



ANNOUNCEMENT TO THE ASX
Address by Malcolm McComas, Chairman
to the
2nd Annual General Meeting of the Company
Sydney, Australia - Friday 4 November, 2005

Welcome

On behalf of the directors of your Company, I am pleased to welcome you all here today to the second annual general meeting of Sunshine Heart, Inc. as a public listed company.

As we are a US company incorporated in Delaware (with a subsidiary Sunshine Heart Pty Ltd operating in Australia) I welcome you here as holders of CDI's [CHESS Depository Interests] and the owners of Sunshine Heart, Inc.

Our first year as a public listed company

It is just over a year since the Company's CDI's were listed on the ASX (28 September, 2004). The management team led by Don Rohrbaugh (based in Southern California), Crispin Marsh (based in Sydney) and Dr William Peters (based in Auckland, New Zealand) the inventor of the Sunshine C-Pulse heart assist device, has come together well during the year. It is now a cohesive and capable group that has achieved a number of important milestones for the Company in that time.

The most significant milestone was, of course, the world-first human implant of the C-Pulse device announced on 9 May, 2005. The procedure was undertaken by lead investigator Dr Paget Milsom at Auckland City Hospital. The recipient was a 56 year old male who had been suffering heart failure for 15 years. The Company acknowledges this man's courage to be the first recipient of the implantable, non blood contacting, C-Pulse heart assist device. The device worked as expected and successfully completed approximately 10 million cycles.

We have also missed some milestones. The rate of patient recruitment for the long term clinical trial has been slower than we had planned for. The original timeline for the development of the driver system has similarly been extended.

We have however made considerable progress in recent months. Two Victorian centres are expected to be approved shortly to participate in the pilot clinical trial, which is a very significant step.

We have also made some important refinements to our business plan. We have an engineering prototype and are now redefining various aspects of the driver design and specification as a result of the first two human implants. We are confident that the work with Plexus, Inc is progressing well; they are a well qualified and experienced team.

These milestones are being regularly addressed by the board and the management team. As a consequence of these changes to the business plan, we have spent less cash than we had originally planned. With cash reserves of \$6.3 million at 30 September, 2005, we are adequately funded for the next 12 months on our current development program. However, we intend to raise new money during that period.

As a board, we have met 15 times since listing. During that period, the Company made 75 announcements to the ASX. In addition, the directors have had numerous other contacts, Committee meetings and discussions with management (and among themselves) during that time. I believe the board works effectively and board performance is measured throughout the year.

Organizational Structure

Let me first talk about the structure of the company and how that has evolved over the last year. We are incorporated in the United States but work across three countries (USA, New Zealand and Australia) and in three different time zones. The management team are to be commended for working together under a diverse geographical structure for a company our size.

We have enhanced our operating procedures, increased the financial planning and control function and have brought our research and development function under one roof at St Leonards.

First Human Implant – a world first

The most important development this year was the placement of the C-Pulse heart assist device in two patients at the Auckland City Hospital. As noted in the October Newsletter, these patients

have provided the Company with a great deal of data about how the C-pulse device improves the quality of life for moderate to severe heart failure patients.

It was found that the device can be inserted in a short operation; the operation is well tolerated by even very sick patients; the patients show improvement in their condition, almost immediately; the patients' aorta's have shown no material change from the counterpulsation pressure applied by the C-Pulse device; the device can be removed, if required, in a well tolerated operation; and the new driver being developed for the C-Pulse heart assist device is likely to be smaller and lighter than first envisaged.

The tireless efforts of Dr William Peters in the achievement of this milestone are acknowledged and appreciated.

New Clinical Trial Sites

The clinicians in Auckland are presently recruiting further patients into the long term clinical trial. Approvals are being finalised for the extension of the trial to a second and third centre in Melbourne. We expect to announce a further centre in NSW in 2006.

It is expected that these new centres will significantly increase the rate of patient enrolment into the trial in the coming months.

Clinical Publications and Presentations

During the year, two manuscripts regarding C-Pulse were published in peer reviewed medical journals, including the first intra-operative study using C-Pulse which was published in the highly regarded Cardiology journal *Circulation*. This study demonstrated short-term safety in humans and a 65% increase in blood flow to the heart muscle as well as significant unloading of the heart.

As announced on October 26, Dr Paget Milsom presented the follow-up data on the first two heart failure patients to receive the C-Pulse as a long-term implant. This Heart Failure Symposium, organised by the Australian Society of Cardiothoracic Surgeons, was attended by many local and international heart failure experts. The early data was very well received, and there is good clinical interest in the utility of the device for heart failure patients.

