

HeartWare International Reports \$68.7 Million In Second Quarter 2016 Revenue

- Global revenue increased approximately 25% from first quarter of 2016
- U.S. revenue of \$41 million represents a 23% sequential-quarter increase and a 5% decrease compared to second quarter of 2015
- International revenue of \$27.7 million represents a 28% sequential-quarter increase and 9% decrease compared to the second quarter of 2015
- Announced a definitive agreement to be acquired by Medtronic in a transaction valued at approximately \$1.1 billion; transaction expected to close during Medtronic's second fiscal quarter, pending customary closing conditions
- HeartWare will not be hosting an investor conference call today due to the pending acquisition -

FRAMINGHAM, Mass., July 28, 2016 /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 \$68.7 million for the quarter ended June 30, 2016, compared to \$73.6 million for the same period in 2015 and \$55.1 million for the first quarter of 2016. Total revenue decreased approximately 7% year-over-year, which is primarily attributable to the third quarter 2015 completion of enrollment of the company's ENDURANCE2 Destination Therapy (DT) clinical trial, which contributed approximately \$5 million to revenue in the second quarter of 2015.

During the second quarter, a total of 715 HeartWare HVAD® Systems were sold globally, representing a sequential-quarter increase of 24% from 578 units sold in the first quarter of 2016. A total of 371 units were sold in the U.S. during the second quarter, representing an increase of 26% on a sequential-quarter basis, primarily due to a rebound in the overall bridge-to-transplant market. A total of 344 units were sold internationally during the second quarter of 2016, representing an increase of 22% on a sequential-quarter basis, primarily due to increased sales in most European markets, with the exception of a slight unit decrease in Germany.

U.S. revenue was \$41.0 million for the second quarter of 2016, compared to \$42.9 million for the same period in 2015. The year-over-year decrease was primarily due to revenue generated from the ENDURANCE2 clinical trial during the second quarter of 2015. International revenue was \$27.7 million for the second quarter of 2016, compared to \$30.6 million for the same period in 2015. The year-over-year decrease was primarily due to the launch of a competitor's new device into the market. Currency fluctuations positively impacted total revenue by approximately \$0.2 million, or 0.3%, during the three months ended June 30, 2016, compared to the same period in 2015.

"Our solid second quarter performance was highlighted by a strong rebound in sales of the HVAD System in the U.S. and in most international markets," said Doug Godshall, President and Chief Executive Officer. "We are proud of the outstanding effort of our field team and are grateful to all of the heart failure specialists, cardiothoracic surgeons and VAD coordinators around the world who continue to demonstrate their enthusiasm and support for HeartWare and the HVAD System.

"During the second quarter, we made significant progress on our key priorities of pursuing a DT indication for the HVAD System and advancing the MVAD® System toward a return to the clinic," continued Mr. Godshall. "We also announced an agreement to be acquired by Medtronic and are looking forward to the close of the acquisition and the tremendous opportunity that we will have as part of the Medtronic organization. The strengths and resources of the combined company will enable accelerated innovation and pipeline development, while maintaining the exceptionally high standards HeartWare has set for being responsive to our customers and their patients."

For the six months ended June 30, 2016, total revenue decreased approximately 14% to \$123.8 million, compared to \$143.6

million for the same period in 2015, primarily due to the completion of patient enrollment for our ENDURANCE2 clinical trial during the third quarter of 2015 and the market adjusting to the introduction of a new competitive device.

Gross margin percentage was 65% during the second quarter of 2016, compared to 66% for the second quarter of 2015. Gross margin percentage for the second quarter of 2016 improved by seven percentage points on a sequential-quarter basis, due to improved sales performance and reduced field action costs during the second quarter.

Total operating expenses for the second quarter of 2016 were \$51.3 million, compared to \$56.2 million for the second quarter of 2015 and \$47.3 million for the first quarter of 2016. Total operating expenses for the second quarter of 2016 included \$0.6 million of expense related to changes in fair value of the contingent consideration associated with the 2013 acquisition of CircuLite, Inc., compared to \$2.2 million of expense in the second quarter of 2015.

