



## ASX ANNOUNCEMENT

### **Sunshine Heart's Feasibility Trial Outcomes to Be Presented at Transcatheter Cardiovascular Therapeutics Conference**

***– Six-Month Follow-up Results for Patients Enrolled in the C-Pulse® Heart Assist System Clinical Study to Be Released –***

**Sydney, Australia and Eden Prairie, MN; October 19, 2011:** Sunshine Heart, Inc. (ASX: SHC), a global medical device company focused on innovative technologies for moderate heart failure, today announced that the C-Pulse Heart Assist System will be featured in two clinical presentations at the 23rd annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium. The TCT symposium, sponsored by the Cardiovascular Research Foundation, will take place November 7 through 11 in San Francisco, California.

Sunshine Heart's presentations scheduled to take place at the TCT meeting include:

**Results of the C-Pulse Feasibility Study: C-PULSE. A Prospective, First-in-Man Study with a Non-Blood Contacting Extra-Aortic Counterpulsation System in Patients with Moderate to Severe Ambulatory Heart Failure** on Monday, November 7, 2011, 7:15 - 7:29 p.m. (PST), Room 121. National co-lead principal investigator, William T. Abraham, M.D., director of the division of cardiovascular medicine at Ohio State University Medical Center will present the most recent data.

**Device-Based Approaches for Heart Failure: Recent Developments and New Directions: Sunshine Heart** on Tuesday, November 8, 2011, 4:51 p.m. (PST), Room 123. Renzo Cecere, M.D., director of the Mechanical Heart Assist Program and surgical director of the Heart Failure and Heart Transplant Program at the McGill University Health Centre in Montreal, Canada will present his single center experience with the C-Pulse technology.

"With the completion of the C-Pulse Heart Assist System twenty-patient feasibility trial, the study results will be presented at the TCT scientific meeting, the largest international meeting of device cardiologists," said Dave Rosa, CEO of Sunshine Heart. "We will now focus our efforts on the next phase of the Company's plan to initiate a pivotal trial in the U.S. next year."

In April 2011, Sunshine Heart announced that it had completed enrollment of 20 patients in its U.S. Food and Drug Administration (FDA)-approved investigational device exemption (IDE) feasibility study. The study was primarily designed to assess safety and provide indications of performance of this device in moderate to severe heart failure patients who suffer from symptoms such as shortness of breath and reduced mobility. Once the feasibility data is reviewed by the FDA, the company will seek approval for the pivotal trial protocol.

#### **About the C-Pulse® Heart Assist System**

The C-Pulse Heart Assist System utilizes the proven scientific principles of intra-aortic balloon counterpulsation applied in an extra-aortic approach to assist the left ventricle by reducing the workload required to pump blood throughout the body, while increasing blood flow to the coronary arteries. Operating outside the patient's bloodstream, the novel extra-aortic approach of the C-Pulse technology offers greater flexibility allowing patients to disconnect as necessary or desired. The C-Pulse system's potential benefits may help reverse the heart failure process or maintain the patient's current condition, thereby preventing the need for later stage heart failure therapies, such as left ventricular assist devices (LVADs), artificial hearts or transplants.

## **About Sunshine Heart®**

Sunshine Heart is a global medical device company committed to the commercialization of the C-Pulse Heart Assist System, a minimally invasive, implantable, non-blood contacting, heart assist therapy for the treatment of moderate heart failure. C-Pulse relieves the symptoms of heart failure through the use of counter-pulsation technology which enables an increase in cardiac output, an increase in coronary blood flow and a reduction in the heart's pumping load. The Company has completed enrolment of an approved U.S. Food and Drug Administration (FDA) 20 patient U.S. clinical trial with the C-Pulse System. Sunshine Heart is a Delaware-based Corporation headquartered in Minneapolis with a subsidiary presence in Australia. The Company has been listed on the ASX since September 2004. For more information, please visit [www.sunshineheart.com](http://www.sunshineheart.com).

## **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 progress of, and presentation of data related to, product development and commercialization efforts, results of clinical trials, expected timing of FDA regulatory filings, FDA acceptance of our filings and research and development activities, ultimate clinical outcomes and benefit of the Company's products to patients, market and physician acceptance of the products, intellectual property protection and competitive product offerings could cause actual events to adversely differ from the expectations indicated in these forward looking statements. 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. Sunshine Heart 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. Sunshine Heart 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, the possibility the FDA does not accept our regulatory application or approve the marketing of the C-Pulse® Heart Assist System in the U.S., the possibility the Company may be unable to raise the funds necessary for the development and commercialization of its products, the possibility the Company may be unable to successfully list its securities on a U.S. securities exchange, and those described in our filings with the ASX. We may update our risk factors from time to time in our filings with the ASX.

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