



ASX Announcement

New Wearable C-Pulse™ Driver ready for US Clinical Trial

Sydney, Australia – 16 May 2007: Sunshine Heart, Inc. (ASX: SHC) announced today it had successfully completed the development of the next generation C-Pulse™ System for use in the US Feasibility Clinical Trial scheduled to commence in the second half of 2007.

The new C-Pulse™ system includes a proprietary Wearable C-Pulse™ Driver (pictured below) that is significantly enhanced from the version that has been used during the Australian and New Zealand Pilot Clinical Trial. It will provide patients with greater freedom and ultimately an improved quality of life.

Key features of the Wearable C-Pulse™ Driver developed for the US clinical trials include:

- A smaller, wearable, portable device
- Comfortable ergonomic design
- Evenly balanced weight of approximately 2kg
- Infrared programming of the Driver by clinicians.

The Wearable C-Pulse™ Driver was developed in conjunction with Sunshine Heart's development partner, the USA based Plexus Corporation. The Driver development was initiated with IPO funding in September 2004 by Sunshine Heart CEO Donald Rohrbaugh. Mr Rohrbaugh indicated that "the Plexus team of engineers worked very closely with our St Leonards engineers to achieve this significant milestone".

With delivery of the Wearable Driver, Sunshine Heart completed preclinical studies that validated all elements of the design and function of this next generation C-Pulse™ System, including the Wearable Driver, the implantable Cuff and the Percutaneous Interface Lead. This pre-clinical data will form an important part of the information to be presented to the Federal Drug Administration (FDA) as part of Sunshine Heart's IDE application to commence the US Feasibility Clinical Trial.

Mr Victor Windeyer, Chief Operating Officer of Sunshine Heart said: "The completion of the preclinical studies is the final milestone in the development sequence of the C-Pulse System for the US Feasibility Clinical Trial which is scheduled to commence during the second half of 2007."

The Plexus Corporation, with sales that exceed US\$1 billion, of which 26% is derived from the medical sector, will produce the Wearable C-Pulse™ Driver in their Chicago, IL

facilities. Drivers are scheduled for delivery to Sunshine Heart in July 2007 to support the US Feasibility Clinical Trial.

ANZ C-Pulse™ Driver



New C-Pulse™ Driver



Old to New Driver

For further information, please visit www.sunshineheart.com or contact:

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About the Sunshine Heart preclinical studies

The preclinical studies involved three specific tests of the C-Pulse™ System including the new wearable Driver and the new Percutaneous Interconnect Lead (PIL). The outcomes from these studies are summarised below:

Study 1: PIL Biostability Validation

This study verified various biostability aspects of the new Percutaneous Interface Lead (PIL) including the Reference Electrode and the Electrocardiogram (ECG) leads. The study also verified, in a chronically implanted test, the timing of the C-Pulse™ System which is based primarily on R-waves present in the ECG waveform.

Study 2: ECG Waveform Performance Validation

This study verified the ability of the new C-Pulse™ Driver to correctly detect R-waves in the ECG waveform when connected to a test subject. In addition, the study verified that the C-Pulse™ Driver could correctly detect the R-wave in various expected adverse conditions including the presence of external cardiac pacing, cardiac defibrillation and electro-cautery procedures.

Study 3: System Validation (in vivo)

This final system study demonstrated that the C-Pulse™ System was able to provide optimised counterpulsation therapy under a variety of clinically expected conditions. The C-Pulse™ was studied under various blood-pressure variations and other possible therapeutic conditions such as the addition of pacemakers.

This press release contains forward-looking statements that are based on current management expectations. These statements may differ materially from actual future events or results due to certain risks and uncertainties from time to time in the Company's filings with the Australian Stock Exchange.

About Sunshine Heart

Sunshine Heart (ASX: SHC) (www.sunshineheart.com) is a global medical device company, committed to the commercialisation of C-Pulse™ an implantable, non-blood contacting, mechanical heart assist device for the treatment of people with heart failure. Sunshine Heart listed on the ASX in September 2004 and has a presence in Australia, New Zealand and the United States of America.

Heart failure is a progressively worsening condition characterised by shortness of breath after mild exercise, fatigue, dizziness and fluid retention. Heart failure is caused by the inability of the heart to pump sufficient blood to meet the body's oxygen requirement. An estimated 325,000 people in Australia have symptomatic heart failure, with 22,000 hospital admissions for heart failure each year. Heart failure is believed to contribute to over 1.4 million days of hospitalization annually at a cost of more than \$1 billion. Over 5 million people in the USA have heart failure.

C-Pulse™ is an implantable, non-blood contacting mechanical heart assist device powered by an external driver unit. The implantable cuff is placed around the aorta just above the heart. The balloon is inflated and deflated to the rhythm of the heart to improve blood supply to both the body and the heart muscle, while reducing the workload on the heart. The wearable external driver is linked by an air tube to the cuff, and detects the heart's natural rhythm and controls inflation and deflation of the cuff in synchrony with the heart.

Implantation of C-Pulse™ involves wrapping the cuff around the aorta. No incisions into the aorta are needed, so that the device never comes into contact with the patient's bloodstream. The cuff is designed to inflate in a way that rolls the wall of the aorta inward in a gentle 'thumb printing' manner. The cuff is inflated and deflated rhythmically to improve blood supply to the heart and body as well as reduce the workload of the heart.

About Plexus Corporation

Plexus (www.plexus.com) is an award-winning participant in the Electronics Manufacturing Services (EMS) industry, providing product design, test, materials procurement, manufacturing, fulfillment and aftermarket solutions to branded product companies in the wireline/ networking, wireless infrastructure, medical, industrial/commercial and defense/security/aerospace industries. The Company's unique Focused Factory manufacturing model and global supply chain solutions are strategically enhanced by value-added product design and engineering services. Plexus specializes in customer programs that require flexibility, scalability, technology and quality. Plexus provides award-winning customer service to more than 120 branded product companies in North America, Europe and Asia.