Medtronic News

# HeartWare International Reports First Quarter 2016 Financial Results

*-- First quarter 2016 revenue of $55 million reflects lower year-over-year clinical trial revenue and competitive dynamics --*
*-- International Society for Heart and Lung Transplantation (ISHLT) scientific sessions reinforce versatility of the HVAD® System --*
*-- Conference call today at 8:00 a.m. ET --*

FRAMINGHAM, Mass., May 4, 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 revenue derived from HeartWare® Ventricular Assist System (HVAD® System) sales of $55.1 million for the first quarter ended March 31, 2016, compared to $70.0 million in revenue for the same period in 2015.

"In the first quarter, our international revenue performance was impacted by competitive dynamics inGermany, as well as lower implant volumes in certain other international markets," said Doug Godshall, President and Chief Executive Officer. "In the U.S., the bridge-to-transplant segment of the market for which the HVAD System is approved, showed softness resulting from a slowdown in the volume of patients eligible for bridge-to-transplant procedures at the start of the year and an evolving trend toward destination therapy (DT) due to ease of reimbursement. Our first quarter financial performance and the overall market dynamics reinforce the importance of our work toward securing a DT indication in the U.S. and focusing our energies upon the continued enhancement of our technologies. Despite first quarter trends, the HVAD System remains the most versatile pump, utilized in the widest range of patients, among currently available ventricular assist systems. The versatility and utility of the HVAD was on full display at the recently concluded International Society for Heart and Lung Transplantation 36th Annual Meeting, where the HVAD System was the subject of more than 90 oral and poster presentations, reinforcing the positive, real-world commercial experience with the device."

First Quarter Financial Results
During the first quarter of 2016, 578 HVAD Systems were sold globally, which represented a 19% decrease from 713 units sold in the first quarter of 2015. During the quarter, U.S. revenue, generated through the sale of 295 units, was $33.3 million, which was a 21% decrease from $42.2 million in the first quarter of 2015. More than half of the comparative decrease in units sold in the U.S. was due to the completion of enrollment in the ENDURANCE2 DT trial in the third quarter of 2015. For the first quarter of 2016, revenue from international markets, generated through the sale of 283 units, was $21.7 million, which represented a decrease of 20% on a constant-currency basis from $27.8 million in the first quarter of 2015. Currency fluctuations negatively impacted total revenue growth by approximately $0.6 million, or approximately 1%, in the first quarter of 2016, compared to the same period in 2015.

Gross margin percentage decreased to 58.2% in the first quarter of 2016, compared to 68.5% in the first quarter of 2015, reflecting lower sales volumes and a $3.5 million charge in the first quarter of 2016 related to ongoing field actions targeting improved battery and controller performance of the HVAD System.

Total operating expenses for the first quarter of 2016 were $47.3 million, compared to $55.3 million for the first quarter of 2015.

Research and development expenses were $25.2 million for the first quarter of 2016, compared to $31.3 million for the first quarter of 2015. Excluding acquisition-related amortization and restructuring cost changes, research and development expenses decreased $3.9 million for the first quarter of 2016, compared to the same period in 2015, primarily as a result of lower project expenses and a decrease in share-based compensation.

Selling, general and administrative expenses were $21.5 million for the first quarter of 2016, compared to $21.9 million for the first quarter of 2015. Excluding acquisition-related amortization and restructuring cost changes, selling, general and

administrative expenses increased $0.1 million for the first quarter of 2016, compared to the same period in 2015. The net increase was primarily due to professional fees, personnel costs and all other expenses, partially offset by savings of $0.9 million resulting from the moratorium on the Medical Device Excise Tax that went into effect on January 1, 2016.

Changes in the fair value of contingent consideration associated with the 2013 acquisition of CircuLite, Inc. resulted in $0.6 million of expense during the first quarter of 2016, compared to $2.1 million of expense in the first quarter of 2015.

Net loss for the first quarter of 2016 was $17.5 million, or a loss of $1.00 per basic and diluted share, compared to a net loss of $14.5 million, or a loss of $0.85 per basic and diluted share, for the first quarter of 2015.

Non-GAAP net loss for the first quarter of 2016 was $16.5 million, or $0.95 per basic and diluted share, compared to a non-GAAP net loss of $9.4 million, or $0.55 per basic and diluted share, for the first quarter of 2015. See "Use of Non-GAAP Financial Measures" and "Reconciliation of GAAP to Non-GAAP Net Loss Per Common Share."

At March 31, 2016, HeartWare had approximately $189 million of cash, cash equivalents and investments, compared to approximately $244 million at December 31, 2015. Total cash used during the first quarter included $31 million in loans made to Valtech Cardio, Ltd. in accordance with the terminated business combination agreement, annual incentive payments and costs associated with the battery and controller field actions.

Conference Call and Webcast Information

HeartWare will host a conference call on Wednesday, May 4, 2016 at 8:00 a.m. ET to discuss its financial results for 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 from 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 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.

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."

