements its GAAP financial reporting with certain non-GAAP financial measures for financial and operational decision making. For example, we use "non-GAAP net loss" and "non-GAAP net loss per common share" to refer to GAAP loss per share excluding certain adjustments such as amortization of intangible assets, impairment charges, purchase accounting and acquisition-related transaction costs, loss on extinguishment of long-term debt, and restructuring and severance costs. These are non-GAAP financial measures under Section 101 of Regulation G under the Securities Exchange Act of 1934, as amended. Management believes that providing this additional information enhances investors' understanding of the financial performance of the company's operations and increases comparability of its current financial statements to prior periods. Non-GAAP measures should not be considered a substitute for measures of financial performance in accordance with GAAP, and they should be reviewed in comparison with their most directly comparable GAAP financial results. Reconciliations of HeartWare's GAAP to non-GAAP financial measures are provided at the end of this news release under "Reconciliation of GAAP to Non-GAAP Net Loss Per Common Share."

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: HeartWare's core ventricular assist device business; commercialization of the HeartWare HVAD System; restarting clinical investigation of the MVAD System; submission for U.S. approval of a destination therapy indication; resolution of our Warning Letter; timing, progress and outcomes of clinical trials; regulatory and quality compliance; research and development activities and our ability to take advantage of acquired and pipeline technology. 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, except as may be required by federal securities laws and the rules and regulations of the Securities and Exchange Commission. 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 Part I, Item 1A. "Risk Factors" in HeartWare's Annual Report on Form 10-K filed with the Securities and Exchange Commission. HeartWare may update risk factors from time to time in Part II, Item 1A "Risk Factors" in Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, or other filings with the Securities and Exchange Commission.

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- Tables to Follow-

HEARTWARE INTERNATIONAL, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

	Three Months Ended		Years Ended	
	December 31,		December 31,	
	2015	2014	2015	2014
Revenue, net	\$ 68,087	\$ 73,209	\$ 276,843	\$ 278,420
Cost of revenue	23,030	23,349	103,287	92,195
Gross profit	45,057	49,860	173,556	186,225
Operating expenses:				
Selling, general and administrative	25,247	21,412	94,594	87,177
Research and development	27,414	30,801	120,769	119,782
Impairment of intangible assets	26,849	2,650	26,849	2,650
Change in fair value of contingent consideration	(38,110)	(9,080)	(31,410)	(23,260)
Total operating expenses	41,400	45,783	210,802	186,349
Income (loss) from operations	3,657	4,077	(37,246)	(124)
Other expense, net	(4,378)	(5,096)	(34,520)	(18,682)
Loss before taxes	(721)	(1,019)	(71,766)	(18,806)
Income tax (benefit) expense	205	(103)	1,014	560
Net loss	\$ (926)	\$ (916)	\$ (72,780)	\$ (19,366)
Net loss per common share – basic and diluted	\$ (0.05)	\$ (0.05)	\$ (4.21)	\$ (1.14)
Weighted average shares outstanding – basic and diluted	17,327	17,037	17,274	16,992

HEARTWARE INTERNATIONAL, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

(unaudited)

December 31,	December 31,
2015	2014

ASSETS

Current assets:

Cash and cash equivalents	\$	175,047	\$	102,946
Short-term investments	68,531		75,535	
Accounts receivable, net	35,570		38,041	
Inventories	47,686		54,046	
Prepaid expenses and other current assets	2,868		5,975	
Total current assets	329,702		276,543	
Property, plant and equipment, net	15,098		19,036	
Other assets, net	112,776		128,234	
Total assets	\$	457,576	\$	423,813

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable	\$	15,249	\$	13,322
Other accrued liabilities	45,889		36,589	
Total current liabilities	61,138		49,911	
Convertible senior notes, net	191,062		114,803	
Other long-term liabilities	16,884		50,565	
Stockholders' equity	188,492		208,534	
Total liabilities and stockholders' equity	\$	457,576	\$	423,813

Reconciliation to Constant-Currency Revenue Growth (unaudited) *(see explanation below)*

(in thousands)

	Three Months Ended		Reported \$ chg	Reported % chg	FX impact	Constant Currency \$ chg	Constant Currency % chg
	December 31, 2015	2014					
Total U.S. Revenue	41,160	41,534	(374)	-0.9%	-	(374)	-0.9%
Total Int'l Revenue	26,927	31,675	(4,748)	-15.0%	3,377	(1,371)	-4.3%
Total Revenue	68,087	73,209	(5,122)	-7.0%	3,377	(1,745)	-2.4%
	Years Ended December 31,		Reported \$ chg	Reported % chg	FX impact	Constant Currency \$ chg	Constant Currency % chg
	2015	2014					
Total U.S. Revenue	161,848	151,335	10,513	6.9%	-	10,513	6.9%
Total Int'l Revenue	114,995	127,085	(12,090)	-9.5%	19,226	7,136	5.6%
Total Revenue	276,843	278,420	(1,577)	-0.6%	19,226	17,649	6.3%

Constant-currency changes in the tables above take into consideration the foreign exchange rates in effect during the three- and twelve-month periods ended December 31, 2015 and 2014.