Federal Government support – Commercial Ready Grant

The award of a Commercial Ready Grant for up to \$2.2 million will help the Company fund the clinical trial work being undertaken in Australia. The Company acknowledges the Australian Government's initiative to provide research grants through the Commercial Ready scheme.

We also acknowledge the assistance of the AusIndustry staff in negotiating the grant. This is the second Federal Government grant the Company has received. The first grant of \$2.5 million in 2000 was a critical part of the Company's early funding. I would like to acknowledge the work of Crispin Marsh in the award of this Grant.

Driver development – Plexus, Inc

The drivers used in the clinical trial, which are leased by Sunshine Heart, have performed very satisfactorily. The development of the Company's proprietary driver is progressing well under an outsourced development program with Plexus, Inc, a technology development company based in Neenah, Wisconsin.

The point of developing our own driver system is three-fold: first, we are able to have a driver that is specifically designed to our unique operating requirements; second, we are able to control this key area of technology which is an important element of the company's intellectual property; and third, from the results of the first 2 patients, we have redesigned several aspects of the driver after seeing the clinical and practical requirements first hand. This refined design and specification is likely to produce a smaller, lighter product with longer battery life.

New office facilities – St Leonards

During the year the Company has established an office, laboratory and workshop facility in St Leonards. Some 5 of our 8 full time and part time staff are now located at St Leonards. This one central location has helped the team progress plans for making the C-Pulse ready for the second stage of clinical trials.

These activities have included developing the Company's quality systems, making enhancements to the implantable components of the C-Pulse, undertaking reliability testing and supporting the clinical trial program.

The Sydney office (although appropriately small) is an important step in bringing our

previously virtual company together as a real business, with a structure, systems and a home. Many analysts and investors have visited the office over the last few months. This central location is an important step in working as one entity with one corporate purpose.

Our employees

The staff of Sunshine Heart deserve our grateful thanks for their efforts over the past year. They have been capably led by CEO, Don Rohrbaugh and Dr William Peters. We have recently hired a Manager of Clinical Affairs and are seeking to employ a Project Engineer to support research and development.

Corporate Governance

Your board has been active in establishing good corporate governance for the Company, refining the strategy proposed by management and supporting the Company in its relations with the investment community. On your behalf, I thank the directors for the energy, time and interest they have shown over the past year.

Our Financial Position

The award of the Commercial Ready grant will assist the Company's 2005/6 cash flow position favourably. For every \$1 of research and development money spent by the Company, on an agreed budget, the Commercial Ready Grant will provide a further \$1 in direct cash subsidy.

We currently expect to spend approximately \$1.7 million of qualifying expenditure during the period to 30 June 2006 which will entitle us to a matching \$1.7 million of grant money. Our current cash reserves are expected to sustain the Company until the end of 2006. The board is reviewing the options for further capital raisings and is planning to undertake a raising following on from the clinical trial results that are likely to emerge in the first quarter of 2006. We may also do this before then.

Share price performance

The share price performance is as disappointing to the board as it is to all of our other shareholders. The management team have worked hard to present the Company to the investment community and they will continue to do that. Part of this process is education about what we do and how our device differs from other heart assist technologies; part is

understanding the inherent valuation that is appropriate for the product, its stage of development and clinical testing and its likely market; and part is an update on progress against milestones.

We are confident that as we achieve further clinical trial results and make meaningful progress towards our US regulatory approval milestone, there will be a significant re-rating of the Company as the investment community comes to better understand the potential in Sunshine Heart.

The outlook

Looking ahead to the coming year we expect that the progress of the Company will accelerate. With more centres actively recruiting patients into the clinical trial, we should see more patients receiving the C-Pulse heart assist device. We also expect to make further progress towards our first meetings with the FDA in the United States. This will be a precursor to the filing of an application to conduct a clinical trial in the USA.

In conclusion, we are making considerable progress after a relatively slow start. Significant foundations have been laid this year that have strengthened our position as a manufacturer of novel heart assist technology. We have a small, complimentary team working very well together. First human long-term clinical trials have demonstrated the C-Pulse works as intended and recent feedback from international heart failure experts at the recent Australasian College of Surgeons Heart Failure Symposium at Noosa was very supportive of the results gained to date. There is strong clinical interest in the C-Pulse device and we are confident that the device will fulfil an unmet clinical need for heart failure patients.

Malcolm McComas
Chairman, Sunshine Heart, Inc
Sydney – Friday 4 November, 2005