

Innovative Therapy for Treating Heart Failure



Sunshine Heart • Annual Report 2009

Sunshine Heart is a global medical device company, committed to the commercialisation of the C-Pulse™, an implantable, non-blood contacting, heart assist device for the treatment of people with heart failure. These patients include a large and under-served potential market segment and provide a significant market opportunity for the Company.

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# Notice of Meeting

The Annual General Meeting of Sunshine Heart, Inc. will be held at the offices of Henry Davis York, 44 Martin Place, Sydney on Thursday 29 October 2009 at 12 noon.

### Chairman's Letter

Dear Shareholders,

You are invited to attend the 2009 Annual General Meeting to be held in Sydney on Thursday 29 October 2009. A notice of meeting is enclosed together with the Company's 2009 annual report.

I am pleased to report a number of successes for Sunshine Heart over the year as we have achieved a number of significant milestones. The main ones concern our progress towards being able to market our C-Pulse $^{\text{TM}}$  device in the key market of the US.

In November 2008, we were successful in obtaining approval from the US Food and Drug Administration (FDA) to conduct the Investigative Device Exemption (IDE) trial. The process of obtaining this approval is inevitably drawnout and we were pleased to have achieved it in what could be seen as better than average time.

Once we had the IDE approval we were able to work with the six sites we had selected for the trials to bring them up to "implant ready" status. We were also able to negotiate favourable reimbursement conditions from Medicare and those insurers who ultimately pay for the operations to implant our device. We are very pleased that the level of reimbursement makes the process financially viable for us and for the doctors and hospitals involved.

The FDA approval was for us to implant up to 20 patients in the US at six university hospitals. This makes the C-Pulse™ the first heart assist system approved for an FDA-approved clinical trial addressing the unmet clinical need of moderate heart failure patients.

After all the work in preparing the clinics for the implants, we saw the first two operations successfully carried out in April 2009. These were done at The Ohio State University Medical Center. Then, just as this letter was being prepared, the Jewish Hospital at the University of Louisville implanted a further two patients.

The Company is very encouraged by all the patients' response with the C-Pulse device. We are also hopeful that, as the first implants demonstrate the early success of the product and give the doctors confidence with the operation, the understandable caution of the medical clinics and doctors with new treatments may start to be reduced and we may see a quickening of the pace of the implants.

Because of the reimbursement agreements, the Company has now recorded its first sales, with payments received for the first implants.

Sunshine Heart is still very much in the development stages as a company. As such, it needs to raise capital to allow it to achieve its milestones. As part of this, we have recently completed placement of 15% of our shares to institutional investors raising \$1.75 million in August 2009. We are currently embarking on a rights issue to raise up to \$8.1 million at the same price per share as the placement. This capital should allow us to complete this initial feasibility IDE trial and prepare for the next steps in being able to market the device both in the US and elsewhere. This will mean a further, larger FDA trial and obtaining CE Mark certification for Europe and other countries. In due course, we will need to raise additional capital to achieve these milestones.

Our optimism comes from the hope that, as we demonstrate the C-Pulse's effectiveness in addressing what is a very sizeable market, our shareholders will be rewarded for their patient support of the Company.

Yours sincerely

Nicholas Callinan

Chairman

21 August 2009

## Chief Executive Officer's Review

#### Dear Shareholders,

Sunshine Heart once again achieved a number of notable accomplishments this past year thanks to a committed team of dedicated employees, an outstanding group of medical advisors and supportive Directors and investors. The Company continues to focus on "developing an international heart assist device business dedicated to improving the quality of life for people in advanced heart failure". The unmet clinical need for these advanced heart failure patients could be a multi-billion global market.

#### 2009 key achievements

The main pathway to that international business is the completion of clinical trials in the US which has been the Company's primary focus this past year. Many important steps towards that goal were achieved with the most notable achievements including the following:

- Full Approval of the feasibility trial by the US Food and Drug Administration (FDA) in November 2008.
- Approval from the ethics committees (Institutional Review Boards, called IRBs) at all six university medical research hospitals.
- Approval for US Medicare reimbursement for C-Pulse™ at all six clinical sites.

#### And most significantly,

- Initiation of the US clinical trial with the first implantations of C-Pulse into two patients at The Ohio State University Medical Center (OSU) in April 2009.
- Continuation of enrolment in the trial.
- Reimbursement (first sales) for the C-Pulse.

#### Approval of the feasibility trial by the FDA

Since C-Pulse is the first heart assist in a FDA sanctioned Class III clinical study, C-Pulse is positioned to be the first-to-market heart assist therapy for moderate/advanced heart failure and the only non-blood contacting heart assist therapy.

The C-Pulse system is a simple, non-blood contacting, implantable counterpulsation pump that is a low-risk, cost-effective therapy that augments the native heart's cardiac output. Implanting C-Pulse involves a straightforward procedure not requiring the use of a heart lung machine with a short recovery compared to other cardiac support devices. Importantly there is a defined reimbursement pathway. The general approach of counterpulsation is the most widely utilized technology for heart assist. For many years before the C-Pulse, intra-aortic balloon pumping (IABP) has used counterpulsation to provide temporary in-hospital, non-ambulatory heart assistance. The C-Pulse approach has built on the general counterpulsation approach and developed it in a unique and patented technology. We are now, through the FDA approved trial, working to demonstrate the safety and overall benefits of the C-Pulse. Our system is unique and "ground-breaking" and addresses a group of patients who are currently not served by other therapies. All these novel features have required frequent interaction with the FDA to define the clinical study path.

Each step of the pathway involved the review of prior C-Pulse clinical experiences, the review of the C-Pulse product and the negotiation of the appropriate agreements. The process has taken longer than anticipated – but not longer than is "normal" for such a process - but efforts have now been rewarded with the initiation of the FDA-approved feasibility clinical trial.

