

HeartWare International Reports \$66.5 Million In First Quarter 2014 Revenue; 35% Increase From First Quarter 2013

- *Record 665 HeartWare® Ventricular Assist Systems sold worldwide in Q1; exceeds previous quarterly high of 549 units*
- *U.S. revenue of \$33.8 million, 29% growth from first quarter 2013*
- *International revenue of \$32.7 million, 42% growth from first quarter 2013*
- *Conference call today at 8:00 a.m. U.S. EDT -*

FRAMINGHAM, Mass., May 1, 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 \$66.5 million for the first quarter ended March 31, 2014, a 35% increase compared to \$49.2 million in revenue for the same period of 2013.

During the first quarter, 665 HeartWare® Ventricular Assist Systems were sold globally, a 38% increase from 482 units in the first quarter of 2013. U.S. revenue during the first quarter of 2014 was \$33.8 million, a 29% increase from \$26.2 million in the first quarter of 2013. Revenue from international markets, generated through the sale of 352 units, was \$32.7 million, an increase of 42% from \$23.1 million in the first quarter of 2013.

"Reflecting expanded global adoption, our team generated sales of more than 300 units in both the U.S. as well as international markets, for the first time in our history," said Doug Godshall, President and Chief Executive Officer. "We continue to see enthusiastic support of the HeartWare® System around the world, with the addition of 12 international and 5 U.S. customers during the first quarter, increasing our global customer base to nearly 250 hospitals."

"During the quarter, we continued to make investments in clinical trials related to the ongoing HVAD® destination therapy study, recently initiated Japan trial and upcoming MVAD® CE Mark studies," noted Mr. Godshall. "Additionally, enrollment in our supplemental destination therapy study in the U.S. continues to gain momentum, with 48 sites receiving Institutional Review Board approval and more than 80 patients currently enrolled."

Currency fluctuations benefitted revenue growth by approximately 2 percentage points in the first quarter in 2014, as compared to the same period in 2013.

Gross margin percentage improved to 65.5% in the first quarter of 2014 compared to 61.9% in the first quarter of 2013, reflecting efficiencies associated with increased manufacturing throughput.

Total operating expenses for the first quarter of 2014 were \$60.0 million, as compared to \$38.6 million in the first quarter of 2013.

Research and development expense was \$32.6 million for the first quarter of 2014, as compared to \$22.1 million in the same period of 2013. Increased development costs are primarily attributable to the addition of a full quarter of expenses from CircuLite, which was acquired by HeartWare in December 2013, as well as preparations for human clinical testing for MVAD and associated peripherals and increasing clinical activity.

Selling, general and administrative expenses were \$24.2 million in the first quarter of 2014, compared to \$16.5 million in the first quarter of 2013. The increase in selling, general and administrative expenses reflects a full quarter of CircuLite expenses, the expansion of sales and marketing activities, increased employee expenses and other administrative expenses.

Net loss for the first quarter of 2014 was \$19.4 million, or a \$1.15 loss per basic and diluted share, compared to a \$13.0 million net loss, or a loss of \$0.87 per basic and diluted share, in the first quarter of 2013. Net loss decreased on a sequential

quarter basis, from a net loss in the fourth quarter of 2013 of \$22.0 million. The first quarter results included CircuLite's operations, as well as approximately \$7.5 million of acquisition and restructuring related costs as set forth in this release under "Reconciliation of GAAP to Non-GAAP Net Loss per Common Share."

Non-GAAP net loss per share for the first quarter of 2014 was \$0.70 per basic and diluted share, compared to a loss of \$0.87 per basic and diluted share in the first quarter of 2013. See "Use of Non-GAAP Financial Measures" and "Reconciliation of GAAP to Non-GAAP Net Loss per Common Share."

At March 31, 2014, HeartWare had \$181 million of cash, cash equivalents and investments.

Conference Call and Webcast Information

HeartWare will host a conference call on Thursday, May 1, 2014 at 8:00 a.m., U.S. Eastern Daylight Time to discuss its financial results, highlights from the first 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 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.

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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, 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	
	March 31, 2014	2013
Revenue, net	\$ 66,472	\$ 49,239
Cost of revenue	22,915	18,780
Gross profit	43,557	30,459
Operating expenses:		
Selling, general and administrative	24,232	16,488

Research and development	32,590	22,142
Change in fair value of contingent consideration	3,140	-
Total operating expenses	59,962	38,630
Loss from operations	(16,405)	(8,171)
Other expense, net	(3,039)	(4,788)
Net loss	\$ (19,444)	\$ (12,959)
Net loss per common share — basic and diluted	\$ (1.15)	\$ (0.87)
Weighted average shares outstanding — basic and diluted	16,934	14,860

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

(unaudited)

	March 31, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 145,588	\$ 162,880
Short-term investments	34,188	37,596
Accounts receivable, net	41,335	28,052
Inventories, net	44,054	40,876
Prepaid expenses and other current assets	10,009	11,205
Total current assets	275,174	280,609
Property, plant and equipment, net	19,646	18,562
Other assets, net	130,677	130,656
Total assets	\$ 425,497	\$ 429,827

LIABILITIES AND STOCKHOLDERS'
EQUITY

Current liabilities:		
Accounts payable	\$ 15,108	\$ 17,914
Other accrued liabilities	38,454	35,276

Total current liabilities	53,562	53,190
Convertible senior notes, net	108,959	107,125
Other long-term liabilities	73,964	70,905
Stockholders' equity	189,012	198,607
	\$	
Total liabilities and stockholders' equity	425,497	\$ 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	
	March 31,	
	2014	2013
GAAP net loss	\$ (19,444)	\$ (12,959)
GAAP net loss per common share – basic and diluted	\$ (1.15)	\$ (0.87)
Adjustments:		
Amortization of purchased intangible assets		
-Selling, general and administrative	(a)331	71
Acquisition-related contingent consideration adjustments	(b)3,140	-
Restructuring costs	(c)	
-Selling, general and administrative	3,026	-
-Research and development	1,026	-
Total adjustments	7,523	71
Non-GAAP adjusted net loss	\$ (11,921)	\$ (12,888)
Non-GAAP adjusted net loss per common share - basic and diluted	\$ (0.70)	\$ (0.87)
Shares used in computing non-GAAP adjusted net loss per common share - basic and diluted	16,934	14,860

(a)	Represents amortization of purchased intangible assets related to CircuLite and WorldHeart during the quarter ended March 31, 2014, and WorldHeart during the quarter ended March 31, 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 quarter ended March 31, 2014 as follows (in thousands):

Lease exit charge for HeartWare's former Massachusetts corporate offices	\$ 528
Charges related to CircuLite acquisition:	
Lease exit charge for former N.J. corporate offices	1,667
Contract termination costs	688
Employee severance	562
Abandoned fixed assets	607
Total	3,524
Total Restructuring costs	\$4,052

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 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.

<https://news.medtronic.com/2014-05-01-HeartWare-International-Reports-66-5-Million-In-First-Quarter-2014-Revenue-35-Increase-From-First-Quarter-2013>