Medtronic News

HeartWare International Reports $68.6 Million In Third Quarter 2014 Revenue; 25% Increase From Third Quarter 2013

- Record 675 HeartWare® Ventricular Assist Systems sold worldwide in Q3
- U.S. revenue of $39.1 million, 39% growth from third quarter 2013
- International revenue of $29.5 million, 11% growth from third quarter 2013
- Conference call today at 8:00 a.m. U.S. EDT -

FRAMINGHAM, Mass., Oct. 30, 2014 /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 revenue of $68.6 million for the third quarter ended September 30, 2014, a 25% increase compared to $54.8 million in revenue for the same period of 2013.

During the third quarter, 675 HeartWare® Ventricular Assist Systems were sold globally, compared to 550 units in the third quarter of 2013. U.S. revenue, generated through the sale of 361 units during the third quarter of 2014, was $39.1 million, a 39% increase from $28.2 million in the third quarter of 2013. Revenue from international markets was $29.5 million, an increase of 11% from $26.6 million in the third quarter of 2013.

"Results for the third quarter were quite encouraging, as we continue building out our global operations," said Doug Godshall, President and Chief Executive Officer. "On top of our strong commercial results, we advanced our clinical initiatives, including preparing our request to commence a CE Mark study of our next-generation MVAD® System, which we expect to submit for regulatory review later this year or in early 2015. For the HVAD® System, we also completed enrollment in our Japan study during the quarter, advanced enrollment in our U.S. Destination Therapy study and are finalizing plans to initiate a U.S. IDE study for the Thoracotomy implant technique later this year.

"As we continue to drive these programs forward, we remain focused on addressing and remedying the observations raised by FDA following an inspection at our Miami Lakes, Florida facility earlier this year," Godshall added.

For the nine months ended September 30, 2014, revenue increased approximately 33% to $205.2 million, compared to $154.9 million in the first nine months of 2013.

Currency fluctuations offset sequential revenue performance by approximately $0.8 million, or 1.1 percentage points, compared to the second fiscal quarter of 2014, yet favorably impacted revenue growth by approximately 0.5 and 1.9 percentage points in the three and nine months ended September 30, 2014, respectively, as compared to the same periods in 2013.

Gross margin percentage improved to 66.5% in the third quarter of 2014, as compared to 64.4% in the third quarter of 2013. The improvement compared to the same period in 2013 primarily reflects efficiencies associated with increased manufacturing throughput.

Total operating expenses for the third quarter of 2014 were $46.4 million, as compared to $45.8 million in the third quarter of 2013. Total operating expenses for the third quarter of 2014 include a $3.6 million reduction in the estimated fair value of the contingent consideration for CircuLite, which was acquired by HeartWare in December 2013.

Research and development expense was $29.5 million for the third quarter of 2014, as compared to $25.9 million in the same period of 2013. Increased development costs are primarily attributable to the acquisition of CircuLite, preparations for human testing of the MVAD® System and associated peripherals, and increasing clinical activity overall.

Selling, general and administrative expenses were $20.6 million in the third quarter of 2014, compared to $19.8 million in the

third quarter of 2013. The increase in selling, general and administrative expenses primarily reflects the acquisition of CircuLite, the expansion of sales and marketing activities globally, increased employee expenses and other administrative expenses.

Net loss for the third quarter of 2014 was $7.4 million, or $0.43 per basic and diluted share, compared to a net loss of $11.4 million, or a loss of $0.69 per basic and diluted share, in the third quarter of 2013. Net loss for the third quarter of 2014 includes a $3.6 million reduction in the estimated fair value of the contingent consideration for the CircuLite acquisition. For the nine months ended September 30, 2014, the company recorded a net loss of $18.5 million, or a $1.09 loss per basic and diluted share, compared to a $37.3 million net loss, or a loss of $2.34 per basic and diluted share, in the first nine months of 2013.

Non-GAAP net loss for the third quarter of 2014 was $0.64 per basic and diluted share, compared to a loss of $0.69 per basic and diluted share in the third quarter of 2013. Non-GAAP net loss for the nine months ended September 30, 2014 was $1.63 per basic and diluted share, compared to a loss of $2.33 per basic and diluted share, in the first nine months of 2013. See "Use of Non-GAAP Financial Measures" and "Reconciliation of GAAP to Non-GAAP Net Loss per Common Share."

At September 30, 2014, HeartWare had $182 million of cash, cash equivalents and investments.

Conference Call and Webcast Information

HeartWare will host a conference call on Thursday, October 30, 2014 at 8:00 a.m., U.S. Eastern Daylight Time to discuss its financial results, highlights from the third quarter and the company's business outlook. The 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.

A live webcast of the call will also be available in the Investor section of the company's website (http://ir.heartware.com/). 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 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 40 countries. The device is also currently the subject of a U.S. clinical trial for destination therapy. For additional information, please visit the Company's website at www.heartware.com.