#### Initiation of the US clinical trial

The first implantations of C-Pulse into the two OSU patients in April 2009 were clearly a major Company milestone. They marked the launch of the C-Pulse feasibility clinical trial in the United States. The total program will involve implanting 20 patients at the six university hospitals, including The Ohio State University, Northwestern University, Pennsylvania State University, University of Louisville, University of Florida and University of Alabama/Birmingham. Enrolment is currently picking up in pace and is expected to continue into the first quarter of 2010. After that, we must collect data on each patient for six months under the FDA agreement.

Both OSU patients with the C-Pulse implants have shown improvement in their physical endurance and quality of life. Both patients were able to disconnect from the device when they wanted to, as is intended, without complications. These patients, now past the first three month evaluation, have re-validated the C-Pulse data achieved in our prior Australia-New Zealand (ANZ) clinical studies. As published in scientific/medical journals, these ANZ clinical studies provided data that the C-Pulse system increases blood flow to the body and to the heart muscle itself without coming into direct contact with the blood. It is this non-blood contacting feature of the device that allows patients to intermittently disconnect from C-Pulse for convenience without risk.

We have most recently reported further implants of two female heart failure patients at the Jewish Hospital at the University of Louisville in Louisville, Kentucky. This is seen as a further milestone as the FDA required that we include both genders in the trial to assure appropriateness for the spectrum of heart failure patients since females represent nearly half of all hospital admissions for heart failure. Females with heart failure typically survive longer than men but commonly have more frequent hospitalizations and a poorer overall quality of life.

Another important achievement of setting up the US clinical trial has been the level of reimbursement for C-Pulse that has been approved. Following the FDA's awarding a Category B reimbursement for implants during the trial, the Company has worked with the clinical sites to help their applications to their regional Medicare CMS offices for reimbursement pre-approval. All six sites have now received their pre-approval for reimbursement. In addition, a private healthcare insurer has granted pre-approval for a patient. Sunshine Heart will invoice US\$54,000 for each of its devices under an existing reimbursement code for a "heart assist system" (DRG MS 1 or 2). We have received payment for the first implants, marking the first recorded sales for Sunshine Heart -- another Company milestone.

#### **Capital raising**

In May 2009, the Company announced its intention to raise additional capital to fund the existing feasibility trial. In July, we appointed ABN Amro Morgans as the broker for that financing. In August, we announce a successful placement of \$1.75 million in new shares and the launch of a \$8.1 million Rights Issue. The main objectives of the financing are:

- Complete enrolment and patient follow-up in the US feasibility trial;
- Prepare the application to the next stage FDA Pivotal Trial, involving a randomised selection of 100 or more patients, and
- Prepare an application for CE Mark certification for Europe and other countries recognising the CE Mark. Our plan is to complete enrolments for the trial by the end of the first quarter of 2010 and then proceed with the next steps towards commercializing C-Pulse.

#### Advancing the fully implanted C-Pulse

The clinical experiences have continued to confirm the fundamental features of the C-Pulse including the performance of the Cuff and the unique counterpulsation features. While we are pleased with the present clinically-ready C-Pulse system, our long-term goal is to provide cardiac assistance for advanced heart failure patients with the smallest, most portable, most reliable system possible. We see this as a fully implantable next generation C-Pulse system ("C-Pulse II") and we are working towards this and are in discussions with several development partners to jointly develop the C-Pulse II.

### Chief Executive Officer's Review continued

#### **Financial management**

In 2009, the Company refined the company structure to change the focus from R&D to focus on the US clinical trial. We eliminated some staff positions and shifted responsibilities for others. This allowed us to keep our operating costs under control. As reported in the financial statements, our achievements for the year were accomplished with an annual cash outflow from operating activities of \$7,747,373, an average cash burn of \$645,614 per month.

#### Foundation for 2010 major achievements

Building upon the foundation established to date, the Company can anticipate significant achievements and announcements in 2010. We can anticipate continued announcements of progress and the completion of enrolment in the US feasibility trial. The Company will proceed towards defining the next FDA clinical study and prepare for CE Mark application. At the same time, progress on the C-Pulse II will be moving forward.

#### **Summary**

In conclusion, with our progress achieved in 2009, highlighted by the implementation of the US FDA-sanctioned clinical trial, the Company is advancing towards "developing an international heart assist device business dedicated to improving the quality of life for people in advanced heart failure".

In the US alone, more than 5.3 million people suffer from heart failure, a progressive disease with treatment costs exceeding \$34.8 billion annually. Among these patients, more than 1.4 million have progressed to advanced heart failure indicated by the presence of shortness-of-breath and fatigue during mild exercise (like walking). With the aging of Baby Boomers and the progressive nature of heart failure, significant growth in the incidence of advanced heart failure is expected. Specifically targeted for the conditions of advanced heart failure, Sunshine Heart's C-Pulse therapy offers an earlier treatment for patients with improvement in quality of life and prevention from further degradation of their condition.

I want to personally thank you for your continued interest and support of Sunshine Heart. I also offer my humble thanks and appreciation to the total Sunshine Heart team and to the medical professionals of the clinical sites who continue to move us closer to our goal.

Best regards

Donald Rohrbaugh
Chief Executive Officer

21 August 2009

## Directors' Report

#### **Directors**

The names and details of the company's directors in office during the financial year and until the date of this report are as follows. Directors were in office for this entire period unless otherwise stated.