Research and development expense was \$27.9 million for the second quarter of 2016, compared to \$31.7 million for the same period in 2015. The decrease in R&D expense reflects the company's focus on a narrowed set of key priorities, as well as reductions in clinical trial costs and stock-based compensation.

Selling, general and administrative expenses were \$22.8 million for the second quarter of 2016, compared to \$22.2 million for the second quarter of 2015. The increase in SG&A expenses was primarily attributable to Medtronic-related transaction costs and increased personnel-related costs, partially offset by a reduction in expenses associated with the suspension of the medical device excise tax at the beginning of 2016, and a reduction in stock-based compensation and other expenses.

Net loss for the second quarter of 2016 was \$10.9 million, or a loss of \$0.62 per basic and diluted share, compared to a net loss of \$27.4 million, or \$1.59 per basic and diluted share, for the second quarter of 2015. Non-GAAP net loss for the second quarter of 2016 was \$7.6 million, or a loss of \$0.43 per basic and diluted share, compared to a non-GAAP net loss of \$8.1 million, or a loss of \$0.47 per basic and diluted share, for the second quarter of 2015.

Net loss for the six months ended June 30, 2016 was \$28.3 million, or a loss of \$1.62 per basic and diluted share, compared to a net loss of \$41.9 million, or a loss of \$2.43 per basic and diluted share, for the six months ended June 30, 2015. Non-GAAP net loss for the six months ended June 30, 2016 was \$24.1 million, or a loss of \$1.38 per basic and diluted share, compared to a non-GAAP net loss of \$17.5 million, or a loss of \$1.02 per basic and diluted share, for the six months ended June 30, 2015.

Items impacting comparability of operating results for the three- and six-month periods ended June 30, 2016 to the same periods in 2015 include purchase accounting amortization, restructuring and lease exit costs, acquisition costs, contingent consideration adjustments and loss on extinguishment of long-term debt, 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 June 30, 2016, HeartWare had \$185 million of cash, cash equivalents and investments, compared to approximately \$189 million at March 31, 2016.

Subsequent to the close of the second quarter of 2016, on July 25, 2016, HeartWare submitted for European regulatory approval of the company's next-generation controller for the HVAD System and plans to submit the new controller for U.S. approval in August 2016, with submissions to other jurisdictions to follow. The new controller features enhancements in component reliability and incorporates multiple enhancements to support the overall user experience. The new controllers are expected to be available in the market upon regulatory approval in each territory, and HeartWare intends to enact a voluntary plan to replace existing controllers in the field with the new, upgraded controllers. The roll-out is expected to result in a charge during the third or fourth quarter of 2016 of approximately \$24 million to \$27 million for prospective replacement of HVAD controllers in the field. Beginning with the first regulatory submission, HeartWare will also defer a portion of revenue on the sales of current controllers that it intends to eventually replace. The deferred revenue will amount to approximately 7% of the

average selling price per HVAD System, and will be recognized as income at the time the new replacement controller is shipped to customers.

Due to Pending Acquisition, HeartWare Will Not Conduct an Investor Call Today

HeartWare will not be hosting an investor conference call and webcast related to the announcement of second quarter financial results due to the pending acquisition by Medtronic. Investors may find a detailed report of the company's second quarter and year-to-date financial results in the tables below, as well as in Form 10-Q filed with the U.S. Securities and Exchange Commission (SEC).

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 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, loss on extinguishment of long-term debt, 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."

About HeartWare International

HeartWare International develops and manufactures miniaturized implantable heart pumps, or ventricular assist devices, to treat patients around the world suffering from advanced heart failure. Dedicated to developing new, minimally invasive technologies to revolutionize the treatment of patients with end-stage heart failure, HeartWare has multiple technologies in development to offer progressively less-invasive mechanical circulatory support options. HeartWare's corporate headquarters are located in Framingham, Massachusetts, and the company has technology, operations, manufacturing and distribution centers in Miami Lakes, Florida; Arden Hills, Minnesota; and Hannover, Germany. For additional information about the company, please visit www.heartware.com.

