Investor Update - December 2006

Highlights

- Progress towards US clinical trial;
- Successful institutional capital raising;
- Second Commercial Ready Grant;
- Clinical update;
- Next generation product

Towards US clinical trial – a major milestone

On 16 November, Sunshine Heart had a very constructive pre-Investigational Device Exemption (pre-IDE) meeting with the US Food and Drug Administration (FDA) in Washington DC, USA

A pre-IDE meeting is the first formal interface with the FDA for companies seeking to conduct clinical trials in the United States of America.

The primary purpose of the pre-IDE meeting was to solicit the FDA's insight into Sunshine Heart's US clinical trial plans. This insight will enable the company to modify and enhance their plans to reflect the FDA's current thinking and best practice before formal submission of the IDE application.

At the pre-IDE meeting, Dr William Peters, Sunshine Heart's Founder and Medical Director introduced the C-Pulse™ and described the ability to assist the heart to pump blood and to relieve the patient's heart failure symptoms without contacting the blood. He also described the results of pre-clinical C-Pulse™ tests, including the cuff reliability tests, which now exceed four years of accelerated cycle testing.

Dr Chris Hayward, an investigator in the C-Pulse™ Australia and New Zealand pilot study also attended the meeting and presented the results of that study.

Dr William Peters, Sunshine Heart's Medical Director, **Dr Christopher Hayward**, (left) and **Dr Patrick McCarthy** (right) met at the American Heart Association meeting to discuss the pre-IDE meeting with the US FDA.

He described the ability of the C-Pulse™ to relieve patient's symptoms of heart failure, including his personal experiences gained at St Vincent's Hospital in Sydney, and the overall clinical experiences at all the pilot trial clinical study centres

Dr Patrick McCarthy, Chief of Cardiothoracic Surgery at Northwestern University School of Medicine, Chicago, presented Sunshine Heart's proposed clinical study design to the FDA and gave his professional opinion regarding the clinical need for a product such as the C-Pulse™ to treat moderate heart failure. He pointed out the strong desire of his and other US hospitals to participate in the proposed 2007 US clinical trial of the C-Pulse™.

The next major FDA milestone towards commencement of the US feasibility study requires that Sunshine Heart submit a complete IDE application. The company is currently preparing the application for submission during the first half of 2007.

US clinical centre preparations

While Dr Peters was in the US for the FDA meeting, Chief Executive Officer Mr Don Rohrbaugh introduced him to the candidate US clinical centres, which included numerous large prestigious university-based hospitals and regional referral hospitals that emphasise clinical trial research and have extensive heart failure experience. All candidate centres also have experience with managing heart failure patients on circulatory support devices.

Dr Peters found the selected centres to be well qualified for the C-Pulse™ US trial. He further indicated that the centres were overwhelmingly positive about both the C-Pulse™ device and the Australia and New Zealand pilot clinical results. All of the centres asked the question: "What's the next step?" Dr Peters commented "one gets the sense that there is a great need and desire in the USA for a C-Pulse™-type product".

Close cooperation with the US centres and our medical advisors will continue as the US Clinical Trial protocol is refined and finalised based upon the feedback received at the pre-IDE FDA meeting.

Pilot Trial Update

Sunshine Heart's C-Pulse™ pilot clinical trial in Australia and New Zealand is progressing well, following the successful implantation of five patients, across four centres.

Hospital	Patients Enrolled
Auckland City Hospital, Auckland	2
Southern Health, Melbourne	1
The Alfred, Sydney	0
St. Vincent's, Sydney	1
Royal Perth, Perth	1

In the last quarter, two patients were implanted at two new trial sites – the Royal Perth Hospital and Southern Health Monash Medical Centre. There are now five clinical trials sites actively screening heart failure patients for suitable recipients of the C-Pulse™.

Interim results of the pilot trial were confidentially presented to the FDA and will be released at the completion of the trial.

Mr Rohrbaugh explained that the Australian and New Zealand pilot trial has provided a significant validation of the C-Pulse™ device and that Sunshine Heart is enthused and energised in driving towards trialing the C-Pulse™ in US heart failure clinics next year.

Capital Raising

The company successfully completed an institutional capital raising of $19.8 million. The new lead investor is CM Capital. GBS Venture Partners Ltd, Three Arch Partners and PCLM Investments Pty Ltd made significant follow-on investments.

Sunshine Heart's newest institutional investor, CM Capital, is one of Australia's largest specialised venture capital firm investing in the telecommunications and life sciences industries.