#### Names, qualifications, experience and special responsibilities

#### Mr Nicholas Callinan BE MBA (appointed director 10 July 2008, appointed Chairman 30 October 2008)

Mr Callinan is the founder and managing partner of Collins Hill Pty Ltd which provides advice to institutional investors and funds managers in the global private equity and venture capital markets where he has worked for over 20 years in Australia and in several countries including the UK and USA. In the early 1990's he set up investment funds in the former communist countries of Central Europe. Previously, in the early 1980's, he was founder and was chief executive of the Advent group of companies which were leaders in venture capital investment in Australia. He has worked with many developing companies throughout his career and serves and has served on a number of company boards both private and public, government bodies and charitable foundations in Australia and overseas. He has degrees in Engineering and Business Administration from the University of Melbourne.

#### Mr John Brennan LLB

Mr Brennan became a non-executive director of Sunshine Heart on 1 November 2006. He is a member of the Remuneration and Nomination Committee.

Mr Brennan is a Partner of CM Capital Investments, an Australian venture capital fund manager. CM Capital Investments manages \$260 million in early stage venture capital funds focused on the life sciences and telecommunications sectors. Mr Brennan has more than 15 years of venture capital, corporate finance, commercial and legal experience. Prior to 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. Mr Brennan started his career as a corporate and commercial lawyer in Brisbane. He subsequently gained international experience in the UK where he worked for GE Capital and Ernst & Young Corporate Finance in M&A and corporate finance roles. At GE Capital Mr Brennan had a pan European M&A role focused on acquisitions, strategic equity investments and divestments for one of its main operating businesses. Mr Brennan holds a Bachelor of Laws degree from Queensland University of Technology.

#### Dr Geoff Brooke MBBS MBA

Dr Brooke became a director of Sunshine Heart on 25 September 2003. He is the Chairman of the Remuneration and Nomination Committee.

Dr Brooke is managing director of GBS Venture Partners, the manager of \$400 million in early staged venture funds. With more than 20 years of venture capital experience, Dr Brooke has been a founder, lead investor and director of many healthcare and bioscience based companies in the US and Australia, a number of which have been sold or undertaken IPO's on either NASDAQ or ASX. A medical graduate of the University of Melbourne with five years of clinical experience, Dr Brooke holds an MBA from IMEDE (now IMD) in Switzerland. During the past 3 years Dr Brooke has served as a director of the following other listed companies:

- Cogstate Limited
- ChemGenex Pharmaceuticals Ltd (current directorship).

## Directors' Report continued

#### Mr Crispin Marsh BSc FAICD

Mr Marsh became a non-executive director of Sunshine Heart on 1 July 2006 and a member of the Audit Committee on 17 July 2008. He was the executive director of Corporate Affairs of Sunshine Heart, until 30 June 2006. He has been associated with Sunshine Heart since its inception in 1999, having been the inaugural Chairman of the company. Mr Marsh has been responsible within Sunshine Heart for administration, legal issues, intellectual property protection, obtaining research grants, contract negotiation and management of corporate relationships.

Mr Marsh is also managing director of SCP Technology and Growth Pty Ltd, an independent innovation commercialisation consultancy. He has been directly involved in the successful commercialisation of a number of technologies in a variety of technical fields including the medical area. It was in this role that he co-founded Sunshine Heart with Dr Peters.

An Australian patent attorney since 1969, Mr Marsh was a partner of an Australian firm of patent attorneys for nearly 30 years before establishing SCP. He has a BSc degree from the University of Sydney, is a registered mediator and a Fellow of the Australian Institute of Company Directors. Mr Marsh is a director of Australian Biotechnology and Healthcare Fund No. 3 Ltd.

#### Mr Donal O'Dwyer BE MBA

Mr O'Dwyer became a non-executive director of Sunshine Heart in July 2004. He is the Chairman of the Audit, Compliance and Corporate Governance Committee.

Mr O'Dwyer relocated to Australia in 2004, having retired as Worldwide President of Cordis Cardiology, the cardiology division of a Johnson & Johnson subsidiary, Cordis Corporation. In this role Mr O'Dwyer saw Cordis Cardiology move from number four to number one in market share of coronary stents worldwide. Prior to joining Cordis he worked 12 years for Baxter Healthcare, rising from plant manager in Ireland to president of the Cardiovascular Group, Europe. He brings a wealth of medical device experience to Sunshine Heart. During the past three years Mr O'Dwyer has also served as a director of the following other listed companies: Cochlear Limited, Mesoblast Limited and AtCor Medical Holdings Limited (Chairman). He remains a director of each of these companies.

#### **Dr William Peters MBChB MD (Medical Director and Chief Technical Officer)**

Dr Peters is the inventor of the C Pulse system and was co founder and start up CEO of Sunshine Heart. He has served as a member of the Board since inception, and in his role as Medical Director and Chief Technology Officer is responsible for defining device development appropriate for clinical need, training US clinical sites and for overseeing the conduct of clinical trials in investigating such devices.

Dr Peters completed a medical degree at Otago University 1989 and a Doctorate of Medicine (MD) at Monash University in 2002. Dr Peters has a track record of successful invention, clinical uptake and commercialisation in the field of cardiac technologies. He previously invented a system for endovascular cardiopulmonary bypass to allow minimally invasive cardiac surgery. This technology was assigned to Heartport, Inc, which listed on NASDAQ in 1996 and was bought by Johnson & Johnson in 1999. Dr Peters spent 2 years as a research fellow in minimally invasive cardiac surgery (1994-1995) at Stanford University, California. He was also employed during this time as manager of medical affairs at Heartport, Inc. Dr Peters has a strong interest in devices to support the failing heart, and has clinical experience in thoracic transplantation and use of various LVADs (including Biomedicus, Abiomed, Thoratec, Novacor and IAB systems). Dr Peters has authored or co-authored over 20 published articles and 4 book chapters regarding cardiac surgery.

Dr Peters holds honorary senior clinical research fellowships in the Green Lane Cardiothoracic Surgery Unit at Auckland City Hospital and the Department of Surgery, Auckland University, the latter with supervisory responsibility of a doctorate candidate.