Additional Information About the Transaction and Where to Find It

The tender offer by Medtronic for the outstanding shares of HeartWare commenced on July 26, 2016. Certain information related to the pending transaction included in this news release is for informational purposes only and shall not constitute an offer to purchase nor a solicitation of an offer to sell any securities of HeartWare. The offer is being made pursuant to a tender offer statement on Schedule TO, which contains an offer to purchase, form of letter of transmittal and other documents relating to the tender offer (collectively, the "Tender Offer Materials"), each filed with the SEC by Medtronic plc, Medtronic, Inc. and Medtronic Acquisition Corp. on July 26, 2016. On the same date, HeartWare filed with the SEC a solicitation/recommendation statement on Schedule 14D-9 with respect to the tender offer. The Tender Offer Materials, as well as the Schedule 14D-9, were mailed to HeartWare stockholders. HeartWare's stockholders are advised to read these documents and any other documents relating to the tender offer that have been or will be filed with the SEC carefully and in their entirety because they contain important information. HeartWare's stockholders may obtain copies of these documents for no charge at the SEC's website at www.sec.gov or by contacting HeartWare's investor relations department at investors@HeartWare.com or HeartWare International, Inc., 500 Old Connecticut Path, Framingham, MA 01701, Attention: Investor Relations.

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: HeartWare's ventricular assist device business; submission for U.S. approval of a destination therapy indication; MVAD System return to clinic; accelerating innovation and development of our technology pipeline; responsiveness to customers and patients; planned product replacement strategies and accounting treatment; and acquisition by Medtronic. 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 (SEC). 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 SEC. 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 SEC.

HEARTWARE, HVAD, MVAD, PAL, SYNERGY, CIRCULITE and HeartWare logos are trademarks of HeartWare, Inc. or its affiliates.

Contact:

Christopher Taylor

HeartWare International, Inc.

Email: ctaylor@heartware.com

Phone: +1 508 739 0864

- 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,	
	2016	2015	2016	2015
Revenue, net	\$ 68,720	\$ 73,569	\$ 123,794	\$ 143,590
Cost of revenue	23,826	25,228	46,848	47,268
Gross profit	44,894	48,341	76,946	96,322
Operating expenses:				
Selling, general and administrative	22,780	22,247	44,254	44,176

Research and development	27,878	31,702	53,099	62,969
Change in fair value of contingent consideration	600	2,240	1,180	4,340
Total operating expenses	51,258	56,189	98,533	111,485
Loss from operations	(6,364)	(7,848)	(21,587)	(15,163)
Other expense, net	(4,321)	(19,239)	(6,410)	(26,228)
Loss before taxes	(10,685)	(27,087)	(27,997)	(41,391)
Income tax expense	198	306	345	537
Net loss	\$ (10,883)	\$ (27,393)	\$ (28,342)	\$ (41,928)
Net loss per common share – basic and diluted	\$ (0.62)	\$ (1.59)	\$ (1.62)	\$ (2.43)
Weighted average shares outstanding – basic and diluted	17,543	17,269	17,503	17,232

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

June 30, 2016 December 31,
2015

ASSETS

Current assets:

Cash and cash equivalents	\$ 129,241	\$ 175,047
Short-term investments	55,981	68,531
Accounts receivable, net	38,698	35,570
Inventories	37,864	39,947
Prepaid expenses and other current assets	5,407	2,868
Total current assets	267,191	321,963
Property, plant and equipment, net	14,535	15,098
Other assets, net	147,646	116,542
Total assets	\$ 429,372	\$ 453,603

LIABILITIES AND STOCKHOLDERS'

EQUITY

Current liabilities:

Accounts payable	\$	15,501	\$	15,249
Other accrued liabilities		35,025		45,889
Total current liabilities		50,526		61,138
Convertible senior notes, net		192,107		187,089
Other long-term liabilities		17,447		16,884
Stockholders' equity		169,292		188,492
Total liabilities and stockholders' equity	\$	429,372	\$	453,603

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

(in thousands)

