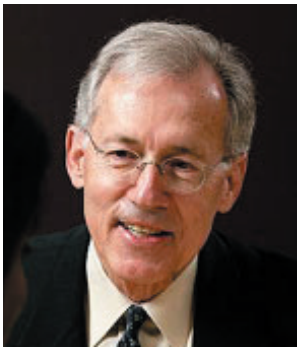
Quarterly Investor Update - October 2005

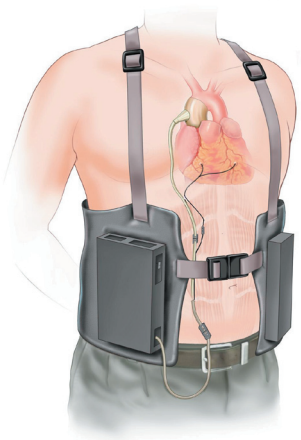
Sunshine Heart has learned a lot of very positive things about the C-Pulse heart assist device from the first two patients who were implanted in the clinical trial to date. This newsletter is aimed at informing the investment community of the significance of these positive findings.



Donald G. Rohrbaugh, CEO, Sunshine Heart, Inc.

"Developing a medical device which improves the Quality of Life of heart failure patients"

"Successful clinical trials conducted in New Zealand and Australia are important forerunners of a pivotal clinical trial in the key US market"



Company Overview

• Sunshine Heart Inc is developing an implantable counterpulsation pump (C-Pulse) to provide therapy for Class III heart failure (HF) patients and to improve their quality of life. The C-Pulse does this by augmenting the native heart function. It is simple to implant and is cost effective. Unlike conventional heart assist devices, it does not contact the patient's blood and can therefore be safely turned on and off.

• The C-Pulse device includes an inflatable cuff positioned around the patient's aorta and a driver located outside the patient's body. The driver is connected to the cuff by a narrow tube which passes through the patient's skin. The driver pumps air into and out of the cuff through the tube. This pumping action is timed to the heart's electrical signal (ECG) to cause additional blood flow to the patient's heart muscle and body, as well as reducing the work of the heart.

• A pilot (or Phase I) clinical trial is being undertaken to determine the safety and performance of the C-Pulse at Auckland City Hospital. Clinical Investigators have also made application for ethics committee approval to enrol patients into the clinical trial at three leading hospitals in Australia.

• Successful Phase I clinical trials conducted in New Zealand and Australia are important to securing approval for a long term human clinical trial (Phase II) in the key US market.

The Sunshine Heart C-Pulse is an implantable, non-blood contacting mechanical heart assist device powered by an external driver unit.

Sunshine Heart, Inc.

Quarterly Highlights

Clinical Trials and Patient Enrolment	• Two of ten patients have been enrolled into the long-term pilot clinical trial at Auckland City Hospital. The clinicians there are actively recruiting a third patient • A third Australian centre has filed an application with its ethics committee to participate in the pilot study. Ethics committee applications have made substantial progress at two centres in Melbourne • The short term (intra-operative) human trial in New Zealand is progressing as planned. One set of intraoperative data was obtained during the quarter. Four of six patients have now been enrolled in this study
Design and Manufacture	• The proprietary C-Pulse driver is continuing to progress at our deleveopment contractor, Plexus, Inc. Prototype drivers are undergoing reliability testing. A *'state-of-the-art'* physician programmer interface has been developed • The cuff wrap has undergone refinement to increase its conformity to the helical-shaped aorta. These wraps will be assembled with balloons (also with the helical-shaping) by Polymer Technology Group in California, packaged and sterilized, ready for IDE testing
Cycle testing	• The first batch of cuffs being tested has now passed 100 million cycles at high pressure (equivalent to 3-4 years of device use). Cycle-testing is ongoing, and further cuffs will be added
Financial highlights	• At 30 September 2005 the Company had $6.36 million cash after a quarterly cash outflow of $1.5 million • The accounts for the 2005 financial year have been audited and published in the Annual Report which has been posted to all shareholders. • The Annual Report may be viewed online at: *www.sunshineheart.com/news/annual_report2005.pdf*
Annual General Meeting	• The AGM will be held in the Boardroom of law firm Henry Davis York, Level 10, 44 Martin Place Sydney NSW at 12 noon on Friday 4 November 2005

Lessons learned from the pilot clinical trial to date

Two patients with severe heart failure have so far been implanted with the C-Pulse heart assist device. One patient who had been classified as unsuitable for heart transplantation due to the number of chronic diseases he suffered from died almost three months after receiving the C-Pulse. The second patient improved by one level of heart failure classification within a month of receiving the device, but developed an infection soon after and had the device removed.