Reconciliation of GAAP to Non-GAAP Net Loss Per Common Share (unaudited)(see explanation of adjustments below)

(in thousands, except per share data)

	<u>Three Months Ended</u>		<u>Years Ended</u>	
	<u>December 31,</u>		<u>December 31,</u>	
	2015	2014	2015	2014
GAAP net loss	\$ (926)	\$ (916)	\$ (72,780)	\$ (19,366)
GAAP net loss per common share – basic and diluted	\$ (0.05)	\$ (0.05)	\$ (4.21)	\$ (1.14)
Adjustments:				
Amortization of purchased intangible assets and goodwill	(a)			
-Selling, general and administrative	84	84	5,136	337
-Research and development	327	348	1,309	1,069
Impairment of intangible assets	(b)26,849	2,650	26,849	2,650
Acquisition-related transaction costs	(c)1,557	—	5,623	—
Contingent consideration adjustments	(d)(38,110)	(9,080)	(31,410)	(23,260)
Loss on extinguishment of long-term debt	(e)—	—	16,588	—
Restructuring costs	(f)			
-Selling, general and administrative	1,001	(27)	1,437	2,962
-Research and development	—	—	2,212	1,053
Total adjustments	(8,292)	(6,025)	22,945	(15,189)
Non-GAAP net loss	\$ (9,218)	\$ (6,941)	\$ (49,835)	\$ (34,555)
Non-GAAP net loss per common share – basic and diluted	\$ (0.53)	\$ (0.41)	\$ (2.89)	\$ (2.03)
Shares used in computing non-GAAP net loss per common share – basic and diluted	17,327	17,037	17,274	16,992

(a) Represents amortization of purchased intangible assets related to CircuLite and WorldHeart during the three and twelve months ended December 31, 2015 and 2014.

(b) Represents impairment of purchased intangible assets related to CircuLite.

(c) Represents transaction costs associated with the terminated business combination with Valtech.

(d) Represents the change in fair value of contingent consideration associated with the acquisition of CircuLite in December 2013.

(e) Represents the loss on extinguishment of 3.5% convertible notes.

(f) Represents certain restructuring costs incurred during the three and twelve months ended December 31, 2015 and 2014 as follows (in thousands):

	<u>Three Months</u> <u>Ended</u>		<u>Years Ended</u> <u>December 31,</u>	
	<u>December 31,</u> 2015	2014	2015	2014
Charges related to CircuLite acquisition:				
Lease exit charge for former N.J. corporate offices	\$ 1,001	\$ 15	\$ 1,465	\$ 1,725
Lease exit charge for Aachen, Germany office	—	—	139	—
Contract termination costs	—	—	338	688
Employee severance	—	(29)	598	588
Abandoned fixed assets	—	—	1,137	655
Total	1,001	(14)	3,677	3,656
Lease exit charge for HeartWare's former Massachusetts corporate offices	\$ —	\$ (13)	\$ (28)	\$ 359
Total restructuring costs	\$ 1,001	\$ (27)	\$ 3,649	\$ 4,015

The terms "non-GAAP net loss" and "non-GAAP net loss per common share" refer to GAAP net (loss)/income and GAAP net (loss)/income per common share excluding certain adjustments such as amortization of purchased intangible assets, impairment charges, purchase accounting and acquisition-related transaction costs, loss on extinguishment of long-term debt, and restructuring and severance costs as follows:

We exclude amortization of purchased intangible assets and periodic impairment charges related to long-lived assets from this 1)measure because such charges do not represent what our management believes are the costs of developing, producing, supporting and selling our products and the costs to support our internal operating structure.

We exclude purchase accounting adjustments and acquisition-related costs from this measure because they occur as a result 2)of specific events and are not reflective of our internal investments and the ongoing costs to support our operating structure.

Purchase accounting adjustments include contingent consideration fair market value adjustments.

We exclude restructuring and severance costs from this measure because they tend to occur as a result of specific events 3)such as acquisitions, divestitures, repositioning our business or other unusual events that could make comparisons of long-range trends difficult and are not reflective of our internal investments and the costs to support our operating structure.

We exclude loss on extinguishment of long-term debt from this measure because these charges, unlike other core business 4)costs, are the result of infrequent and irregular events.

To view the original version on PR Newswire, visit <http://www.prnewswire.com/news-releases/heartware-international-reports-fourth-quarter-and-full-year-2015-financial-results-300226018.html>

SOURCE HeartWare International, Inc.

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