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

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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 adjusted net loss" and "non-GAAP adjusted 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, 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 as a substitute for measures in accordance with 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 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 the commercialization of the HeartWare® Ventricular Assist System, progress of clinical trials and post-approval studies, regulatory status 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 September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenue, net	$ 68,608	$ 54,800	$ 205,211	$ 154,875
Cost of revenue	22,977	19,529	68,846	57,175
Gross profit	45,631	35,271	136,365	97,700
Operating expenses:				
Selling, general and administrative	20,584	19,844	65,765	53,548
Research and development	29,477	25,930	88,981	72,201
Change in fair value of contingent consideration	(3,620)	-	(14,180)	-
Total operating expenses	46,441	45,774	140,566	125,749
Loss from operations	(810)	(10,503)	(4,201)	(28,049)
Other expense, net	(6,472)	(868)	(13,586)	(9,214)
Loss before income taxes	(7,282)	(11,371)	(17,787)	(37,263)
Provision for income taxes	88	-	663	-
Net loss	$ (7,370)	$ (11,371)	$ (18,450)	$ (37,263)
Net loss per common share - basic and diluted	$ (0.43)	$ (0.69)	$ (1.09)	$ (2.34)
Weighted average shares outstanding - basic and diluted	17,007	16,439	16,977	15,895

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

(unaudited)

	September 30, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 113,648	$ 162,880
Short-term investments	66,617	37,596

Accounts receivable, net	37,428	28,052
Inventories	51,835	40,876
Prepaid expenses and other current assets	8,125	11,205
Total current assets	277,653	280,609
Property, plant and equipment, net	19,777	18,562
Other assets, net	131,432	130,656
Total assets	$ 428,862	$ 429,827
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 15,458	$ 17,914
Other accrued liabilities	38,004	35,276
Total current liabilities	53,462	53,190
Convertible senior notes, net	112,796	107,125
Other long-term liabilities	59,436	70,905
Stockholders' equity	203,168	198,607
Total liabilities and stockholders' equity	$ 428,862	$ 429,827

Reconciliation of GAAP to Non-GAAP Net Loss per Common Share (unaudited)*(see explanation of adjustments below) (in thousands, except per share data)*

		Three Months Ended September 30,		Nine Months Ended September 30,	
		2014	2013	2014	2013
GAAP net loss		$ (7,370)	$ (11,371)	$ (18,450)	$ (37,263)
GAAP net loss per common share – basic and diluted		$ (0.43)	$ (0.69)	$ (1.09)	$ (2.34)
Adjustments:					
Amortization of purchased intangible assets	(a)				
-Selling, general and administrative		84	50	252	150
-Research and development		247		721	
Acquisition-related contingent consideration adjustments	(b)	(3,620)	-	(14,180)	-
Restructuring costs	(c)				
-Selling, general and administrative		(79)	-	2,985	-
-Research and development		(66)	-	1,032	-
Total adjustments		(3,434)	50	(9,190)	150

Non-GAAP adjusted net loss	$ (10,804)	$ (11,321)	$ (27,640)	$ (37,113)
Non-GAAP adjusted net loss per common share – basic and diluted	$ (0.64)	$ (0.69)	$ (1.63)	$ (2.33)
Shares used in computing non-GAAP adjusted net loss per common share – basic and diluted	17,007	16,439	16,977	15,895

(a)	Represents amortization of purchased intangible assets related to CircuLite and WorldHeart during the three and nine months ended September 30, 2014, and WorldHeart during the three and nine months ended September 30, 2013.
(b)	Represents the change in fair value of contingent consideration associated with the acquisition of CircuLite in December 2013.
(c)	Represents certain restructuring costs incurred during the three and nine months ended September 30, 2014, respectively, as follows (in thousands):

	Q3	YTD
Lease exit charge for HeartWare's former Massachusetts corporate offices	$ (98)	$ 373
Charges related to CircuLite acquisition:		
Lease exit charge for former N.J. corporate offices	19	1,709
Contract termination costs	-	688
Employee severance	(66)	618
Abandoned fixed assets	-	629
Total	$ (47)	$3,644
Total restructuring costs	$ (145)	$4,017

The terms "non-GAAP adjusted net loss" and "non-GAAP adjusted net loss per common share" refer to GAAP net loss and GAAP net loss per common share excluding certain adjustments such as amortization of purchased intangible assets, impairment charges, purchase accounting and acquisition-related transaction costs, and restructuring and severance costs as follows:

1. We exclude amortization of purchased intangible assets and periodic impairment charges related to long-lived assets from this 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.
2. We exclude purchase accounting adjustments and acquisition-related costs from this measure because they occur as a result 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 value adjustments.
3. We exclude restructuring and severance costs from this measure because they tend to occur as a result of specific events 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.

SOURCE HeartWare International, Inc.

https://news.medtronic.com/2014-10-30-HeartWare-International-Reports-68-6-Million-In-Third-Quarter-2014-Revenue-25-Increase-From-Third-Quarter-2013