The first observation doctors treating the first two patients enrolled in the pilot clinical trial noted was **the ease and speed of the device implantation** in operations taking just over two hours. This is less than the time required for a routine by-pass operation. There was no need to place the patient on a heart-lung machine, thereby avoiding the risk of bleeding and blood clotting associated with such machines. As there was no blood contact, there was no need to use blood thinners or for the use of donor blood products. Despite being very ill the patients tolerated the operation and initial recovery was good. The device started providing benefit from the moment it was turned on.

The second observation was the **symptomatic improvements in the condition of each patient**. The first patient reported that his breathing was easier and his fingers and toes were warm for the first time in many years (both signs of improved circulation). The second patient improved from Class IV to Class III during the month he had the device. His 6 minute walk test also improved. These patient improvements will, in the long term, lead to significant improvements in a patient's Quality of Life.

Thirdly, both patients were **able to turn the C-Pulse device on and off whenever they wanted to**. This ability is a major advantage of the C-Pulse as compared with conventional heart assist devices because it provides the patient with flexibility of lifestyle through a choice of treatment times. It also means that death does not ensue if the device stops inadvertently, such as through battery exhaustion. Both of these factors contribute to the patient's Quality of Life.

Fourthly, researchers were able to look at the effect of the C-Pulse on the aorta at post mortem. Prior to this trial Sunshine Heart had done long term trials only in sheep. These showed that the sheep aorta remained functional after counterpulsation for up to 10 months. The internal lining of the aorta remained normal although some thinning in aortic outer wall was observed. These changes appeared at 1 month and had not increased by 2, 5 and 10 months. In the human aorta counterpulsated for 3 months there were **no histological changes in the inner wall of the aorta and only inconsequential changes in the outer wall**. These changes were similar to, but less than, those seen in sheep. While this is an observation from only one patient it provides confidence that counterpulsation of the human aorta is well tolerated.

Fifthly, when the second patient developed sepsis **removal of the device was a straightforward process**. While the infection was very unfortunate, a proportion of all surgical patients become infected, so it is important to know that the device can be safely removed.

The sixth finding from these two patients was the least expected. It was found that the device needs less power than had been forecast. **The driver can be even smaller, lighter and less energy consuming that originally conceived**.

cont'd

Sunshine Heart, Inc.

Lessons learned from the pilot clinical trial to date *(cont'd)*

We believe that when these six major findings are taken into account, the trial to date has been very positive despite the outcome for the patients themselves.

The clinicians involved in the clinical trial have expressed their confidence in the C-Pulse heart assist device by their ongoing recruitment of further patients into the trial. With the two Melbourne hospitals expected to enter the trial shortly, the rate of enrolment of patients is anticipated to accelerate.

Sunshine Heart expresses its sincere gratitude to the families of those involved in the trial to date – such patients are true pioneers. It is only through careful study to ensure the device is safe and performs as expected that clinicians will have the confidence in the C-Pulse heart assist device to refer Class III patients for the trial.

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1. Click on 'Access My Holding' (along the left hand side of screen)
2. Select Sunshine Heart Inc. and enter either your SRN or HIN, which you will find on your shareholder statement. You will also need to enter your Surname and Postcode to validate your holding.
3. Select 'Communications Options' from the dropdown menu and select 'Email Market Announcements' Check that you have your email address correctly entered.

If you have any problems please contact our share registrar, Link Market Services (formerly ASX Perpetual Registrars Ltd) on (02) 8280 7181 or email *registrars@linkmarketservices.com.au*

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