#### *Mr Donald Rohrbaugh MSME (Director and Chief Executive Officer)*

Mr Rohrbaugh joined Sunshine Heart in September 2002 as a consultant. Mr Rohrbaugh became the CEO and was appointed to the board in January 2003 and is responsible for implementing the Company's strategies and tactics approved by the Board of Directors.

Previously, Mr Rohrbaugh was the founding CEO and director of Acorn Cardiovascular, Inc., a company engaged in developing a non-active device treatment for heart failure. During Mr Rohrbaugh's role as President and Chief Executive Officer, from December 1997 to December 2001, Acorn completed 4 rounds of financing totalling \$US47.6 million to advance the innovative Cardiac Support Device, CorCap, from concept to Phase II randomised clinical trials in the USA and Europe.

Mr Rohrbaugh has also served as a consultant to various venture capital firms. At times he served as CEO for start-up companies such as Embolix, which was acquired by Edwards Lifesciences, eMED Corporation and AMED Systems. In those roles he also served on the Board of Directors.

From 1977 to 1996, Mr Rohrbaugh held a variety of executive management positions with Baxter Healthcare International, including Vice President of Research and Development for the Edwards Critical Care Division and Vice President/General Manager of the Edwards MDS and the Novacor Division (an LVAD manufacturer).

Mr Rohrbaugh has over 30 years of business and product development experience in both the domestic and international medical device markets, including nearly 15 years with heart failure devices. He also has 10 years experience in the scientific instrumentation business and 4 years in the aerospace field.

Mr Rohrbaugh's formal education includes a Bachelor of Science in Mechanical Engineering from Pennsylvania University and a Master of Science in Mechanical Engineering from University of Southern California.

#### Mr Malcolm McComas BEc LLB SF Fin FAICD

#### (resigned as Chairman 30 October 2008, resigned as director 16 December 2008)

Mr McComas became a director and the chairman of Sunshine Heart on 20 July 2004 and was a member of the Audit, Compliance and Corporate Governance Committee until his resignation.

Mr McComas has 25 years investment banking experience and 6 years legal experience. He has experience in equity and debt finance, acquisitions and divestments, and the structuring and implementation of major equity issues and privatisations.

Since 1999, he has been a director and is now a consultant to Grant Samuel, the corporate advisory, property services and funds management group. In the previous 10 years, he established and developed County NatWest's corporate finance business which in 1998 became, through merger, the investment banking division of Salomon Smith Barney in Australia (a subsidiary of Citigroup, Inc). Mr McComas was a managing director and co head of investment banking at Salomon Smith Barney and managing director of investment banking at County NatWest. Mr McComas has a Bachelor of Economics and a Bachelor of Laws from Monash University. He is a Senior Fellow and a National Council Member of the Financial Services Institute of Australia. During the past 4 years Mr McComas has served as a director of Pharmaxis Limited, a listed entity.

#### Dr Conrad Wang MD BS MBA (appointed 15 November 2007, resigned 10 July 2008)

Dr Wang is an associate of Three Arch Partners, a Silicon Valley-based venture capital firm specialising in funding the development of medical technologies, healthcare services, biotechnology, and information technology. Prior to joining Three Arch Partners, he completed his medical and orthopaedic training at the Harvard Medical School where he also spent time as a research scientist. Dr Wang also holds an MBA from Harvard Business School and a Bachelor of Science in Mechanical Engineering from Massachusetts Institute of Technology.

## Directors' Report continued

#### **Company Secretary**

#### Mrs Rowena Hubble B Bus CPA (appointed 15 May 2009)

Mrs Hubble was appointed Company Secretary of Sunshine Heart in May 2009. She is responsible for all financial, taxation, compliance (non-clinical), risk and company secretarial functions.

Mrs Hubble commenced her professional career with the Australian based Gresham Partners. She has held various senior finance positions over a 15 year period including Company Secretary with McDonald's Australia Ltd and was involved with domestic and global projects for this US multinational. Mrs Hubble is a Director of Laymitch Pty Ltd providing financial advisory services to various organisations.

#### Mr Brian Bolton BCom MBA FCPA (retired 15 May 2009)

Mr Bolton was the Chief Financial Officer and Company Secretary of Sunshine Heart until his retirement on 15 May 2009.

Mr Bolton has held various financial and treasury executive positions with Esso Australia Ltd during his 16 year tenure in both Australia and the USA. In addition he has 12 years of experience as Chief Financial Officer with ASX listed Plutonic Resources Ltd and Atlantic Gold NL.

#### **Directors' Interests**

The direct and indirect interests of the directors in the shares of the Company (including interest in options) are set out in note 20. There has been no change in director's interests post year end.

#### **Earnings per Share**

Basic Earnings per Share (2.8) cents
Diluted Earnings per Share (2.8) cents.

#### Dividends

No dividends were paid or recommended to be paid during the year (2008: Nil).

#### **Corporate Information**

#### **Corporate structure**

Sunshine Heart, Inc. is a company limited by shares that is incorporated in Delaware, USA. It has prepared a consolidated financial report incorporating the entity that it controlled during the financial year, Sunshine Heart Company Pty Limited.

#### Nature of operations and principal activities

The principal activity during the year of entities within the consolidated entity was the design and development of heart assist devices.

There have been no significant changes in the nature of those activities during the year.

#### **Employees and Consultants**

The consolidated entity employed 6 employees and 5 consultants as at 30 June 2009 (2008: 13 employees and 5 consultants).

#### **Operational and Financial Review**

#### **Group Overview**

The Group has continued the development of the C-Pulse heart assist device during the year including activities to support an IDE trial in the US.