Brisbane-based CM Capital, which has extensive networks in North America, elects to invest in companies that offer differentiated products with high barriers to market entry and substantial market opportunities.

The new funds will be used to progress our pilot clinical trial in Australia and New Zealand, to continue development of the C-Pulse™ driver and to advance the US C-Pulse™ clinical trial.

To date, Sunshine Heart has received the first tranche of the capital raising ($13.8 million). The second tranche ($6 million) is subject to FDA approval of the IDE application for a human clinical trial of the C-Pulse™ device, expected during the second half of 2007.

Profile of new director, CM Capital's John Brennan

John Brennan, Sunshine Heart's new director

Sunshine Heart's new director, John Brennan, is a partner at CM Capital.

Mr Brennan began his career as a corporate and commercial lawyer in Brisbane and has accrued more than 15 years of experience in venture capital, corporate finance, commerce and the law.

Before he joined CM Capital in 2004, Mr Brennan had worked extensively in the areas of mergers and acquisitions, divestments, capital raisings, venture capital and private equity, in corporate and advisory roles in Australia and overseas, including with GE Capital and Ernst & Young in the UK.

Commercial Ready Grant

In September 2006, Sunshine Heart was one of the first Australian public companies to be awarded a second Commercial Ready Grant (CRG) by the Australian Government's AusIndustry Commercial Ready Grant program.

This $2.157 million second grant will fund up to 50% of a project designed to make the C-Pulse™ Driver more patient-friendly, that is lighter, quieter and more energy efficient.

The Company was previously awarded (in October 2005) a $2.223 million grant to support the further development of the C-Pulse™ and to establish the Company's current pilot clinical trial program in Australia

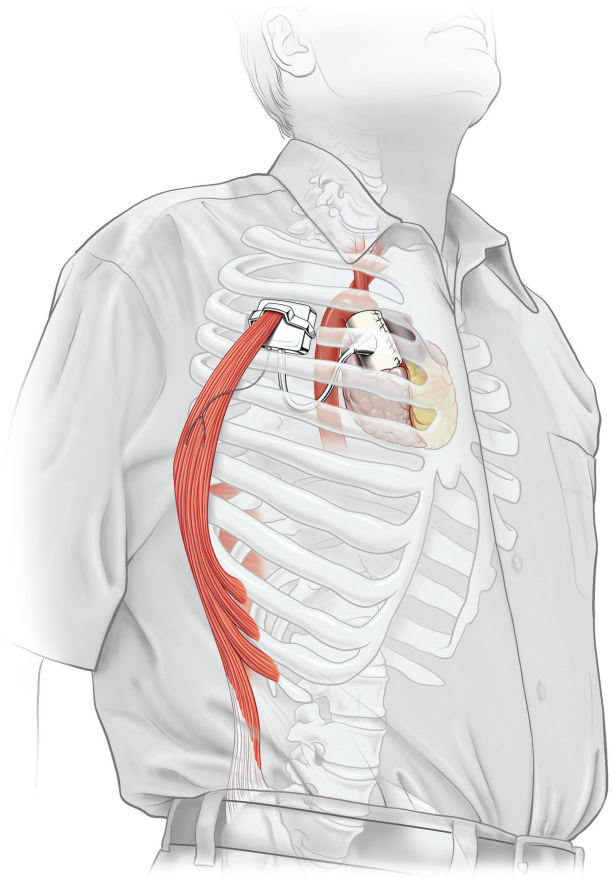
Victor Windeyer, Sunshine Heart's Chief Operating Officer said we are delighted that the government is continuing to support our programs. He explained that the CRG government grants are concurrently contributing to Sunshine Heart's product development and clinical trial programs.

Innovations for the future

Sunshine Heart's primary focus is on the C-Pulse™ clinical trial currently under way in Australia and New Zealand. The Company also constantly assesses the market for innovative technology that could be used in the development of next generation products.

In October, we announced collaboration with the Allegheny Singer Research Institute (ASRI) in Pittsburgh, Pennsylvania to evaluate the feasibility of using their patented muscle energy converter (MEC) to power future generations of the C-Pulse™ device. The MEC eliminates the need for the patient to wear a battery pack attached via a percutaneous lead to the implanted device.

Sunshine Heart is also looking at alternative Transcutaneous Energy Transfer (TET) technology for future product variants that would have the advantage of eliminating the need for a percutaneous lead.



Artist's impression of a next generation, biomechanically powered C-Pulse™ system.

For More Information

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