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; commercialization of the HeartWare HVAD System; submission for U.S. approval of a destination therapy indication; our ability to enhance our technologies; the timing, progress and outcomes of clinical trials; and achieving the benefits of our 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 (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.*

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- Tables to Follow-

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(unaudited)

| | Three Months Ended March 31, | |
|---|---|---|
| | 2016 | 2015 |
| Revenue, net | $ 55,074 | $ 70,021 |
| Cost of revenue | 23,021 | 22,040 |
| Gross profit | 32,053 | 47,981 |
| Operating expenses: | | |
| Selling, general and administrative | 21,474 | 21,929 |
| Research and development | 25,221 | 31,267 |

| | | |
|---|---|---|
| Change in fair value of contingent consideration | 580 | 2,100 |
| Total operating expenses | 47,275 | 55,296 |
| Loss from operations | (15,222) | (7,315) |
| Other expense, net | (2,090) | (6,988) |
| Loss before taxes | (17,312) | (14,303) |
| Income tax (benefit) expense | 147 | 232 |
| Net loss | $ (17,459) | $ (14,535) |
| Net loss per common share — basic and diluted | $ (1.00) | $ (0.85) |
| Weighted average shares outstanding — basic and diluted | 17,462 | 17,193 |

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

(unaudited)

| | | March 31, 2016 | December 31, 2015 |
|---|---|---|---|
| ASSETS | | | |
| Current assets: | | | |
| Cash and cash equivalents | | $ 113,256 | $ 175,047 |
| Short-term investments | | 74,952 | 68,531 |
| Accounts receivable, net | | 29,472 | 35,570 |
| Inventories | (a) | 43,407 | 39,947 |
| Prepaid expenses and other current assets | | 6,905 | 2,868 |
| Total current assets | | 267,992 | 321,963 |
| Property, plant and equipment, net | | 14,602 | 15,098 |
| Other assets, net | (a)(b) | 148,720 | 116,542 |
| Total assets | | $ 431,314 | $ 453,603 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | | |
| Current liabilities: | | | |
| Accounts payable | | $ 13,709 | $ 15,249 |
| Other accrued liabilities | | 35,521 | 45,889 |
| Total current liabilities | | 49,230 | 61,138 |

| | | | |
|---|---|---|---|
| Convertible senior notes, net | (b) | 189,572 | 187,089 |
| Other long-term liabilities | | 16,945 | 16,884 |
| Stockholders' equity | | 175,567 | 188,492 |
| Total liabilities and stockholders' equity | | $ 431,314 | $ 453,603 |

(a) Includes reclassification of non-current inventory to other assets, net of approximately $7.4 million and $7.7 million as of March 31, 2016 and December 31, 2015, respectively.

(b) In the first quarter of 2016, the Company implemented ASU 2015-03:*Simplifying the Presentation of Debt Issuance Costs* The presentation includes the reclassification of deferred financing costs as a direct deduction to convertible senior notes of $3.8 million and $4.0 million as of March 31, 2016 and December 31, 2015, respectively.

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

*(in thousands)*

| | Three Months Ended March 31, | | Reported $ chg | Reported % chg | FX impact | Constant Currency $ chg | Constant Currency % chg |
|---|---|---|---|---|---|---|---|
| | 2016 | 2015 | | | | | |
| Total U.S. Revenue | 33,348 | 42,189 | (8,841) | -21.0% | - | (8,841) | -21.0% |
| Total Int'l Revenue | 21,726 | 27,833 | (6,106) | -21.9% | 566 | (5,540) | -19.9% |
| Total Revenue | 55,074 | 70,021 | (14,947) | -21.3% | 566 | (14,381) | -20.5% |

Constant-currency changes in the tables above take into consideration the foreign exchange rates in effect during the three-month period ended March 31, 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 March 31, | |
|---|---|---|---|
| | | 2016 | 2015 |
| GAAP net loss | | $ (17,459) | $ (14,535) |
| GAAP net loss per common share – basic and diluted | | $ (1.00) | $ (0.85) |
| Adjustments: | | | |
| Acquisition-related contingent consideration adjustments | (a) | 580 | 2,100 |
| Amortization of purchased intangible assets | (b) | 327 | 411 |
| Restructuring costs | (c) | 20 | 2,631 |
| Total adjustments | | 927 | 5,142 |
| Non-GAAP net loss | | $ (16,532) | $ (9,393) |

| | | |
|---|---|---|
| Non-GAAP net loss per common share - basic and diluted | $ (0.95) | $ (0.55) |
| Shares used in computing non-GAAP net loss per common share - basic and diluted | 17,462 | 17,193 |

Reconciliation of GAAP to Non-GAAP Selling, General & Administrative (SG&A) and Research and Development (R&D) Expenses (unaudited) *(see explanation of adjustments below)*

| | | Three Months Ended March 31, | | |
|---|---|---|---|---|
| (In thousands) | | 2016 | 2015 | change |
| SG&A operating expenses on a GAAP basis | | $21,474 | $21,929 | $ (455) |
| -Amortization of purchased intangibles | (b) | - | (84) | 84 |
| -Restructuring costs | (c) | (20) | (467) | 447 |
| SG&A operating expenses on a non-GAAP basis | | 21,454 | 21,378 | 76 |
| R&D operating expenses on a GAAP basis | | 25,221 | 31,268 | (6,046) |
| -Amortization of purchased intangibles | (b) | (327) | (327) | - |
| -Restructuring costs | (c) | - | (2,164) | 2,164 |
| R&D operating expenses on a non-GAAP basis | | 24,894 | 28,777 | (3,882) |
| Total SG&A and R&D on a non-GAAP Basis | | $46,348 | $50,155 | $(3,807) |

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

(b) Represents amortization of purchased intangible assets related to CircuLite and WorldHeart during the quarters ended March 31, 2016 and March 31, 2015.

(c) Represents restructuring costs comprised of lease exit costs, employee severance, abandoned fixed assets and contract termination charges primarily related to the CircuLite acquisition of $20,000 and $2.6 million during the quarters ended March 31, 2016 and 2015, respectively.

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.

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