#### **Operating Results for the Year**

The Group incurred a net loss for the year of \$8,079,055 (2008 loss: \$9,738,183). The level of expenditure was less than the prior year due to lower C-Pulse development costs.

#### **Likely Developments and Expected Results**

Over the coming year, Sunshine Heart's efforts shall focus on the following key areas:

- Completing enrolment in the US clinical trial
- Analysing patient data
- Defining the next FDA clinical study
- Prepare for FDA application for the Pivotal trial
- Prepare for filing the CE Mark application
- Continue development of the C-Pulse II.

The Company expects to make an operating loss for the 2010 financial year. The Company's business plan necessitates continued spending in pursuit of the business objectives. The Company's ongoing success will depend on its continued ability to raise additional capital in the future.

#### **Cash Used in Operations**

Net cash flows used in operating activities was \$7,747,373 (2008: \$9,151,862).

#### **Liquidity and Funding**

The Company is seeking to raise additional capital through a rights issue, announced on 10 August, to allow the Company to continue its C-Pulse clinical trial however further funding will be required in order to commercialise C-Pulse.

#### **Significant Events After Balance Date**

On 10 August 2009 the Company announced the successful completion of a private placement to raise \$1.75 million. The Company also announced it intends to offer eligible Sunshine Heart shareholders the opportunity to participate in a non-renouncable rights issue, to raise up to an additional \$8.1 million. ABN AMRO Morgans Corporate Limited has agreed to underwrite \$5.5 million of the rights issue. This includes \$4.2 million from major shareholders GBS Venture Partners and CM Capital who have committed to take up their pro rata entitlement of new shares under the offer.

#### **Share Options**

#### **Unissued shares**

As at the date of this report, there were 70,334,472 employee options and placement options over unissued ordinary shares in Sunshine Heart, Inc.

#### **Employee Options**

During the year ended 30 June 2009, a total of 10,315,277 options over unissued ordinary shares were issued as remuneration to consultants and employees of the Company. During the year 3,480,228 options were forfeited.

Refer to note 12(c) of the financial statements for further details of the options outstanding.

Option holders do not have any right, by virtue of the option, to participate in any share issue of the Company or any related body corporate or in the interest issue of any other registered scheme.

## Directors' Report continued

#### **Environmental Regulation and Performance**

There have been no known breaches by the consolidated entity of any significant environmental regulations or obligations.

#### **Directors' Indemnity**

During the financial year, Sunshine Heart, Inc. has paid premiums to insure the Directors and Officers against liabilities and expenses incurred by them in defending any legal proceedings arising out of their conduct while acting in the capacity of officer of the Company, other than conduct involving a wilful breach of duty in relation to the Company. The amount of the premium is not disclosable under the terms and conditions of the policy.

#### **Remuneration Report – Audited**

This Remuneration Report outlines the director and executive remuneration arrangements of the Company and the Group in accordance with the requirements of the Corporations Act 2001 and its Regulations. For the purposes of this report, Key Management Personnel of the Group are defined as those persons having authority and responsibility for planning, directing and controlling the major activities of the Company and the Group, directly or indirectly, including any director (whether executive or otherwise) of the parent Company and includes the five executives in the parent and the Group receiving the highest remuneration.

For the purposes of this report, the term 'executive' encompasses the Chief Executive and senior executives of the Parent and the Group.

#### Remuneration philosophy

The performance of the Group depends upon the quality of its Directors and Executives. To prosper, the Company must attract, motivate and retain highly skilled Key Management Personnel. To this end, the Company embodies the following principles in its remuneration framework:

- Provide competitive rewards to attract high calibre individuals; and
- Link rewards to shareholder value.

#### Remuneration and nomination committee

The remuneration and nomination committee of the Board of Directors of the Company is responsible for determining and reviewing compensation arrangements for the Key Management Personnel. The committee assesses the appropriateness of the nature and amount of remuneration of the Key Management Personnel on a periodic basis by reference to relevant employment market conditions with the overall objective of ensuring maximum stakeholder benefit from the retention of a high quality team.

The remuneration and nomination committee has in place a process to review the performance of the board, sub committees and that of individual Key Management Personnel. To assist in this process an independent advisor may be used. The committee conducts a survey of directors to review the role of the board, assess the performance of the board since the previous survey and to examine ways of assisting the board in performing its duties more effectively. The issues examined include board interaction with management, the type of information provided to the board by management, and overall management performance in helping the board meet its objectives.

A similar review is performed of the Board sub committees, to assist in assessing the performance of each committee and to identify areas where improvement can be made.

The committee is also responsible for reviewing the performance of Key Management Personnel. This evaluation is based on specific criteria, including the Group's business performance, whether strategic objectives are being achieved and the development of management and personnel.

Further details on the remuneration of Directors and Executives are also provided in Note 20 to the financial statements and Table 1 and 2 of the Directors' Report.

#### **Remuneration structure**

In accordance with best practice corporate governance, the structure of non-executive director and other Key Management Personnel remuneration is separate and distinct.

#### Non-executive director remuneration

#### Objective

The board seeks to set aggregate remuneration at a level which provides the Company with the ability to attract and retain directors of the highest calibre, whilst incurring a cost which is acceptable to shareholders.

#### Structure

Remuneration consists of the following key elements:

- Fixed Remuneration; and
- Options Long Term Incentive ('LTI') refer below for details of the objective and structure of options granted as LTI.

The amount of fixed remuneration and share based compensation through options (potential long term incentives) is established for each non-executive director by the remuneration and nomination committee.

The ASX Listing Rules specify that the aggregate remuneration of non-executive directors shall be determined from time to time by a general meeting. An amount not exceeding the amount determined is then divided between the directors as agreed. The latest determination was at the Annual General Meeting held on 30 November 2004 when shareholders approved an aggregate remuneration of \$250,000 per year. The amount of aggregate remuneration sought to be approved by shareholders and the manner in which it is apportioned amongst directors is reviewed annually. The Board may consider advice from external consultants as well as the fees paid to non-executive directors of comparable companies when undertaking the annual review process.

