Medtronic News

HeartWare International Reports $70.1 Million In Second Quarter 2014 Revenue; 38% Increase From Second Quarter 2013

- Record 674 HeartWare® Ventricular Assist Systems sold worldwide in Q2
- U.S. revenue of $36.9 million, 47% growth from second quarter 2013
- International revenue of $33.2 million, 29% growth from second quarter 2013
- Conference call today at 8:00 a.m. U.S. EDT -

FRAMINGHAM, Mass., July 31, 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 $70.1 million for the second quarter ended June 30, 2014, a 38% increase compared to $50.8 million in revenue for the same period of 2013.

During the second quarter, 674 HeartWare® Ventricular Assist Systems were sold globally compared to 523 units in the second quarter of 2013. U.S. revenue, generated through the sale of 338 units during the second quarter of 2014, was $36.9 million, a 47% increase from $25.1 million in the second quarter of 2013. Revenue from international markets was $33.2 million, an increase of 29% from $25.7 million in the second quarter of 2013.

"We are pleased to announce another encouraging quarterly performance, with record sales and more than 300 units in both the U.S. as well as international markets for the second consecutive quarter," said Doug Godshall, President and Chief Executive Officer. "More than 6,000 patients from 40 countries around the globe have received the HeartWare System as a treatment for their advanced heart failure, with patient support extending as long as seven years.

"In addition to our commercial efforts, we continue to make investments to advance our clinical trials, including enrolling the second phase of our destination therapy study in the U.S., moving toward completion of enrollment of our Japan trial and preparing to initiate the clinical evaluation of our next-generation MVAD® System," Godshall said. "As we continue to drive these programs forward, our highest internal priority remains addressing and remedying the observations raised by FDA following an inspection at our Miami Lakes, Florida facility earlier this year."

For the six months ended June 30, 2014, revenue increased approximately 36% to $136.6 million, compared to $100.1 million in the first six months of 2013.

Currency fluctuations benefitted revenue growth by approximately 3.1 and 2.6 percentage points in the three and six months ended June 30, 2014, respectively, as compared to the same periods in 2013.

Gross margin percentage improved to 67.3% in the second quarter of 2014, as compared to 62.9% in the second quarter of 2013. The improvement compared to the same period in 2013 primarily reflects efficiencies associated with increased manufacturing throughput, partially offset by a charge of $1.7 million for the extension of a prior field safety corrective action to replace certain older batteries through a voluntary recall initiated yesterday, July 30, 2014.

Total operating expenses for the second quarter of 2014 were $34.2 million, as compared to $41.4 million in the second quarter of 2013. Total operating expenses for the second quarter of 2014 include a $13.7 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 $26.9 million for the second quarter of 2014, as compared to $24.2 million in the same period of 2013. Increased development costs are primarily attributable to the acquisition of CircuLite, preparations for human clinical testing for the MVAD® System and associated peripherals, and increasing clinical activity.

Selling, general and administrative expenses were $20.9 million in the second quarter of 2014, compared to $17.2 million in the second quarter of 2013. The increase in selling, general and administrative expenses primarily reflects the acquisition of CircuLite, the expansion of sales and marketing activities, increased employee expenses and other administrative expenses.

Net income for the second quarter of 2014 was $8.4 million, or $0.49 per basic and $0.48 per diluted share, compared to a net loss of $12.9 million, or a loss of $0.79 per basic and diluted share, in the second quarter of 2013. Net income for the second quarter of 2014 includes a $13.7 million reduction in the estimated fair value of the contingent consideration for the CircuLite acquisition. This non-recurring benefit was the primary factor resulting in positive net income in the second quarter of 2014. For the six months ended June 30, 2014, the company recorded a net loss of $11.1 million, or a $0.65 loss per basic and diluted share, compared to a $25.9 million net loss, or a loss of $1.66 per basic and diluted share, in the first six months of 2013.

Non-GAAP net loss for the second quarter of 2014 was $0.29 per basic and diluted share, compared to a loss of $0.79 per basic and diluted share in the second quarter of 2013. Non-GAAP net loss for the six months ended June 30, 2014 was $0.99 per basic and diluted share, compared to a loss of $1.65 per basic and diluted share, in the first six months of 2013. See "Use of Non-GAAP Financial Measures" and "Reconciliation of GAAP to Non-GAAP Net Income per Common Share."

At June 30, 2014, HeartWare had $184 million of cash, cash equivalents and investments, an increase from $181 million at the end of the first quarter on March 31, 2014.

