

#### CHAIRMAN'S ADDRESS

## Malcolm McComas, Chairman to the Third Annual General Meeting of the Company

Sydney, Australia – Wednesday 1 November 2006

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#### Welcome

On behalf of the directors, I am pleased to welcome you all to the third annual general meeting of Sunshine Heart, Inc.

As we are a US company incorporated in Delaware, I welcome you here both as holders of CHESS Depository Interests or CDIs, and as the owners of Sunshine Heart, Inc.

## Our Second Year as a Listed Company

This has certainly been a year of significant development for the company.

We received considerable press and analyst commentary after the first human implant of a C-Pulse heart failure device in May 2005 at Auckland City Hospital. Both Channel Nine News and ABC National News in Australia featured lead articles on C-Pulse and respected publications, including New Scientist, produced major articles for their international audiences.

Sunshine Heart commenced the financial year focused on signing up additional recruitment centres. We are honoured that such respected medical institutions as The Alfred Hospital and Southern Health Monash Medical Centre in Melbourne, St Vincents Hospital in Sydney and Royal Perth Hospital all gave ethics approval for patient enrolment.

The first Australian patient was enrolled in the clinical trial in June and to date, five patients have been implanted with the C-Pulse. We are still recruiting patients in Australia and New Zealand and are pleased with the improved rate of recruitment this year.

In addition to the clinical trial enrolment, major progress has been made with our supply partners on the development of the C-Pulse system. Our supplier, Polymer Technology Group, shipped more than 150 quality sterile cuffs during the year. We have been delighted with the performance of our robust and scaleable supply chain.

Our driver development partner, Plexus Corporation, has completed the initial reliability testing of the driver's critical components and commenced the production build and testing of the Alpha Driver units. We anticipate significant advancement in the driver development program in the current financial year.

In considering the recent development and progress of the C-Pulse system, I would like to acknowledge the support that AusIndustry have provided the Company through their Commercial Ready Grant Program. The company was awarded \$2.22 million under this scheme in October 2005 for the extended cycle testing of the cuff and the development of an improved percutaneous lead. In September 2006 we received an additional \$2.15 million to develop a quieter, more energy efficient gas driver.

## **Capital Raising**

As you are aware, Sunshine Heart has recently completed a \$19.8 million capital raising that was ratified by shareholders at an EGM held on 20 October. The capital raising included an \$8 million investment by CM Capital Investments, the Brisbane-based venture capital group, and \$8.5 million in follow-on investments by founding shareholders GBS Venture Partners, Three Arch Partners and PCLM Investments. In addition, other investors subscribed for \$3.3 million in new shares.

The capital raising was priced at a premium to the market price before it was announced and the Board would like to thank all those investors who participated. The raising is being undertaken in two tranches – tranche 1 will raise \$13.8 million and tranche 2 will raise \$6 million. The second tranche is subject to the FDA approving the IDE application to conduct the feasibility human clinical trial in the United States. Don Rohrbaugh, our CEO, will provide more information on this a little later.

With the \$3.3 million raised in January 2006, we are confident that Sunshine Heart has sufficient funds to progress into the US FDA clinical trial program.

#### The Year Ahead

With the capital raising completed, the focus has turned to completing development of the company's proprietary driver, completing development of the new Percutaneous Interconnect Lead, submitting an application to the FDA for approval of the IDE human clinical trials, initiating clinical sites in the US and commencing enrolment of patients into the feasibility study.

## **Board and Executive Appointments**

As indicated in the Notice of Meeting, the Board is recommending the appointment of Mr John Brennan as a non-executive director. A partner in CM Capital Investments, Mr Brennan has more than 15 years of experience in venture capital, corporate finance, commercial and legal experience. Before joining CM Capital in 2004, Mr Brennan had experience in mergers and acquisitions, divestments, capital raisings, venture capital and private equity gained from corporate and advisory roles both internationally and in Australia. The directors believe that he will provide a significant contribution to both the Board and the company.

I would also like to note Mr Crispin Marsh's transition from director of corporate affairs to non-executive director on 30 June 2006. A co-founder of the company, Mr Marsh has been a major asset and we are delighted to retain his valuable experience in his non-executive capacity. Mr Marsh advised the company during the Commercial Ready Grant application process and we are very grateful for his contribution to our success with these grants.