Each non-executive director receives a fee for being a director of the Company except for Dr Geoff Brooke and John Brennan. No additional fees are paid for each board committee on which a director sits. Non-executive directors are not required by the board to hold shares in the Company.

The remuneration of non-executive directors for the period ending 30 June 2009 is detailed in Table 1 of this report.

## **Key Management Personnel and Executive Director remuneration Objective**

The Company aims to reward executives with a level and mix of remuneration commensurate with their position and responsibilities within the Company and so as to:

- align the interests of executives with those of shareholders;
- link reward with the strategic goals and performance of the Company; and
- ensure total remuneration is competitive by market standards.

#### Structure

It is the remuneration and nomination committee's policy that employment contracts are entered into with the Executive Director's and other Key Management Personnel. Details of these contracts are provided on page 13. Remuneration consists of the following key elements:

- Fixed Remuneration Base Salaries;
- Short Term Incentive Plan ('STIP'); and
- Long Term Incentive Plan ('LTIP').

The amount of fixed remuneration and share based compensation through options (potential long term incentives) is established for each senior manager by the remuneration and nomination committee.

## Directors' Report continued

#### Remuneration Report – Audited continued

#### **Fixed Remuneration**

#### **Objective**

The level of fixed remuneration is set so as to provide a base level of remuneration, which is both appropriate to the position and is competitive in the market. Fixed remuneration is reviewed annually by the remuneration and nomination committee and the process consists of a review of company wide, business unit and individual performance, relevant comparative remuneration in the market and internal and, where appropriate, external advice on policies and practices. As noted above, the committee has access to external advice independent of management.

#### Structure

Key Management Personnel receive their fixed (primary) remuneration in cash. The fixed remuneration component of the Key Management Personnel remuneration is detailed in Tables 1 and 2 of the Directors' Report. The Company has no other Key Management Personnel at the date of this Report.

#### **Short Term Incentive Plan (STIP)**

#### Objective

The objective of the STIP is to reward staff including Key Management Personnel in a manner that focuses participants on achieving personal and business goals which contribute to the creation of sustained shareholder value. Bonus differential reflects performance against these goals.

#### Structure

The STIP facilitates bi-annual cash and/or options bonus opportunities that reflect performance outcomes against pre-determined personal and business goals (as determined by the Board) which are key drivers for short term success and delivering long term value. The amount of any bonus is at the discretion of the Board.

Details of the cash bonuses earned under the STIP is provided in Tables 1 and 2 of the Directors' Report for Key Management Personnel.

### Options – Long Term Incentive Plan (LTIP)

#### **Objective**

The objective of the LTIP plan is to reward staff including Key Management Personnel in a manner that aligns this element of remuneration with the creation of shareholder value. As such LTIP grants are made to staff that are able to influence the generation of shareholder wealth and thus have an impact on the Company's performance.

#### **Structure**

LTIP grants to staff including Key Management Personnel are delivered in the form of options. The Company uses a premium to the market price of the shares under option as the performance hurdle for the long-term incentive plan. Option recipients are required to meet certain length-of-service obligations.

Details of options granted, including the value of options and vesting periods under the LTIP plan, is detailed in Note 15 for employees and Note 20(c) for directors.

#### **Employment and Consultancy Contracts**

The Key Management Personnel salaries and fees are as set out below and are for full time services unless otherwise noted. All contracts are terminable as described below:

NAME	TITLE	ANNUAL BASE FEES
D Rohrbaugh	Chief Executive Officer	\$US311,304 <sup>1</sup>
W Peters	Medical Director/Chief Technology Officer	\$A265,152 <sup>2</sup>
V Windeyer	Chief Operating Officer to 31 October 2008	A\$235,550 <sup>3</sup>
B Bolton	Chief Financial Officer/Company Secretary to 15 May 2009	\$A235,550 <sup>4</sup>
M Kepler	Director of Regulatory and Clinical Affairs to 27 April 2009	\$US201,492 <sup>5</sup>
J Weitzner	Vice President of Operations	\$US210,000 <sup>6</sup>
S Miller	Director Australian Operations	\$A178,899 <sup>7</sup>
R Parkin	Director of Clinical Engineering	\$A178,899 <sup>8</sup>

#### NOTES:

- 1 Mr Rohrbaugh's consulting contract commenced on 1 July 2005 and is ongoing. If Sunshine Heart terminates Mr Rohrbaugh's contract other than for cause, he is entitled to receive continued payment of his monthly fee until the earlier of: (i) the date he begins providing full time services to a third party or (ii) the six month anniversary of his termination date.
- 2 Dr Peters' consulting contract commenced on 3 August 2004 and is ongoing. If Sunshine Heart terminates Dr Peters' contract other than for cause, he is entitled to receive one months notice of termination, or payment in lieu of actual notice.
- 3 Mr Windeyer ceased in his position as Chief Operating Officer on 31 October 2008.
- 4 Mr Bolton ceased in his position as Chief Financial and Company Secretary on 15 May 2009.
- 5 Ms Kepler ceased in her position as Director of Regulatory and Clinical Affairs on 27 April 2009.
- 6 Mr Weitzner's consulting contract commenced on 17 October 2007 and is ongoing. If Sunshine Heart terminates Mr Weitzner's contract other than for cause, he is entitled to receive one months notice of termination, or payment in lieu of actual notice.
- 7 Mr Miller's employment contract commenced on 1 March 2002 and is ongoing. If Sunshine Heart terminates Mr Miller's contract other than for cause, he is entitled to receive one months notice of termination, or payment in lieu of actual notice. In addition, the Company also contributes superannuation on behalf of Mr Miller.
- 8 Mr Parkin's employment contract commenced on 1 January 2009 however he worked as a consultant to the Company prior to that time. If Sunshine Heart terminates Mr Parkin's contract other than for cause, he is entitled to receive one months notice of termination, or payment in lieu of actual notice. In addition, the Company also contributes superannuation on behalf of Mr Parkin.

