Medtronic News

HeartWare International Reports Third Quarter 2015 Results

-- Total revenue of $65.2 million reflects completion of enrollment in destination therapy clinical trial and international currency weakness
-- International unit sales increased 18% from third quarter of 2014
-- 697 HeartWare HVAD® Systems sold worldwide
- Conference call today at 8:00 a.m. U.S. ET -

FRAMINGHAM, Mass., Oct. 29, 2015 /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 total revenue of $65.2 million for the quarter ended September 30, 2015, compared to $68.6 million for the third quarter of 2014. Currency fluctuations impacted revenue growth by approximately $4.9 million, or seven percentage points, during the three months ended September 30, 2015, as compared to the same period in 2014. Third quarter global revenue increased 2.2% on a constant-currency basis, compared to the same period in 2014.

"Our financial performance during the third quarter demonstrated the underlying strength of our business but was impacted by anticipated headwinds, including clinical trial activity and foreign currency fluctuation," said Doug Godshall, President and Chief Executive Officer. "The HVAD® System drove strong, double-digit international unit sales growth for the second quarter in a row, signifying continued physician confidence in HVAD as the leading ventricular assist therapy for end-stage heart failure.

"In early August, we successfully completed enrollment in the 465-patient ENDURANCE2 destination therapy study of our HVAD System. As a result, we sold 15 units for the destination therapy study in the third quarter of 2015, compared to 62 units sold for this study in the third quarter of 2014. Exclusive of ENDURANCE2 trial units, U.S. unit sales increased by approximately 4% over the third quarter of 2014," added Mr. Godshall. "We plan to complete the one-year patient follow-up for ENDURANCE2 next summer and prepare a Pre-Market Approval (PMA) application for submission late next year, seeking a destination therapy indication."

During the third quarter, a total of 697 HeartWare HVAD Systems were sold globally, which represented a 3.3% increase from 675 units sold during the same period in 2014. U.S. revenue, generated through the sale of 327 units during the third quarter of 2015, was $35.6 million, or an 8.9% decrease from the third quarter of 2014, due to the completion of ENDURANCE2 enrollment during the quarter. International revenue, generated through the sale of 370 units during the third quarter of 2015, was $29.6 million, compared to $29.5 million during the third quarter of 2014. On a constant-currency basis, international sales improved approximately 17% on 18% unit sales growth.

"Since pausing enrollment in the MVAD® System CE Mark trial during the third quarter, we have made substantial progress toward resolving the manufacturing process issue with the MVAD System's controller and expect to resume production next month," said Mr. Godshall. "We are also reviewing reported adverse events, which are typical of those seen in other clinical trials for ventricular assist devices, and we are confident that we will resolve the issues in order to resume the MVAD CE Mark clinical trial. The MVAD System represents an important advancement in next-generation technology, and clinicians around the world remain eager to gain access to this innovative, novel device.

"In September, we also announced our plan to acquire Valtech Cardio – a strategic acquisition that will deepen our leadership in the heart failure market. Valtech's differentiated mitral and tricuspid valve repair and replacement platforms augment our mechanical circulatory support business and will establish HeartWare as a dynamic player in two of the potentially largest categories in heart failure device therapies. Valtech's flagship product, Cardioband® Mitral Reconstruction System, which received CE Mark approval for mitral valve repair during the third quarter, is well-positioned to be a leading technology in the

mitral repair market and represents one of several new technologies that comprise the Valtech portfolio. We are excited by the opportunity that the Valtech acquisition represents and look forward to continuing to introduce Valtech to investors and completing the transaction."

For the nine months ended September 30, 2015, total revenue increased by approximately $3.5 million to $208.8 million, compared to $205.2 million for the same period in 2014. This increase was primarily attributable to growth from new sites and increased utilization of the HVAD System in the U.S. during the first half of 2015, offset by international revenue declines driven by currency fluctuation. Currency headwinds negatively impacted total year-to-date revenues by approximately $16 million, or 7.8%, compared to the same nine-month period in 2014, reflecting a stronger U.S. dollar. Total revenue increased by 9.5% on a constant-currency basis compared to the first nine months of 2014. For the nine months ended September 30, 2015, HVAD System unit sales grew 12.7% in the U.S., excluding destination therapy clinical trial units, and 8.2% internationally, compared to the same period in 2014.

Gross margin percentage declined to 49.4% during the third quarter of 2015, from 65.7% during the second quarter of 2015 and 66.5% in the third quarter of 2014. This was attributable to a charge of $8.5 million primarily related to a previously announced voluntary corrective action related to certain older batteries. Foreign exchange rates and geographic mix of revenue sources were other factors contributing to the decline.

Total operating expenses for the third quarter of 2015 were $57.9 million, compared to $46.4 million for the third quarter of 2014 and $56.2 million for the second quarter of 2015. Total operating expenses for the third quarter of 2015 included Valtech acquisition transaction costs of $3.6 million and a $6.0 million net change associated with accounting for the estimated fair value of the contingent consideration recorded in connection with the CircuLite acquisition, which was completed in 2013.

