Letter from the Chairman

17 September 2008

Dear Shareholder

In the recent underwritten rights issue prospectus I indicated that the Company remained optimistic that approval by the US Food and Drug Administration (FDA) of the Company’s Investigational Device Exemption (IDE) application would occur in the second half of this year. I am pleased to advise that we have now received conditional approval from the FDA to undertake a 20 person US clinical trial with our heart assist device C-Pulse™. This very significant milestone was announced to the market on Friday 12 September 2008.

The FDA approval conditions are acceptable to the Company and will result in minor changes to the clinical protocol, patient record keeping and device labelling.

C-Pulse provides a treatment therapy for the substantial number of patients suffering from moderate heart failure who no longer receive symptom relief from medication or CRT pacemakers. Left untreated moderate heart failure normally leads to increased hospitalisations and premature death. Since C-Pulse is located outside of the blood system, there is minimal risk of blood clots and strokes, and blood thinning medication is not required. In the US alone there are approximately 1.5 million patients with moderate heart failure.

We expect patient enrolment to begin in the fourth quarter of 2008 at six US medical institutions. Each patient will be closely monitored for six months to record the effect of the C-Pulse device.

After completion of this clinical trial, the Company plans to seek CE Mark approval for C-Pulse to enable the device to be marketed in the European Union and other countries accepting CE Mark. The Company will also apply to the FDA for approval to undertake a larger US clinical study as a precursor to gaining approval to market the device in the USA.

I thank you for your continued support of the Company and I congratulate the Company for achieving this major milestone.

The September 2008 edition of Investor News is enclosed as well as your invitation to attend an investor briefing to hear more about the Company and its future plans.

Yours faithfully

Malcolm McComas
Chairman
INVESTOR BRIEFINGS

On September 12, 2008, Sunshine Heart, Inc. (ASX:SHC) passed its most significant milestone since listing on ASX in 2004.

The US Food and Drug Administration (FDA), following an exhaustive process of review, granted conditional approval for the first US clinical trial for C-Pulse™, Sunshine Heart’s heart assist therapy for patients suffering from moderate heart failure. Patient enrolment is expected to begin in the fourth quarter of 2008 at six US medical institutions.

Senior management of the Company will conduct a series of short investor presentations in Australia and New Zealand according to the schedule below.

Shareholders and interested parties are invited to attend these sessions as our guests to learn more about Sunshine Heart and its plans following this exciting development.

The presentation schedule is as follows:

<table>
<thead>
<tr>
<th>AUCKLAND</th>
<th>BRISBANE</th>
<th>PERTH</th>
<th>MELBOURNE</th>
<th>SYDNEY</th>
</tr>
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<tbody>
<tr>
<td>Friday, 26th Sept 10am</td>
<td>Monday, 29th Sept 10am</td>
<td>Tuesday, 30th Sept 10am</td>
<td>Wednesday, 1st Oct 10am</td>
<td>Thursday, 2nd Oct 10am</td>
</tr>
<tr>
<td>THE DUXTON AUCKLAND 100 Greys Avenue</td>
<td>THE HILTON HOTEL 190 Elizabeth Street</td>
<td>SHERATON PERTH HOTEL 207 Adelaide Terrace</td>
<td>HOTEL WINDSOR 111 Spring Street</td>
<td>THE RADISSON PLAZA HOTEL 27 O’Connell Street</td>
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</tbody>
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CEO UPDATE

The moment we’ve been waiting for is here and I am very pleased to announce the FDA approval for our US C-Pulse™ IDE Feasibility Trial! We can now commence the first FDA sanctioned chronic heart assist therapy trial for moderate heart failure. I would like to extend great appreciation for the hard work of the collective “WE” who are responsible for this monumental corporate milestone: The entire St. Leonard’s-based engineering team, with special mention of Rodney Parkin and Scott Miller; Victor Windeyer; the Pilot ANZ Clinical Teams under the direction of Dr. William Peters; the US Clinical team, led by Mary Beth Kepler; and finally, the Company investors who believe in C-Pulse and our dream of fulfilling the unmet clinical need for moderate heart failure treatment. We all share this accomplishment. The enthusiasm has fueled our continued focus on what follows the FDA approval — US Clinical Trial commencement.

