Medtronic News

HeartWare International Reports Fourth Quarter 2013 Results

- U.S. revenue increased 94% in fourth quarter 2013 to $25.9 million, from $13.4 million in fourth quarter of 2012
- Revenue for 2013 increased 87% to $208 million from $111 million in 2012, reflects first year of commercialization in U.S.
- Conference call today at 8:00 a.m. U.S. EST -

FRAMINGHAM, Mass., Feb. 27, 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 $53.1 million for the fourth quarter ended December 31, 2013, a 62% increase compared to $32.7 million in revenue for the same period of 2012. For the fiscal year 2013, the company generated revenue of $207.9 million, an 87% increase compared to revenue of $110.9 million in fiscal year 2012.

"We experienced strong market adoption of the HeartWare® Ventricular Assist System during our first full year of U.S. commercialization, with nearly 1,000 units sold and a total of 96 U.S. customers at the close of the year," said Doug Godshall, President and Chief Executive Officer. "In addition, we continue to receive enthusiastic support from markets outside of the U.S., with the addition of 28 international customers in new and existing markets. We are proud to have finished the year with 230 customers worldwide, an increase of nearly 50% in 2013."

During the fourth quarter, 524 HeartWare Systems were sold globally, a 52% increase from 345 units in the fourth quarter of 2012. U.S. revenue during the fourth quarter of 2013 was $25.9 million, a 94% increase from $13.4 million in the fourth quarter of 2012. Revenue from international markets, generated through the sale of 282 units, was $27.1 million, an increase of approximately 41% from $19.3 million in the fourth quarter of 2012.

"Our strong commercial growth was complemented by advances made in the clinical development of the HeartWare System," added Mr. Godshall. "During 2013, we initiated enrollment in the U.S. for our supplemental cohort study for destination therapy, received approval to commence enrollment in our trial in Japan, and we obtained conditional approval from the FDA for our U.S. thoracotomy trial. We are eagerly anticipating the upcoming initiation of first-in-human testing of our next generation MVAD® pump and Pal™ peripherals, which is expected to precede the commencement of a 63-patient, CE Mark study at nine international hospital sites.

"The acquisition of CircuLite, developer of the SYNERGY® Circulatory Support System, in December 2013, provides an opportunity for us to expand our core business into the partial-support market segment, through the treatment of heart failure patients who are less sick," Mr. Godshall said. "Our team is working diligently to make refinements to this device in order to position the SYNERGY System for re-launch at select European sites and to enhance the SYNERGY® Endovascular System when it enters the clinic."

Currency fluctuations benefitted revenue growth by approximately two percentage points in the fourth quarter, as well as on a full-year basis, in 2013 compared to the same periods in 2012.

Total operating expenses for the fourth quarter of 2013 were $53.3 million, as compared to $35.4 million in the fourth quarter of 2012. Total operating expenses included CircuLite's results for the month of December.

Research and development expense was $30.3 million for the fourth quarter of 2013, as compared to $22.2 million in the same period of 2012. Development costs are primarily attributable to clinical trials and research and development related to advancing HeartWare's existing products and pipeline technologies.

Selling, general and administrative expenses were $23.0 million in the fourth quarter of 2013, compared to $13.3 million in the

fourth quarter of 2012. The increase in selling, general and administrative expenses reflects expansion of sales and marketing activities, particularly in the U.S., and an overall increase in corporate infrastructure to support the company's significant growth.

Net loss for the fourth quarter of 2013 was $22.0 million, or a $1.33 loss per basic and diluted share, compared to a $21.1 million net loss, or a loss of $1.46 per basic and diluted share, in the fourth quarter of 2012. The fourth quarter results included CircuLite's operations for the month of December, as well as approximately $6.7 million of non-recurring costs as set forth in this release under "Reconciliation of GAAP to Non-GAAP Net Loss per Share." For the fiscal year ended December 31, 2013, the company recorded a net loss of $59.3 million, or a $3.69 loss per basic and diluted share, compared to an $87.7 million net loss, or a loss of $6.15 per basic and diluted share, in fiscal year 2012.

Non-GAAP net loss per share for the fourth quarter of 2013 was $0.92 per basic and diluted share, compared to a loss of $1.46 per basic and diluted share in the fourth quarter of 2012. Non-GAAP net loss per share for 2013 was $3.24 compared to a loss of $6.07 per basic and diluted share in 2012. See "Use of Non-GAAP Financial Measures" and "Reconciliation of GAAP to Non-GAAP Net Loss per Share."

At December 31, 2013, HeartWare had $201.7 million of cash, cash equivalents and investments.

