



Financial Tear Sheet

Corporate Profile

HeartWare International, Inc. (HeartWare) is a medical device company developing a family of implantable Left Ventricular Assist Devices ("LVADs") for the treatment of advanced heart failure. The Company is listed on both the Nasdaq Exchange and the Australian Securities Exchange (ASX). HeartWare common shares trade on Nasdaq under the symbol "HTWR". HeartWare CDIs (Chess Depository Interests) trade on ASX under the symbol "HIN". Each common share on Nasdaq is equivalent to 35 CDIs on ASX.

Heart failure is a degenerative, terminal disease affecting over 20 million patients worldwide. Approximately 1 million patients suffer from "Class IV" heart failure, the end stage of the disease. Heart transplantation is considered the best available treatment option, but only approximately 3,000 donor hearts become available worldwide each year. LVADs are used to bridge patients until a donor heart becomes available (so called "Bridge-to-Transplant" therapy) or, increasingly, as a long term alternative to transplantation (so called "Destination Therapy").

The HeartWare® Ventricular Assist System features a miniaturized implantable centrifugal pump capable of producing up to 10 Liters per minute of blood flow. The pump is designed to be implanted above the diaphragm, directly adjacent to the heart, thereby avoiding the abdominal surgery generally required to implant competing devices.

HeartWare has completed enrollment of a 50-patient international clinical trial. The Company received CE Mark approval for the System in January 2009 and the System is now commercially available in Europe. In the United States, the System is the subject of an ongoing Bridge-to-Transplant clinical trial under which HeartWare enrolled 140 patients at 30 participating centers. Patient follow-up for that study is expected to conclude in August 2010, with subsequent PMA submission to the FDA.

In June 2010, HeartWare announced that the FDA granted the Company conditional approval to begin enrollment in an Investigational Device Exemption (IDE) destination therapy clinical study for the HeartWare® Ventricular Assist System. Designed to enroll up to 450 patients at 50 U.S. hospitals, the non-inferiority study, which is named "ENDURANCE," is a randomized, controlled, unblinded, multi-center clinical trial to evaluate the use of the HeartWare Ventricular Assist System as a destination therapy in advanced heart failure patients. The study population will be selected from patients with end stage heart failure who have not responded to standard medical management and who are ineligible for cardiac transplantation. Patients in the study will be randomly selected to receive either the HeartWare Ventricular Assist System or, as part of a control group they will be implanted with any alternative LVAD approved by the FDA for destination therapy, in a 2:1 ratio. Each implanted patient will be followed to the primary endpoint at two years, with a subsequent follow-up period extending to five years post implant.

HeartWare is also developing a portfolio of further miniaturized devices, implantable by progressively less invasive surgery.

HeartWare's corporate headquarters are in Framingham, Massachusetts. The Company's operating and manufacturing activities are based in Miami Lakes, Florida.

Recent Headlines & Events

- 09/06/10 - 7:01 p.m.
[Option Exercise - ASX Appendix 3B](#)
- 09/06/10 - 7:00 p.m.
[FDA Grants HeartWare Second Patient Allotment Under CAP](#)
- 09/03/10 - 6:39 p.m.
[HeartWare Receives Second Patient Allotment Under Continued Access Protocol for Pivotal U.S. Bridge-To-Transplant Clinical Trial](#)

Stock Performance



Choose listing:

HTWR (NASDAQ)	HIN (ASX)
Price	\$71.24
Change (%)	↑ 0.90 (1.28%)
Volume	85,034

Recent Reports

- [2009 Annual Report](#)

Date	Title
09/21/10 12:30 p.m. ET	HeartWare International at UBS Global Life Sciences Conference
	Location New York, NY

SEC Filings

Filing Date	Form
09/07/10	8-K
08/19/10	8-K
08/11/10	8-K
08/06/10	10-Q

Corporate Governance

Douglas Godshall	Managing Director, Chief Executive Office
David McIntyre	EVP, Chief Financial Officer and Chief Operating Officer
Jeffrey A. LaRose	EVP, Chief Scientific Officer
Dr David Hathaway	Chief Medical Officer
James Schuermann	Vice President, Sales and Marketing
Ramon Augusto Paz	Vice President, Quality Assurance

Top Holders				
	Shares Held	% O/S	Share Change	Filing Date
Apple Tree Partners	2,673,962	19.5	-3	12/31/09
Satter (Muneer A)	1,374,433	10.0	3,004	12/31/09
Fidelity Management & Research	986,292	7.2	647,494	06/30/10
Wellington Management Company, LLP	710,850	5.2	35,860	06/30/10
Janus Capital Management LLC	666,123	4.9	170,085	06/30/10
Stark Investments	639,954	4.7	639,954	10/20/09
T. Rowe Price Associates, Inc.	532,921	3.9	380	06/30/10
TCW Asset Management Company	387,041	2.8	253,323	06/30/10
Franklin Advisers, Inc.	342,720	2.5	342,720	06/30/10
Adage Capital Management, L.P.	320,239	2.3	-242,380	06/30/10