Research and development (R&D) expense was $30.4 million for the third quarter of 2015, compared to $29.5 million for the same period in 2014. This increase in R&D expense was primarily attributable to increased clinical and regulatory expenses and quality system improvements.

Selling, general and administrative (SG&A) expenses were $25.2 million for the third quarter of 2015, compared to $20.6 million for the third quarter of 2014. The increase in SG&A expenses was primarily attributable to Valtech acquisition transaction costs, as well as additional headcount-related expenses.

Net loss for the third quarter of 2015 was $29.9 million, or a loss of $1.73 per basic and diluted share, compared to a net loss of $7.4 million, or $0.43 per basic and diluted share, for the third quarter of 2014. Non-GAAP net loss for the third quarter of 2015 was $23.5 million, or a loss of $1.36 per basic and diluted share, compared to a non-GAAP net loss of $10.8 million, or a loss of $0.64 per basic and diluted share, for the third quarter of 2014.

For the nine months ended September 30, 2015, the company recorded a net loss of $71.9 million, or a loss of $4.16 per basic and diluted share, compared to a net loss of $18.5 million, or a loss of $1.09 per basic and diluted share, for the nine months ended September 30, 2014. Non-GAAP net loss for the nine months ended September 30, 2015 was $40.8 million, or a loss of $2.36 per basic and diluted share, compared to a non-GAAP net loss of $27.6 million, or a loss of $1.63 per basic and diluted share, for the nine months ended September 30, 2014.

Items impacting comparability of operating results for the three- and nine-month periods ended September 30, 2015 to the same periods in 2014 include purchase accounting amortization, restructuring charges, contingent consideration adjustments, loss on extinguishment of long-term debt and transaction-related expenses, as described later in this news release under "Use of Non-GAAP Financial Measures" and "Reconciliation of GAAP to Non-GAAP Net Loss per Common Share."

At September 30, 2015, HeartWare had approximately $249 million of cash, cash equivalents and investments. This compares to approximately $252 million of cash, cash equivalents and investments as of June 30, 2015, which included approximately $76 million in net proceeds from a convertible note exchange and issuance executed during the second quarter of 2015.

Conference Call and Webcast Information

HeartWare will host a conference call on Thursday, October 29, 2015 at 8:00 a.m., U.S. Eastern 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 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 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 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."

Participants in the Solicitation

HeartWare, Valtech and their respective directors, executive officers, certain members of management and certain employees may be deemed to be participants in the solicitation of proxies in connection with the proposed acquisition of Valtech Cardio, Ltd. A description of the interests in HeartWare of its directors and executive officers is set forth in HeartWare's proxy statement for its 2015 Annual Meeting of Shareholders, which was filed with the Securities and Exchange Commission (the "SEC") on April 30, 2015. This document is available free of charge at the SEC's website at www.sec.gov or by going to HeartWare's Investors page on its corporate website at www.heartware.com. Additional information regarding the persons who may, under the rules of the SEC, be deemed participants in the solicitation of proxies in connection with the proposed transaction, and a description of their direct and indirect interests in the proposed transaction, which may differ from the interests of HeartWare stockholders or Valtech shareholders generally, will be set forth in a proxy statement/prospectus when it is filed with the SEC.

Additional Information and Where To Find It

In connection with the proposed Transactions, HW Global, Inc. ("Holdco"), has filed a Registration Statement on Form S-4 that contains a preliminary proxy statement/prospectus, which is not yet final and will be amended. Holdco intends to file a final prospectus and other relevant materials and HeartWare intends to file a definitive proxy statement and other relevant materials with the SEC in connection with the proposed Transactions. Investors and security holders of HeartWare and Valtech are urged to read these materials when they become available because they will contain important information about HeartWare, Valtech and the Transactions. The proxy statement/prospectus and other relevant materials (when they become available), and any other documents filed by Holdco or HeartWare with the SEC, may be obtained free of charge at the SEC website at www.sec.gov. In addition, investors and security holders may obtain free copies of the documents filed with the SEC by Holdco or HeartWare by directing a written request to HeartWare's investor relations department at HeartWare International, Inc., 500 Old Connecticut Path, Framingham, MA 01701, Attention: Investor Relations. Investors and security holders are urged to read the proxy statement/prospectus and the other relevant materials when they become available before making any voting or investment decision with respect to the Transactions.

This communication shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended (the "Securities Act").