# Directors' Report continued

### Remuneration Report - Audited continued

#### Remuneration of Key Management Personnel ("KMP")

Table 1: Remuneration for the year ended 30 June 2009

	r ended <b>30 June 2009</b> SHORT TERM		POST EMPLOYMENT	SHARE BASED PAYMENTS	TOTAL	PERFORMANO RELATED
	SALARY & FEES	CASH STI	SUPERANNUATION AND OTHER	OPTIONS b		%
Non-executive Directors <sup>c</sup>						
N Callinan	81,989	_	_	16,707	98,696	_
M McComas	33,333	_	_	_	33,333	_
C Marsh	50,000	_	_	2,523	52,523	-
D O'Dwyer	50,000	-	_	_	50,000	-
Subtotal Non-executive Directors	215,322	_	_	19,230	234,552	
<b>Executive Directors</b>						
D Rohrbaugh	436,630	44,062	_	60,525	541,217	8.1
W Peters	265,152	30,224	_	28,771	324,147	9.3
Other KMP						
B Bolton	227,365	20,836	20,571	3,702	277,474	7.5
V Windeyer	161,810	20,836	16,438	8,978	208,062	10.0
M Kepler	230,621	18,316	_	874	249,811	7.3
J Weitzner	237,033	_	_	12,095	249,128	-
S Miller	178,899	17,586	24,084	7,848	228,017	7.9
R Parkin	181,491	19,261	4,904	8,763	214,419	9.0
Subtotal Executive KMP	1,919,001	171,121	65,997	136,556	2,292,675	
Total	2,134,323	171,121	65,997	155,786	2,527,227	

Table 2: Remuneration for the year ended 30 June 2008

Non-executive Directors <sup>c</sup>						
M McComas	75,000				75,000	
	,	_	_		•	_
C Marsh	50,000	_	_	5,688	55,688	_
D O'Dwyer	50,000	_	_	_	50,000	
Subtotal Non-executive Directors	175,000	-	_	5,688	180,688	
<b>Executive Directors</b>						
D Rohrbaugh	332,070	_	_	115,914	447,984	_
W Peters	250,140	_	_	39,196	289,336	_
Other KMP						
B Bolton	222,200	_	19,998	49,385	291,583	_
V Windeyer	222,200	_	19,998	62,588	304,786	_
G Frugard	176,605	_	_	15,579	192,184	_
M Kepler	56,568	_	_	1,543	58,111	
Subtotal Executive KMP	1,259,783	_	39,996	284,205	1,583,984	
Total	1,434,783	-	39,996	289,893	1,764,672	

#### NOTES

- a No future maximum or minimum total value of performance related remuneration has been determined as at the date of this report.
- b Options issued to Director's related parties and other Key Management Personnel as described in Note 20(c).
- c  $\,\,$  J Brennan and G Brooke received no remuneration for the years ended 30 June 2009 and 30 June 2008.

Table 3: Options granted as part of remuneration for the year ended **30 June 2009** (Nil granted for the year ended 30 June 2008. The options with a grant date of 14 February 2008 were performance based and did not meet their milestones until the current financial year.)

	GRANT DATE	EXERCISE PRICE \$	GRANT NUMBER	VALUE PER OPTION AT GRANT DATE \$	VALUE OF OPTIONS GRANTED DURING THE YEAR \$	REMUNERATION CONSISTING OF OPTIONS FOR THE YEAR %
N Callinan <sup>a</sup>	10-Jul-08	0.08	1,000,000	0.0127	12,700	
N Callinan <sup>b</sup>	10-Jul-08	0.10	1,000,000	0.0101	10,100	
			2,000,000		22,800	16.9
D Rohrbaugh <sup>c</sup>	10-Jul-08	0.20	97,500	0.0747	7,283	
D Rohrbaugh <sup>d</sup>	21-Aug 08	0.08	1,015,918	0.0123	12,496	
			1,113,418		19,779	11.2
W Peters <sup>c</sup>	10-Jul-08	0.20	97,500	0.0747	7,283	
W Peters d	21-Aug 08	0.08	945,101	0.0123	11,625	
			1,042,601		18,908	8.9
V Windeyer <sup>c</sup>	14-Feb-08	0.18	127,500	0.0395	5,036	
V Windeyer <sup>c</sup>	10-Jul-08	0.20	65,000	0.0747	4,855	
			192,500		9,891	4.3
B Bolton <sup>c</sup>	14-Feb-08	0.18	127,500	0.0395	5,036	
B Bolton <sup>c</sup>	10-Jul-08	0.20	65,000	0.0747	4,855	
B Bolton <sup>d</sup>	21-Aug-08	0.08	860,252	0.0123	10,581	
			1,052,752		20,472	3.1
M Kepler <sup>c</sup>	14-Feb-08	0.18	35,063	0.0395	1,385	
M Kepler <sup>d</sup>	21-Aug-08	0.08	794,667	0.0123	9,774	
			829,730		11,159	0.3
J Weitzner <sup>c</sup>	14-Feb-08	0.18	85,000	0.0395	3,358	
J Weitzner <sup>d</sup>	21-Aug-08	0.08	630,730	0.0123	7,758	
			715,730		11,116	4.8
S Miller <sup>c</sup>	10-Jul-08	0.20	63,750	0.0395	2,518	
S Miller <sup>d</sup>	21-Aug-08	0.08	344,845	0.0123	4,241	
			408,595		6,759	3.5
R Parkin <sup>c</sup>	14-Feb-08	0.18	31,875	0.0395	1,259	
R Parkin <sup>d</sup>	21-Aug-08	0.08	379,655	0.0123	4,669	
			411,530		5,928	4.1

#### NOTES

a Vesting is 1/6th at grant date of 10 July 2008, 1/6th on appointment to Chairman on 30 October 2008 and balance 1/36th every month thereafter. Options will be fully vested on 30 October 2010.

b Vesting is 1/3rd on appointment to Chairman on 30 October 2008 and balance 1/36th every month thereafter. Options will be fully vested on 30 October 2010.

c Options fully vested at grant date.

d Vesting is 1/4th on 1st anniversary, 21 August 2009 and and 1/48th every month thereafter. Options will be fully vested on 21 August 2013.

