Medtronic News

HeartWare International Provides Corporate Updates And Announces Preliminary Revenue For Fourth Quarter 2015

· Fourth Quarter 2015 Preliminary Revenue Approximately $68 Million
· Submission for Destination Therapy Indication for HVAD® System in Mid-2016
· Evaluation of MVAD® System Ongoing With Goal of Restarting CE Mark Trial
· Distinguished Cardiologist and Industry Veteran, Stephen Oesterle, M.D., Appointed to Board of Directors

FRAMINGHAM, Mass., Jan. 11, 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 provided corporate updates and announced preliminary revenue expectations for the fourth quarter of 2015 as part of its presentation at the 34th Annual J.P. Morgan Healthcare Conference in San Francisco.

Fourth Quarter 2015 Revenue – HeartWare's fourth quarter 2015 preliminary revenue was approximately $68 million. This preliminary revenue estimate incorporates previously described headwinds compared to the fourth quarter of 2014, which included foreign currency translation effects of approximately $3.4 million and a $6.4 million decrease in U.S. revenue due to completion of enrollment in the company's ENDURANCE2 Destination Therapy (DT) clinical trial of the HVAD® System during the third quarter of 2015. In the fourth quarter of 2014, HeartWare generated revenue from 58 HVAD Systems included in the ENDURANCE2 trial.

HVAD® System PMA Submission for DT Planned for Mid-2016 – HeartWare intends to submit to the U.S. Food and Drug Administration (FDA) a Premarket Approval (PMA) application for a DT indication for the HVAD System based on positive trends observed in the ENDURANCE2 data contained within the company's regulatory reports and filings. The submission will be based on a combination of the two-year data from the ENDURANCE trial, which achieved its primary endpoint as reported in April 2015, and data from at least six months of follow-up of all patients from the ongoing ENDURANCE2 trial, which was designed to confirm the benefits of enhanced blood pressure monitoring in advanced heart failure patients treated for one year with the HVAD System as a destination therapy. Enrollment was completed in August 2015 for this 465-patient study conducted at 50 U.S. hospital centers. Six-month follow-up for all patients will be completed in February 2016, with adjudication of the data occurring prior to submission, which is expected in mid-2016.

MVAD® System Update – HeartWare continues its review of the MVAD System performance as part of the previously announced voluntary pause of its CE Mark clinical trial. In consultation with study investigators, the company is evaluating MVAD System performance and the observed adverse event profile, including events that showed evidence of pump thrombus. Meaningful progress has been made to identify improvements to manufacturing specifications, and the company has detected certain software algorithms, which appear to increase the potential for pump thrombus. In parallel, the company is evaluating various aspects of the system design to determine whether additional changes could be made to improve performance. Should design changes be identified that could enhance outcomes, initiation of a new trial would likely be required. The company expects that these efforts may take several months to complete, and the timetable for regulatory filings and restarting clinical implants cannot be precisely projected at this time.

Appointment to Board of Directors – As announced in a separate news release issued today, HeartWare has expanded its Board of Directors to nine directors with the appointment of Stephen Oesterle, M.D. Dr. Oesterle is a Venture Partner focused on the medical device investing practice at New Enterprise Associates (NEA), a global venture capital firm investing in technology and health care. Prior to joining NEA in 2015, Dr. Oesterle served as Senior Vice President for Medicine and Technology and was a member of the Executive Committee at Medtronic, Inc., which he joined in 2002.

"HeartWare's ENDURANCE trials are by far the largest cohort of ventricular assist device patients ever prospectively studied, and it is extremely gratifying to see that our hypothesis in ENDURANCE2 – that tighter patient management would meaningfully decrease the stroke rate among HVAD patients – appears to be valid based on the data trends to date," said Doug Godshall, President and Chief Executive Officer. "As the market in the U.S. shifts increasingly toward destination therapy, a positive outcome and earlier submission for the DT indication has the potential to be a significant catalyst for the company. By submitting these data for earlier review, we move one step closer toward access to the broader U.S. VAD market, and importantly, ensuring compliance with enhanced blood pressure monitoring for the benefit of all HVAD patients.

"The HVAD System continues to have strong market appeal, and the possibility of earlier DT approval supports continued investment in enhancements of the current HVAD System, as we work toward advancing the clinical development of the MVAD System in the U.S. and internationally," Mr. Godshall stated. "The promising DT data suggest a more sustained competitive position for the HVAD System, and we are continuing to make investments in areas such as surgical tools and electronics to further reinforce its competitiveness. We were hoping to be able to state when we expect to re-initiate the MVAD System clinical program with certainty, but it is essential that we complete our analysis and work with trial investigators and regulatory authorities on the path forward that enhances the opportunity for the MVAD System to realize its considerable potential. While the initial MVAD clinical experience has not fully met our expectations, we have made meaningful progress in our investigation and have identified some software algorithms that we plan to adjust to improve pump performance. As the MVAD System is performing well on most fronts, we remain optimistic that an improved MVAD System will emerge from this additional evaluation.

"We are extraordinarily fortunate to welcome Dr. Oesterle to our Board of Directors, as we are poised to broaden our heart failure portfolio and to extend our reach into the interventional cardiology community he knows so well," added Mr. Godshall. "Steve will provide a valuable new perspective to our Board, not only in terms of new customers and new segments of the heart failure population, but also in our endeavors to improve the performance of our current devices."

The business updates and preliminary results in this news release are being provided in conjunction with the company's presentation to the investment community today at the 34th Annual J.P. Morgan Healthcare Conference. HeartWare's presentation commences at 2:00 p.m. Pacific Time (5:00 p.m. ET).

The company's presentation and ensuing question and answer session will be webcast live at the conference and are available via a link provided at www.heartware.com. A replay of the webcast will be available for 90 days after the presentation.

The financial estimates presented above are preliminary and remain subject to management's final review, as well as audit by the company's independent registered accounting firm. The company intends to report complete fourth quarter and full-year 2015 financial results in late February. Details regarding the timing of the release of those results, as well as details of a conference call and publicly available webcast, will be announced in a subsequent news release.

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.

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Market.

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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 clinical evaluation of the MVAD System; timing, progress and outcomes of clinical trials; regulatory submissions and quality compliance; investigation, 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 (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.

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