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 HVAD System and introduction of the MVAD System; timing, progress and outcomes of clinical trials; regulatory and quality compliance; research and development activities; consummation of our proposed acquisition of Valtech 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 theSecurities 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		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Revenue, net	$ 65,166	$ 68,608	$ 208,756	$ 205,211
Cost of revenue	32,990	22,977	80,258	68,846
Gross profit	32,176	45,631	128,498	136,365
Operating expenses:				
Selling, general and administrative	25,171	20,584	69,347	65,765
Research and development	30,386	29,477	93,355	88,981
Change in fair value of contingent consideration	2,360	(3,620)	6,700	(14,180)
Total operating expenses	57,917	46,441	169,402	140,566
Loss from operations	(25,741)	(810)	(40,904)	(4,201)

Other expense, net	(3,914)	(6,472)	(30,142)	(13,586)
Loss before taxes	(29,655)	(7,282)	(71,046)	(17,787)
Income tax (benefit) expense	272	88	809	663
Net loss	$ (29,927)	$ (7,370)	$ (71,855)	$ (18,450)
Net loss per common share – basic and diluted	$ (1.73)	$ (0.43)	$ (4.16)	$ (1.09)
Weighted average shares outstanding – basic and diluted	17,303	17,007	17,256	16,977

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

	September 30, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 184,882	$ 102,946
Short-term investments	63,391	75,535
Accounts receivable, net	34,968	38,041
Inventories	47,245	54,046
Prepaid expenses and other current assets	6,744	5,975
Total current assets	337,230	276,543
Property, plant and equipment, net	15,711	19,036
Other assets, net	135,525	128,234
Total assets	$ 488,466	$ 423,813
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 12,731	$ 13,322
Other accrued liabilities	47,463	36,589
Total current liabilities	60,194	49,911
Convertible senior notes, net	188,790	114,803
Other long-term liabilities	55,120	50,565
Stockholders' equity	184,362	208,534
Total liabilities and stockholders' equity	$ 488,466	$ 423,813

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

(dollars in thousands)

	Three Months Ended September 30,		Reported $ chg	Reported % chg	FX impact	Constant Currency $ chg	Constant Currency % chg
	2015	2014					
Total U.S. Revenue	35,578	39,068	(3,490)	-8.9%	-	(3,490)	-8.9%
Total Int'l Revenue	29,588	29,540	48	0.2%	4,936	4,984	16.9%
Total Revenue	65,166	68,608	(3,442)	-5.0%	4,936	1,494	2.2%

	Nine Months Ended September 30,		Reported $ chg	Reported % chg	FX impact	Constant Currency $ chg	Constant Currency % chg
	2015	2014					
Total U.S. Revenue	120,689	109,801	10,888	9.9%	-	10,888	9.9%
Total Int'l Revenue	88,068	95,410	(7,343)	-7.7%	16,013	8,671	9.1%
Total Revenue	208,756	205,211	3,545	1.7%	16,013	19,558	9.5%

Constant currency changes in the tables above take into consideration the foreign exchange rates in effect during the three- and nine-month periods ended September 30, 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)*

		Three Months Ended September 30,		Nine Months Ended September 30,	
		2015	2014	2015	2014
GAAP net loss		$ (29,927)	$ (7,370)	$ (71,855)	$ (18,450)
GAAP net loss per common share – basic and diluted		$ (1.73)	$ (0.43)	$ (4.16)	$ (1.09)
Adjustments:					
Amortization of purchased intangible assets and goodwill	(a)				
-Selling, general and administrative		84	84	252	252
-Research and development		327	247	981	721
Acquisition-related transaction costs	(b)	3,641	—	3,941	—
Contingent consideration adjustments	(c)	2,360	(3,620)	6,700	(14,180)
Loss on extinguishment of long-term debt	(d)	—	—	16,588	—
Restructuring costs	(e)				
-Selling, general and administrative		13	(79)	436	2,985
-Research and development		—	(66)	2,213	1,032
Total adjustments		6,425	(3,434)	31,111	(9,190)

Non-GAAP adjusted net loss	$ (23,502)	$ (10,804)	$ (40,744)	$ (27,640)
Non-GAAP adjusted net loss per common share – basic and diluted	$ (1.36)	$ (0.64)	$ (2.36)	$ (1.63)
Shares used in computing non-GAAP adjusted net loss per common share – basic and diluted	17,303	17,007	17,256	16,977

(a) Represents amortization of purchased intangible assets related to CircuLite and WorldHeart during the three and nine months ended September 30, 2015 and 2014.

(b) Represents transaction costs associated with the possible business combination with Valtech.

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

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

(e) Represents certain restructuring costs incurred during the three and nine months ended September 30, 2015 and 2014 as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Lease exit charge for HeartWare's former Massachusetts corporate offices	$ —	$ (98)	$ (28)	$ 373
Charges related to CircuLite acquisition:				
Lease exit charge for former N.J. corporate offices	13	19	464	1,709
Lease exit charge for Aachen, Germany office	—	—	139	—
Contract termination costs	—	—	340	688
Employee severance	—	(66)	598	618
Abandoned fixed assets	—	—	1,137	629
Total	13	(47)	2,677	3,644
Total restructuring costs	$ 13	$ (145)	$ 2,649	$ 4,017

The terms "non-GAAP adjusted net loss" and "non-GAAP adjusted 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, 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.

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