Clinical readiness has been on-going in parallel with our FDA communications. In fact, we are immediately submitting applications for Institutional Review Board (IRB) study approval within each of our six university-based heart failure research centres. Our world-class investigational team is lead by the two National Co-Principal Investigators (Co-PIs); Drs. William Abraham and Patrick McCarthy. Each of our six premier Clinical Trial sites has a medical research team that consists of both the referral heart failure

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REFLECTIONS OF THE COMPANY FOUNDER

William S. Peters M.D, Company Co-founder and C-Pulse™ Inventor

The FDA’s approval of a protocol to trial C-Pulse™ in the US is undoubtedly a pinnacle of achievement for Sunshine Heart. I am both delighted and relieved that the C-Pulse concept has evolved from an idea to bench-top models, through the rigors of advanced engineering development, extensive testing and validation and a careful ANZ trial before now entering six world class heart failure hospitals for an FDA approved clinical trial.

We take the long-term view that a safe, simple to implant heart assist device is an essential part of the armamentarium available to heart failure physicians and their patients. As such, having tolerant and supportive investors has been vital in developing C-Pulse and we value the ongoing support of investors to allow the trialing of C-Pulse in the USA to determine its labeling and for obtaining marketing approvals in the USA and CE Mark-regulated countries. This approval is clearly a key milestone on the pathway to serving a huge unmet clinical need and a great market opportunity for Sunshine Heart.

Similarly, Sunshine Heart recognizes the value of its board, employees, contractors and clinicians — their creativity, commitment and enthusiasm has made possible the achievement of this milestone, and their ongoing input in realizing the necessary steps for product to market is the company’s life-blood.

Most importantly, in getting to this milestone, Sunshine Heart gracefully acknowledges the patients and their families and friends who participated in the Australia-New Zealand pilot study — they are true pioneers.

Heart failure pacemakers are designed to fix the timing of heart pumping but there is an existing clinical need for patients not
GREAT TEAM EFFORT ACHIEVES MILESTONE

After thousands of pages and hours, Sunshine Heart achieved the milestone approval to start the C-Pulse™ US Clinical Trial. Victor Windeyer, COO and General Manager, said, “It is outstanding that after the many years of development and focus we have achieved this Company goal.” Mary Beth Kepler, US Director of Clinical Trials and Regulatory added, “We look forward to commencing the safety and efficacy study of this novel heart assist therapy, C-Pulse. We are pleased with the high quality of our clinical research team as well as the support teams from the Clinical Research Organization, Alquest, as well as our core labs, Henry Ford Hospital and University of Pittsburgh.”

REFLECTIONS....continued from page 1

suitable for this type of therapy. Approximately 60-70% of the moderate heart failure patients cannot be treated with pacemaker technology and many patients have recurrent symptoms following pacing therapy. Sunshine Heart’s C-Pulse is designed to improve heart pumping function by increasing the hearts own coronary blood supply 65+% and by reducing its left ventricular load 30+%. Key to safety and patient convenience is that C-Pulse can be turned on and off and is disconnectable.

In addition to supporting the surgical training and initial implants for the US clinical sites, I am pleased to be working with the engineering team on a fully implanted device, C-Pulse II. Our design uses power transmission across the skin, with no broach of the skin, thus broadening the applicability of the device. We look forward to all the advances as C-Pulse moves closer and closer to commercialisation.
Geographical representation of US Incidence of Heart Failure is shown with darker red. The six premier Clinical Trial sites are targeted within the high incidence areas and shown with yellow markers.

**UNIVERSITY HEART FAILURE RESEARCH SITES**

- Northwestern University Feinberg School of Medicine
- Ohio State University Medical Center
- Penn State Hershey Medical Center
- University of Louisville – Jewish Hospital
- University of Alabama at Birmingham
- University of Florida – Gainesville

**CLINICAL PUBLICATIONS TO DATE**

**ANZ: Heart Lung and Circulation**
  Extra-ascending Aortic versus Intra-descending Aortic Balloon counterpulsation – Effect on Coronary Blood Flow

**AHA: Circulation**
  Extra-aortic Balloon Counterpulsation: An Intra-operative Feasibility Study

**ISHLT: Journal**
- Hayward, Raygok, Jansz, et al (February 2008)
  First-in-human Study of a Novel Implantable Extra-ascending-aortic Counterpulsation Pump with End-stage Heart Failure