During the year, the Company also appointed Mr Victor Windeyer as Chief Operating Officer. He has extensive experience in the medical device field – including a role as Program Manager with Ventracor Limited. Since his appointment in December, Mr Windeyer has been a key advocate of the C-Pulse device and has been a significant influence in the company's development and success this year.

## **Management and Staff**

On behalf of the Board, I would like to thank all of the management and staff of Sunshine Heart Inc. Under the leadership of Don Rohrbaugh and Medical Director and founder Dr William Peters, they have worked hard to progress the Australia/New Zealand clinical trial program and C-Pulse system development.

I would also like to thank the members of the Medical Advisory Board for their valuable advice.

### Conclusion

In conclusion, I would also like to thank my fellow non-executive directors – Donal O'Dwyer (who chairs the Audit, Compliance and Corporate Governance Committee), Geoff Brooke (who chairs the Remuneration and Nomination Committee), Richard Lin and Crispin Marsh.

Together with all shareholders we look forward to Sunshine Heart's continued progress in the present year as it moves towards the US IDE human clinical trial program.

Malcolm McComas Chairman, Sunshine Heart, Inc. Sydney - 1 November, 2006

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#### **CEO'S PRESENTATION**

# Donald G Rohrbaugh, CEO to the Third Annual General Meeting of the Company

Sydney, Australia – Wednesday 1 November 2006

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#### Dear Shareholders:

I am pleased to report to you on Sunshine Heart's achievements of this past year. We have made great progress towards providing a new therapy to treat patients with the debilitating condition, heart failure. We have made progress across all aspects of the business.

#### **C-Pulse Clinical achievements**

Most significantly, we have clearly demonstrated the clinical benefit of the C-Pulse in a group of heart failure patients in Australia and New Zealand. Soon after implantation of the C-Pulse, the patients sensed a relief from the symptoms of heart failure. Most significantly, their ability to breathe and move were greatly improved. Table A summarizes the typical improvements experience by patients within the first month:

**TABLE A: Typical patient recovery with C-Pulse** 

Pre C-Pulse <sup>TM</sup>	1 month post C-Pulse <sup>TM</sup>
Tired, fatigued	Improved mobility
Short of breath	Easier breathing
Dizziness	Sustained endurance
Swollen legs or ankles	Good circulation
Repeat hospitalisations	Turn ON/OFF at will
Poor quality of life	Improved quality of life

Less subjective assessments by cardiologists also showed that the C-Pulse improved the function of the heart. For instance, the typical patient experienced a 60% improvement in the blood flow to heart muscle, allowing the damaged heart to pump blood to the body more effectively. This increased blood flow from the heart coupled with the "second" pulse of blood provided by C-Pulse appears as a 30% increase in total blood flow. These important cardiac improvements relate to a potential sustained and improved quality of life for this group of very sick patients.

Importantly, the C-Pulse was shown to be safe as well as functional. We can now tick the boxes for several features important to a patient's quality of life and market acceptance. The implant procedure is simple, safe and short. The patient recovery is quick. The C-Pulse provides an adequate improved blood flow and can be safely disconnected for the patient's convenience.

#### 2007 Readiness for the US FDA Clinical Trial

The company has achieved key elements of the business plan that are focused on initiating the US clinical trials to be overseen by the FDA – the critical pathway to the global markets. This is the Company's key objective for 2007 as outlined in Table B. The two key plan elements are:

a) product readiness and b) clinical design appropriate for the US physicians and FDA.

## **Table B: FDA Trial Objectives for 2007**

## IDE Feasibility Trial:

FDA Submission 1st half 2007Start enrolment 2nd half 2007

#### **IDE Trial Centres:**

- 5 to 7 initial clinical sites
- HF cardiologists and surgical teams
- Experienced with HF devices and trials
- Large HF patient pool

## Sunshine Heart US organisation:

- Regulatory executive and consultants in place
- Add COO management
- Add clinical management team

From the standpoint of product-readiness, activities with our supply partners have progressed. The Polymer Technology Group in Berkeley, California has produced several lots of sterile clinical quality Cuffs. Some of them have been used clinically and others have been used to expand our reliability tests, which have demonstrated a very reliable cuff that exceeds four years of simulated life.