Conference Call and Webcast Information

HeartWare will host a conference call on Thursday, July 31, 2014 at 8:00 a.m., U.S. Eastern Daylight Time to discuss its financial results, highlights from the second 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 Class IIIB / IV 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	Six Months Ended
	June 30,	June 30,

	2014	2013	2014	2013
Revenue, net	$ 70,131	$ 50,836	$ 136,603	$ 100,075
Cost of revenue	22,955	18,866	45,870	37,646
Gross profit	47,176	31,970	90,733	62,429
Operating expenses:				
Selling, general and administrative	20,948	17,217	45,180	33,704
Research and development	26,913	24,188	59,504	46,330
Change in fair value of contingent consideration	(13,700)	-	(10,560)	-
Total operating expenses	34,161	41,405	94,124	80,034
Income (loss) from operations	13,015	(9,435)	(3,391)	(17,605)
Other expense, net	(4,651)	(3,499)	(7,689)	(8,288)
Net income (loss)	$ 8,364	$ (12,934)	$ (11,080)	$ (25,893)
Net income (loss) per common share:				
Basic	$ 0.49	$ (0.79)	$ (0.65)	$ (1.66)
Diluted	$ 0.48	$ (0.79)	$ (0.65)	$ (1.66)
Weighted average shares outstanding:				
Basic	16,989	16,370	16,962	15,619
Diluted	17,305	16,370	16,962	15,619

HEARTWARE INTERNATIONAL, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

(unaudited)

	June 30, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 146,595	$ 162,880
Short-term investments	36,104	37,596
Accounts receivable, net	36,487	28,052
Inventories	45,692	40,876
Prepaid expenses and other current assets	7,780	11,205
Total current assets	272,658	280,609

Property, plant and equipment, net	19,843	18,562
Other assets, net	129,710	130,656
Total assets	$ 422,211	$ 429,827
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 11,794	$ 17,914
Other accrued liabilities	35,348	35,276
Total current liabilities	47,142	53,190
Convertible senior notes, net	110,849	107,125
Other long-term liabilities	60,431	70,905
Stockholders' equity	203,789	198,607
Total liabilities and stockholders' equity	$ 422,211	$ 429,827

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

		Three Months Ended June 30,		Six Months Ended June 30,	
		2014	2013	2014	2013
GAAP net income (loss)		$ 8,364	$ (12,934)	$ (11,080)	$ (25,893)
GAAP net income (loss) per common share:					
Basic		$ 0.49	$ (0.79)	$ (0.65)	$ (1.66)
Diluted		$ 0.48	$ (0.79)	$ (0.65)	$ (1.66)
Adjustments:					
Amortization of purchased intangible assets	(a)				
-Selling, general and administrative		84	50	168	100
-Research and development		247	-	474	-
Acquisition-related contingent consideration adjustments	(b)	(13,700)	-	(10,560)	-
Restructuring costs	(c)				
-Selling, general and administrative		38	-	3,064	-
-Research and development		72	-	1,098	-
Total adjustments		(13,259)	50	(5,756)	100
Non-GAAP adjusted net loss		$ (4,895)	$ (12,884)	$ (16,836)	$ (25,793)
Non-GAAP adjusted net loss per common share – basic and diluted		$ (0.29)	$ (0.79)	$ (0.99)	$ (1.65)
Shares used in computing non-GAAP adjusted net loss per common share – basic and diluted		16,989	16,370	16,962	15,619

(a) Represents amortization of purchased intangible assets related to CircuLite and WorldHeart during the three and six months ended June 30, 2014, and WorldHeart during the three and six months ended June 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 six months ended June 30, 2014, respectively, as follows (in thousands):

	Q2	YTD
Lease exit charge (recovery) for HeartWare's former Mass. corporate offices	$ (57)	$ 471
Charges related to CircuLite acquisition:		
Lease exit charge for former N.J. corporate offices	14	1,690
Contract termination costs	-	688
Employee severance	153	684
Abandoned fixed assets	-	629
Total	$ 167	$3,691
Total Restructuring costs	$ 110	$4,162

The terms "non-GAAP adjusted net loss" and "non-GAAP adjusted net loss per common share" refer to GAAP net income (loss) and GAAP net income (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 market 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.

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https://news.medtronic.com/2014-07-31-HeartWare-International-Reports-70-1-Million-In-Second-Quarter-2014-Revenue-38-Increase-From-Second-Quarter-2013