Conference Call and Webcast Information

HeartWare will host a conference call on Thursday, February 27, 2014 at 8:00 a.m., U.S. Eastern Standard Time to discuss its financial results from the fourth quarter, highlights from the 2013 fiscal year and the company's business outlook. The call may be accessed by dialing 1-877-941-4774 five minutes prior to the scheduled start time and referencing "HeartWare." Callers outside the U.S. should dial +1-480-629-9760.

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.

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 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 Share."

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 37 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.

HEARTWARE, HVAD, MVAD, PAL, SYNERGY, CIRCULITE and HeartWare logos are registered trademarks of HeartWare, Inc.

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, continued support from international customers, progress of clinical trials and post-approval studies, regulatory status, 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 December 31,		Year Ended December 31,	
	2013	2012	2013	2012
Revenue, net	$ 53,054	$ 32,662	$ 207,929	$ 110,922
Cost of revenue	19,293	16,606	76,468	51,023
Gross profit	33,761	16,056	131,461	59,899
Operating expenses:				
Selling, general and administrative	22,976	13,257	76,524	53,945
Research and development	30,281	22,157	102,483	83,548
Total operating expenses	53,257	35,414	179,007	137,493
Loss from operations	(19,496)	(19,358)	(47,546)	(77,594)
Other expense, net	(1,926)	(1,747)	(11,298)	(10,124)
Loss before income taxes	(21,422)	(21,105)	(58,844)	(87,718)
Provision for income taxes	626	–	467	–
Net loss	$ (22,048)	$ (21,105)	$ (59,311)	$ (87,718)
Net loss per common share — basic and diluted	$ (1.33)	$ (1.46)	$ (3.69)	$ (6.15)
Weighted average shares outstanding — basic and diluted	16,574	14,451	16,066	14,252

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

(unaudited)

	December 31, 2013	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$ 162,880	$ 85,921
Short-term investments	37,596	16,887

Accounts receivable, net	28,052	25,225
Inventories	40,876	38,443
Prepaid expenses and other current assets	11,205	5,925
Total current assets	280,609	172,401
Property, plant and equipment, net	18,562	19,380
Goodwill	61,596	1,190
In-process research and development	35,500	2,536
Other intangible assets, net	15,975	5,258
Other assets, net	17,585	5,734
Total assets	$ 429,827	$ 206,499
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 17,914	$ 12,024
Other accrued liabilities	35,276	22,020
Total current liabilities	53,190	34,044
Convertible senior notes, net	107,125	100,315
Contingent liabilities	67,000	–
Other long-term liabilities	3,905	3,929
Stockholders' equity	198,607	68,211
Total liabilities and stockholders' equity	$ 429,827	$ 206,499

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

(in thousands except per share data)

		Three Months Ended December 31,		Year Ended December 31,	
		2013	2012	2013	2012
GAAP net loss		$ (22,048)	$ (21,105)	$ (59,311)	$ (87,718)
GAAP EPS – basic and diluted		$ (1.33)	$ (1.46)	$ (3.69)	$ (6.15)
Adjustments:					
Amortization and impairment of purchased intangible assets and goodwill	(a)	3,747	21	3,809	35
Acquisition related transaction costs	(b)	2,349	-	2,849	1,100
Restructuring and severance costs	(c)	649	-	649	-
Total adjustments		6,745	21	7,307	1,135

Per share effect of adjustments - basic and diluted	$ 0.41	$ 0.00	$ 0.45	$ 0.08
Non-GAAP net loss	$ (15,303)	$ (21,084)	$ (52,004)	$ (86,583)
Non-GAAP net loss per share - basic and diluted	$ (0.92)	$ (1.46)	$ (3.24)	$ (6.07)
Shares used in computing non-GAAP loss per share - basic and diluted	16,574	14,451	16,066	14,252

(a)	Represents amortization of purchased intangible assets related to WorldHeart and CircuLite as well as $3.7 million related to goodwill and in-process research and development impairment charges related to WorldHeart during the quarter ended December 31, 2013.
(b)	Represents acquisition transaction costs associated with the purchase of WorldHeart in August 2012 and CircuLite in December 2013.
(c)	Represents separation costs incurred in connection with the termination of certain employees of CircuLite during the quarter ended December 31, 2013.

The terms "non-GAAP net loss" and "non-GAAP net loss per share" 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 as follows:

1)	We exclude amortization of purchased intangible assets and periodic impairment charges related to long-lived assets from this measure because these 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.

Non-GAAP net loss per share is calculated by subtracting the total per share effect of these adjustments from GAAP EPS.

SOURCE HeartWare International, Inc.

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https://news.medtronic.com/2014-02-27-HeartWare-International-Reports-Fourth-Quarter-2013-Results