The design of Sunshine Heart's wearable Driver is nearing completion with the Plexus Corporation in Neehah, Wisconsin. Reliability tests of the driver have demonstrated durability and the manufacturing phase is proceeding. The products will be ready for the FDA trial.

From the clinical trial standpoint, many activities have been achieved. Most significantly, Sunshine Heart's medical advisor board has guided the company in defining a study design for the first phase of the FDA trial, which has been submitted to the FDA for review and discussion and to the heart failure teams at multiple premier US hospital groups. Both the C-Pulse device and the study design have been well received from the perspective of clinical need and as desired therapy for the targeted patient group.

Sunshine Heart is well positioned to achieve the goals and objectives for 2007. The management and clinical teams are currently applying their proven expertise to address these key elements of this value enhancing goal.

## **Corporate Financial Management**

Financial year 2006-07 has been a significant year for Sunshine Heart. First, the company has continued to manage its financial resources consistently while achieving its goals. The CFO and financial controller have provided appropriate reports to the Board to assure prudent management of the company's assets.

Most significantly, Sunshine Heart completed a round of capital raising in October for a total of A\$19.8 million, to be achieved in two tranches. The first was approved recently, and the second tranche will be funded on receipt of approval from the FDA for the clinical trial. Details of the funding structure are outlined in Table C.

Table C: Funding Summary for Capital Raising of \$19.8 million

Pricing:	A\$0.15; with 3 options per 10 shares, exercised at A\$0.20, 3-year term
First Tranche:	A\$13.8 million approved at EGM, 20 Oct 2006
Second Tranche:	A\$6.0 million, approved at EGM, 20 Oct 2006, subject to FDA approval of US clinical trial
Major Investors:	CM Capital (A\$8 million), GBS Ventures (A\$7 million), Three Arch Partners (A\$1 million)

This funding will support the company well into the first phase of the FDA trial and provides a firm financial position for Sunshine Heart.

#### **Sunshine Heart Recap**

Sunshine Heart is proud of the accomplishments of 2005-06, in particular, of the demonstrated clinical performance of the C-Pulse. Most significantly, the C-Pulse was shown to increase blood flow to the body as well as to heart muscle. Patients reported that this increased blood circulation resulted in the relief of symptoms and an improvement in their quality of life. In 2006-07, we look forward to expanding these clinical experiences in Australian and New Zealand and extending into the US FDA clinical trial.

Sunshine Heart is sincerely appreciative of the support provided by the five clinical centers in the ANZ pilot trial. The support from the clinical teams was essential in providing insight into the clinical applicability of the C-Pulse. The company offers a huge thank you to the clinical teams at Auckland City Hospital (Auckland), St Vincent's Hospital (Sydney), The Alfred Hospital (Melbourne), Southern Health/Monash Medical Centre (Melbourne) and Royal Perth Hospital (Perth).

As we approach the 2007 US clinical trial, we are also appreciative of the support provided by the members of our outstanding international Medical Advisor Board who continue to encourage the development of the C-Pulse therapy. Their guidance is invaluable.

Looking forward, Sunshine Heart's enhanced management team, its employees and supply partners are energized by the challenges and opportunities coming up in 2006-7.

Our US clinical C-Pulse system will be available soon, including our unique wearable Driver and our enhanced Cuff.

We are preparing to submit an application to the FDA in the first half of 2007 to request the initiation of a US clinical trial. We have strong support from multiple premiere US hospitals for the process of patient enrolment. We have the start of an experienced US based clinical management structure positioned to train and monitor clinical enrolment and to collect data. Collectively, these initiatives are the foundation of a major valuation step in the evolution of the Sunshine Heart Company.

Personally, I applaud the dedication and commitment of our employees, our supply partners, our Board of Directors and our investors. We remain committed to providing a very unique product for patients diagnosed as having moderate heart failure. The C-Pulse promises to return patients to a more normal life style with an enhanced quality of life.

We sincerely thank you for your continuing support and confidence in Sunshine Heart, Inc.

Donald G Rohrbaugh Chief Executive Officer Sydney - 1 November, 2006

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For further information: Please see www.sunshineheart.com or contact

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