



ASX ANNOUNCEMENT

Chief Executive Officer's Annual General Meeting Update

- **CE Mark filing to take place in December 2011**
- **On track to commercialize in Europe in 2012**
- **Growing corporate, physician and investor interest**
- **C-Pulse feasibility data highlighted at recent US trade show**
- **Preparations underway for North American pivotal trial in 2012**
- **Numerous product enhancements completed**

Sydney, Australia; 29 November 2011: Sunshine Heart, Inc. Chief Executive Officer, Dave Rosa, today provided a strategic company update at the 2011 Annual General Meeting in Sydney.

Mr. Rosa confirmed that the company had accomplished its major stated objectives in 2011 and that the company is prepared to meet a number of important development and clinical milestones in 2012.

CE Mark filing and first sales in Europe

He said the company was on track to file for CE Mark for the C-Pulse Heart Assist System in December of this year. CE Mark approval will allow the company to market the C-Pulse system in Europe. Mr. Rosa said he expected the C-Pulse to be available in Europe as early as the first half of the 2012 calendar year.

Positive feasibility trial data

Mr. Rosa remarked that a major achievement in 2011 had been the successful completion of Sunshine Heart's 20-patient feasibility trial and the release of the trial data.

According to Mr. Rosa, the trial data demonstrated statistically significant improvements in New York Heart Association (NYHA) heart failure classification, improved quality of life and ejection fractions. The data also showed trends towards improvement in standard six-minute walk test and reductions in left ventricular end diastolic diameter. Most patients that were being treated with inotrope and diuretic medications experienced a reduction or discontinuation of the therapy.

"We have learned a tremendous amount about our technology and how best to implant and manage patients who are supported by the device during this initial clinical experience", stated Rosa. "The company remains on track for CE Mark filing before the end of 2011. Sunshine Heart's European Notified Body has indicated that the North American feasibility trial data may be submitted for CE Mark approval."

US Pivotal trial on track

Mr. Rosa said the positive initial experience from the feasibility trial and the information gained from that experience gave the company a strong base on which to launch its US Pivotal trial.

He said the Company is planning to meet with the US Food & Drug Administration (FDA) in January 2012 to discuss the clinical data, final design and protocol for the US Pivotal trial. Patient recruitment is anticipated to begin in mid-2012.

“Growing interest among the global interventional cardiology community is helping to drive further interest in site participation for the North American pivotal trial.”

“In preparation for the pivotal trial, we are building the necessary internal infrastructure required to gain greater control of the assembly and manufacturing process for the C-Pulse Heart Assist System. We have recently identified a new location for our US operations that will give us our own new clean room manufacturing facilities that will help provide units for Europe and the US trial. We are also expanding the resources to successfully support and manage the trial to the company’s timelines,” Rosa continued.

Corporate Partnership and Funding Strategy

Mr. Rosa said that a supportive shareholder base of existing and new institutional investors had helped the company successfully raise \$7.7 million in late 2011 and that Sunshine Heart continued to exercise tight control over its capital resources to keep its cash burn in line within budget.

Mr. Rosa also told shareholders that the company was in discussions with potential corporate partners. “A growing number of global medical technology companies believe that new minimally invasive differentiated therapies like the C-Pulse, which are designed to address the large and underserved heart failure patient population, could have a significant impact in the future,” Mr. Rosa said.

The company has also recently engaged with US funds with an investment focus on medical device companies with unique technology advantages and global potential. Mr. Rosa said the company’s anticipated listing on NASDAQ by early 2012 will benefit the company’s supportive Australian shareholders and help the company to execute its growth strategy and attract a broader base of US shareholders.

Product pipeline development

Mr. Rosa said that in 2012 the company anticipates building on its achievements by introducing a new single unit driver and software enhancements to the current C-Pulse product in addition to other improvements and consumables, one of which is designed to minimise exit site infections. He said the company has also made excellent progress in the development of a fully-implantable system.

Board and management

Mr. Rosa said the company had assembled an impressive global management team and a Board of Directors with the industry experience and skills required to guide the business through its pending clinical and commercialization milestones.

“In 2012, we are set to move Sunshine Heart to the next level of success. We are committed to setting and meeting ambitious commercial and clinical development milestones in order to create long-term value for our shareholders,” Mr. Rosa concluded.

About the C-Pulse® Heart Assist System

The C-Pulse Heart Assist System, an investigational device, utilizes the proven scientific principles of intra-aortic balloon counter-pulsation 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, which may reduce the need for later stage heart failure

therapies, such as left ventricular assist devices (LVADs), artificial hearts or transplants.

Caution: Investigational device, limited by Federal (or United States) Law to Investigational use.

About Sunshine Heart®

Sunshine Heart is a global medical device company committed to the commercialization of the C-Pulse Heart Assist System, an implantable, non-blood contacting, heart assist therapy for the treatment of moderate to severe heart failure which can be implanted using a minimally invasive procedure. C-Pulse is designed to relieve 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 enrollment of an approved U.S. Food and Drug Administration (FDA) 20 patient feasibility clinical trial with the C-Pulse System. Sunshine Heart is a Delaware 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.

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 product development and commercialization efforts, results of clinical trials, expected timing of regulatory filings and approvals, regulatory acceptance of our filings and research and development activities, ultimate clinical outcomes and benefit of our 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 regulatory authorities do not accept our application or approve the marketing of the C-Pulse® Heart Assist System, the possibility we may be unable to raise the funds necessary for the development and commercialization of our products, the possibility we may be unable to successfully list our 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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