- Extra-Aortic Implantable Counterpulsation Pump in Chronic Heart Failure

**NATIONAL CO-PRINCIPAL INVESTIGATORS**

Dr. Patrick M. McCarthy
Chief, Division of Cardiothoracic Surgery and Co-Director, Bluhm Cardiovascular Institute
“It’s an exciting time to be the co-principal investigator with Dr. Abraham of the Sunshine Heart Trial, because this is really very novel — this is not anything that we have seen for about ten years — since we introduced the biventricular synchronous pacing. This is a new kind of therapy for patients with heart failure. We’ve really needed it; the drugs only work so far, pacing improves some patients pretty well, but there’s still a lot of people that weren’t treated well, so, we’re cautiously optimistic that some patients are going to respond well to this therapy.”

Dr. William T. Abraham
Professor of Medicine and Chief, Division of Cardiovascular Medicine
“It’s a true honor for me to be the National Co-Principal Investigator for the C Pulse trial in the United States. It really is a special opportunity to be able to contribute to something that may ultimately help tens of thousands of patients in the U.S. and outside of the U.S.”
CEO UPDATE... continued from page 1

Cardiologists and the cardiac surgeons. You will learn more in the following pages about the excellent support teams ready to provide surgical training, technical support and all the clinical services to complete a successful IDE study. The entire Clinical Study team is poised to begin the first chronic non-blood contacting heart assist therapy trial for moderate heart failure.

SUNSHINE HEART COMPLETES $5.4 MILLION RIGHTS ISSUE

In June, Sunshine Heart announced the successful closing of our fully underwritten non renounceable rights issue of new ordinary shares to raise approximately $5.4 million. Existing shareholders for subscribed $3.851 million which represents 71% of the issue. GBS Ventures and CM Capital, the underwriters, were issued the remaining $1.594 million of new shares. Following the rights issue, the Company maintained its Australian/New Zealand ownership — now 94%. Ownership of shares within the Company are the following types: 65% Venture Capital Funds, 8% Institutional Investors, 6% Bio Tech Funds, 5% Founders and 16% other.

Sunshine Heart’s Chief Executive, Don Rohrbaugh said, “We are encouraged by the support of shareholders in difficult market conditions.” He added, “The funds will strengthen the company’s balance sheet in anticipation of the forthcoming United States based clinical trial.”

NEW SUNSHINE HEART DIRECTOR APPOINTED

The Sunshine Heart Board of Directors announced in July the appointment of Mr. Nicholas Callinan as a Director of the Company to fill the vacancy caused by the retirement of Dr. Conrad Wang. After more than 20 years of global venture capital market experience, Mr. Callinan now serves as the founder and managing partner of Collins Hill Pty Ltd, which advises institutional investors and funds managers in the global private equity venture capital markets. He was founder and chief executive of the Advent group of companies which were among the first venture capital investment firms in Australia. Mr. Callinan has a depth of experience in working with fast growing organizations and holds degrees in Engineering and Business Administration from the University of Melbourne.

Chairman Malcolm McComas said “Nick’s global reputation in technology venture capital will be good for Sunshine Heart. We are a company in change; moving from development to a US clinical trial. Nick’s first hand experience with growth companies is a very good fit and we welcome him to the board.”

Forward Looking Statement
Statements in this document that are not purely historical are forward looking statements. Various factors could cause actual results to differ materially from any forward looking statement, such as the timing and outcomes of clinical results including the efficacy of products, financing availability, and product sales and marketing. Whilst we believe any forward looking statement made to be reasonable as of the date hereof, we can give no assurance that our expectations are correct. All forward looking statements are expressly qualified in their entirety by this cautionary statement.

US Securities Statement
The shares of Sunshine Heart have not been registered under the Securities Act of 1933 (the “US Securities Act”) and may not be offered, sold or delivered in the United States, or to, or for the account or benefit of, any US Person, as such term is defined in Regulation S of the US Securities Act. In addition, hedging transactions with regard to the shares may not be conducted unless in accordance with the US Securities Act.

C-Pulse is a trademark of Sunshine Heart, Inc. and is registered in the United States Patent and Trademark Office. The C-Pulse System is undergoing clinical evaluation and is not available for commercial sale.