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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**  
Pursuant to Section 13 OR 15(d)  
of the Securities Exchange Act of 1934

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**Date of report (date of earliest event reported): September 14, 2015**

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**HEARTWARE INTERNATIONAL, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-34256**  
(Commission  
File Number)

**26-3636023**  
(I.R.S. Employer  
Identification No.)

**500 Old Connecticut Path**  
**Framingham, MA 01701**  
(Address of principal executive offices)

**Registrant's telephone number, including area code:**  
**508.739.0950**

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 8.01. Other Events.**

On September 14, 2015, Valtech Cardio, Ltd., a private company incorporated under the laws of Israel (“Valtech”) issued a press release announcing that its Cardioband® Mitral Reconstruction System received CE Mark approval for the treatment of mitral regurgitation. The Valtech press release is attached hereto as Exhibit 99.1 and is hereby incorporated by reference into this report.

HeartWare International, Inc., a Delaware corporation (“HeartWare” or the “Company”) intends to distribute this Current Report on Form 8-K in connection with its entry into a Business Combination Agreement with Valtech, HW Global, Inc., a Delaware corporation and a direct wholly-owned subsidiary of HeartWare (“Holdco”), HW Merger Sub, Inc., a Delaware corporation and a direct wholly-owned subsidiary of Holdco (“US Merger Sub”), Valor Merger Sub Ltd., a private company incorporated under the laws of Israel and a direct wholly-owned subsidiary of Holdco (“ISR Merger Sub”) and Valor Shareholder Representative, LLC, a Delaware limited liability company, pursuant to which, subject to satisfaction or waiver of the conditions therein, HeartWare and Valtech will effect a strategic combination of their respective businesses under Holdco wherein (a) US Merger Sub shall merge with and into HeartWare, with HeartWare surviving the merger as a wholly-owned subsidiary of Holdco (the “US Merger”), and (b) ISR Merger Sub shall merge with and into Valtech, with Valtech surviving the merger as a subsidiary of Holdco (the “ISR Merger”, together with the US Merger and the other transactions contemplated by the Business Combination Agreement, the “Transactions”).

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## Important Information

### Additional Information about the Transactions and Where to Find It

In connection with the Transactions, Holdco intends to file relevant materials with the Securities and Exchange Commission, or the SEC, including a Registration Statement on Form S-4 that will contain a joint proxy statement/prospectus. 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 joint 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 web site at [www.sec.gov](http://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 joint 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.

### 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 from the stockholders of HeartWare and Valtech in connection with the proposed transaction. Information regarding the special interests of these directors and executive officers in the transaction will be included in the joint proxy statement/prospectus referred to above. Additional information regarding the directors and executive officers of HeartWare is also included in the HeartWare Annual Report on Form 10-K for the year ended December 31, 2014, which was filed with the SEC on March 2, 2015. This document is available free of charge at the SEC web site ([www.sec.gov](http://www.sec.gov)) and from Investor Relations at HeartWare at the address described above.

### Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements involve certain risks and uncertainties that could cause actual results to differ materially from those indicated in such forward-looking statements, including, but not limited to, the ability of the parties to consummate the proposed Transactions; satisfaction of closing conditions to the consummation of the proposed Transactions; the impact of the announcement of the proposed Transactions on HeartWare's relationships with its employees, existing customers or potential future customers; and such other risks and uncertainties pertaining to the HeartWare's business as detailed in its filings with the SEC on Forms 10-K and 10-Q, which are available on the SEC's web site at [www.sec.gov](http://www.sec.gov). Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date thereof. HeartWare assumes no obligation to update any forward-looking statement contained in this document.

### Item 9.01 Financial Statements and Exhibits.

#### (d) Exhibits

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
99.1	September 14, 2015 Valtech Press Release.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

HeartWare International, Inc.

Date: September 14, 2015

By: /s/ Lawrence J. Knopf

Name: Lawrence J. Knopf

Title: Senior Vice President, General Counsel and Secretary

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**INDEX TO EXHIBITS**

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
99.1	September 14, 2015 Valtech Press Release.