	Three Months Ended		Reported \$	Reported %	FX	Constant Currency \$	Constant Currency %
	June 30,		chg	chg	impact	chg	chg
	2016	2015					
Total U.S. Revenue	40,984	42,922	(1,938)	-4.5%	-	(1,938)	-4.5%
Total Int'l Revenue	27,736	30,647	(2,911)	-9.5%	(240)	(3,151)	-10.3%
Total Revenue	68,720	73,569	(4,849)	-6.6%	(240)	(5,089)	-6.9%

	Six Months Ended June		Reported \$	Reported %	FX	Constant Currency \$	Constant Currency %
	30,		chg	chg	impact	chg	chg
	2016	2015					
Total U.S. Revenue	74,332	85,111	(10,779)	-12.7%	-	(10,779)	-12.7%
Total Int'l Revenue	49,462	58,480	(9,018)	-15.4%	356	(8,661)	-14.8%
Total Revenue	123,794	143,591	(19,796)	-13.8%	356	(19,440)	-13.5%

Constant-currency changes in the tables above take into consideration the foreign exchange rates in effect during the three- and six-month periods ended June 30, 2015.

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		Six Months Ended	
June 30,		June 30,	
2016	2015	2016	2015

GAAP net loss	\$ (10,883)	\$ (27,393)	\$ (28,342)	\$ (41,928)
GAAP net loss per common share – basic and diluted	\$ (0.62)	\$ (1.59)	\$ (1.62)	\$ (2.43)
Adjustments:				
Acquisition-related contingent consideration adjustments	(a)600	2,240	1,180	4,340
Acquisition-related transaction costs	(b)2,650	-	2,650	-
Amortization of purchased intangible assets	(c)327	411	654	822
Loss on extinguishment of long-term debt	(d)-	16,588	-	16,588
Restructuring costs	(e)(288)	5	(268)	2,636
Total adjustments	3,289	19,244	4,216	24,386
Non-GAAP net loss	\$ (7,594)	\$ (8,149)	\$ (24,126)	\$ (17,542)
Non-GAAP net loss per common share - basic and diluted	\$ (0.43)	\$ (0.47)	\$ (1.38)	\$ (1.02)
Shares used in computing non-GAAP net loss per common share - basic and diluted	17,543	17,269	17,503	17,232

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
SG&A operating expenses on a GAAP basis	\$22,780	\$22,247	\$44,254	\$44,176
-Acquisition-related transaction costs	(b)(2,650)	-	(2,650)	-
-Amortization of purchased intangibles	(c)-	(84)	-	(168)
-Restructuring costs	(d)288	44	268	(423)
SG&A operating expenses on a non-GAAP basis	20,418	22,207	41,872	43,585
R&D operating expenses on a GAAP basis	27,878	31,702	53,100	62,969
-Amortization of purchased intangibles	(c)(327)	(327)	(654)	(654)
-Restructuring costs	(d)-	(49)	-	(2,213)
R&D operating expenses on a non-GAAP basis	27,551	31,326	52,446	60,102
Total SG&A and R&D on a non-GAAP Basis	\$47,969	\$53,533	\$94,318	\$103,687

(a)	Represents the change in fair value of contingent consideration associated with the acquisition of CircuLite in December 2013.
(b)	Represents transaction expenses related to the acquisition of HeartWare by Medtronic.
(c)	Represents amortization of purchased intangible assets related to CircuLite and WorldHeart during the three and six months ended June 30, 2016 and 2015.
(d)	Represents the loss on extinguishment of 3.5% convertible notes

	Represents restructuring costs comprised of lease exit costs, employee severance, abandoned fixed assets and contract (e) termination charges primarily related to the CircuLite acquisition during the three and six months ended June 30, 2016 and 2015.
--	--

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

Logo - <http://photos.prnewswire.com/prnh/20150901/262901LOGO>

To view the original version on PR Newswire, visit <http://www.prnewswire.com/news-releases/heartware-international-reports-687-million-in-second-quarter-2016-revenue-300305368.html>

SOURCE HeartWare International, Inc.

<https://news.medtronic.com/2016-07-28-HeartWare-International-Reports-68-7-Million-In-Second-Quarter-2016-Revenue>