**For Immediate Release**

**Valtech's Cardioband® Receives CE Mark Approval  
for Mitral Valve Repair**

- Regulatory approval clears the path for Valtech to market its implantable mitral reconstruction device in European markets -

**Or Yehuda, Israel – Sept. 14, 2015** – Valtech Cardio, Ltd., (Valtech), an innovator in the development of devices for mitral and tricuspid valve repair and replacement, announced today it has received Conformité Européenne (CE) Marking for its Cardioband® Mitral Reconstruction System (Cardioband), a proprietary, implantable mitral reconstruction device with a transfemoral, transseptal delivery system for mitral valve repair. The designation, received from Dekra, Valtech's notified body in the European Union, was based on the results of a multicenter feasibility trial that demonstrated the safety and effectiveness of Cardioband in mitral valve repair and will allow Valtech to market and sell the device in the European Union. Results of the study demonstrated that Cardioband is a highly effective first-line treatment option for reducing mitral regurgitation (MR) and improving quality of life scores.

Valtech will officially unveil the Cardioband at the upcoming PCR London Valves meeting, being held Sept. 20 to 22, 2015, in Berlin.

MR is a vastly underserved condition in which the mitral valve leaflets fail to close properly, allowing backflow of blood from the left ventricle into the left atrium during systole. Left untreated, severe MR can eventually lead to a meaningful deterioration in cardiac function and, eventually, death. Approximately 4.2 million patients in the U.S. alone are affected by mitral valve disease, which represents a several-billion-dollar global market opportunity.

The CardioBand Mitral Reconstruction System enables surgical-like repair of the mitral valve annulus via a transfemoral, transseptal delivery system, allowing for real-time adjustment on a beating heart. The transcatheter, supra-annular approach does not interfere with the mitral valve leaflets or chordae, and does not preclude subsequent treatment options if they become necessary.

"We are pleased to be able to introduce Cardioband to the European markets," said Amir Gross, founder and CEO of Valtech. "Receipt of the CE Mark is the culmination of concerted and concentrated efforts by many individuals, and it is the result of productive collaboration with the medical community. We are confident that Cardioband will prove to be a meaningful addition to physician's available treatment options in addressing MR, providing a first-line mitral valve repair option that preserves the ability to perform future percutaneous or surgical valve repair and replacement."

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In a multicenter feasibility trial including more than 50 patients, Cardioband was shown to significantly reduce annular size, with significant improvement in MR. After six months of follow-up, 82% of patients (n = 22) were categorized in NYHA Class I-II, with significant improvement of quality of life (Minnesota Living With Heart Failure Questionnaire) score of 38 to 18 [p<0.05]; and had six-minute walk test score of 250 to 322 [p<0.05]. At 12 months' follow-up, 94% of patients (n = 17) had sustained MR  $\leq$ 2+.

“The future of functional mitral regurgitation (FMR) treatment lies in the repair-and-replace paradigm,” commented Francesco Maisano, M.D., first user of the Cardioband procedure and chairman and professor of cardiovascular surgery at The University Hospital of Zurich. “MR repair with Cardioband can be the first-line therapy for severe MR patients. Additionally, early-stage repair can support ventricular reverse remodeling while keeping the options open for the patient, supporting the technology’s use at earlier stages.”

### **Cardioband Mitral Reconstruction System**

The Cardioband System combines a reconstruction implant, similar to the surgical annuloplasty devices, with a transfemoral, transseptal delivery system. Connection of the implant to the mitral annulus is sutureless, using specially designed anchors. Reshaping of the mitral annulus to eliminate mitral regurgitation (MR) is done under physiological conditions and echocardiographic guidance for optimal results. Cardioband received CE Mark approval after clinical trial results demonstrated the device is a safe and efficacious intervention option for patients with functional mitral regurgitation (FMR).

### **About Valtech Cardio, Ltd.**

Valtech Cardio, Ltd., founded in 2005, is a privately held company specializing in the development of devices for mitral and tricuspid valve repair and replacement. Valtech has full in-house development, manufacturing, and clinical research capabilities, and over 150 patents and patent applications. The company, comprised of multidisciplinary development teams, works in close collaboration with world-renowned heart specialists to provide the best possible therapy for mitral patients. Funded in part from investments made by HeartWare International, Inc. (Nasdaq: HTWR) and other private investors, Valtech is headquartered in Or Yehuda, Israel. For more information, visit the company’s website: [www.valtechcardio.com](http://www.valtechcardio.com).

#### **For Additional Valtech Information:**

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