## Directors' Report continued

#### Remuneration Report – Audited continued

For details on the valuation of the options, including models and assumptions used, refer to Note 15. There were no alterations to the terms and conditions of options granted as remuneration since their grant date.

No options held by Key Management Personnel were exercised during the year. For details of options vested and lapsed during the year refer note 20(c).

#### **Corporate Governance**

In recognising the need for the highest standards of corporate behaviour and accountability, the Directors of Sunshine Heart, Inc. support and have adhered to the principles of corporate governance. The Company's corporate governance statement is contained in the following section of this annual report.

#### **Auditor Independence**

We have obtained the independence declaration from our auditors, Ernst & Young, a copy of which is included on page 55 of this annual report.

#### **Directors' Meetings**

The number of meetings of Directors (including meetings of committees of Directors) held during the year and the number of meetings attended by each Director were as follows:

	DIRECTORS' MEETINGS	MEETINGS OF CO	
		AUDIT,COMPLIANCE AND GOVERNANCE	REMUNERATION AND NOMINATION
Number of meetings held:	11	5	2
Number of meetings attended:			
N Callinan	10	3	_
M McComas	6	2	_
G Brooke	10	_	2
C Marsh	8	4	_
D O'Dwyer	10	5	_
W Peters	11	-	-
D Rohrbaugh	11	_	_
J Brennan	11	_	2
C Wang	1	_	_

All directors were eligible to attend all meetings held, except for N Callinan who was eligible to attend 10 Directors' meetings and 3 Audit, Compliance and Governance Committee meetings, M McComas who was eligible to attend 6 Directors' meetings and 2 Audit, Compliance and Governance Committee meetings and C Wang who was eligible to attend 1 Directors' meeting.

#### **Committee membership**

The Company established an Audit, Compliance and Governance Committee and a Remuneration and Nomination Committee of the Board of Directors on 20 July 2004. Members acting on the committees of the board are:

- Audit, Compliance and Governance D O'Dwyer (Chairman), M McComas (resigned 16 December 2008),
   C Marsh (appointed 17 July 2008) and N Callinan (appointed 16 December 2008).
- Remuneration and Nomination G Brooke (Chairman) and J Brennan.

#### **Non-Audit Services**

The Company's auditors, Ernst & Young, provided non-audit services during the year ended 30 June 2009. The Directors are satisfied that the provision of non-audit services is compatible with the general standard of independence for auditors imposed by the Corporations Act. The nature and scope of each type of non-audit service provided means that auditor independence was not compromised.

Refer to Note 19 of the financial statements for details of the remuneration that Ernst & Young received or are due to receive for the provision of audit and other services.

Signed in accordance with a resolution of the Directors.

Donald Rohrbaugh

Director

Sydney, 21 August 2009

D.G. Raluly

## Corporate Governance Statement

Sunshine Heart's corporate governance is the system by which the Company is directed and managed. Within this framework:

- The board of directors is accountable to shareholders for the performance of the Company;
- The Company's goals to achieve milestones are set and promulgated;
- The risks of the business are identified and managed; and
- The Company's established values and principles underpin the way in which it undertakes its operations.

Sunshine Heart has in place an entrenched, well developed governance culture which has its foundations in the ethical values that the board, management and staff bring to the Company and their commitment to positioning the Company as a world leader in heart assist technology.

This statement is organised under headings based on the Australian Securities Exchange (ASX) Corporate Governance Council's Principles of Good Corporate Governance and Best Practice Recommendations dated August 2007.

#### 1 Lay solid foundations for management and oversight

Recognise and publish the respective roles and responsibilities of board and management

#### 1.1 Formalise and disclose the functions reserved to the board and those delegated to management.

A copy of the Board Charter is available on the Company's website.

#### 1.2 Disclose the process for performance evaluation of senior executives.

The Board undertakes an annual process of assessing the performance of senior executives. To ensure this process is objective and constructive, external advisors may assist the board and provide independent advice to enhance and improve the process and the board's performance. During the year the performance of the senior executives were assessed. Areas for improvement were identified and strategies adopted to implement improvements.

#### 2 Structure the board to add value

Have a board of an effective composition, size and commitment to adequately discharge its responsibilities and duties

#### 2.1 A majority of the board should be independent directors.

The board has a majority of non-executive directors comprising five non-executive directors and two executive directors. The ASX recommendations on director independence classify three of the non-executive directors as not independent. Dr Brooke and Mr Brennan are classified as not independent as they are associated with companies who hold a voting interest of more than 5% in Sunshine Heart. Mr Marsh who retired as an executive director of the Company in July 2006 is classified as not independent as within the last three years he was an executive of the Company. The Company's board of directors consider that Dr Brooke and Messrs Brennan and Marsh operate at all times as independent directors and in the best interest of all shareholders.

The Company considers the following five directors to be independent: Messrs Callinan (Chairman), Brennan, Marsh and O'Dwyer and Dr Brooke.

The Company considers that the composition of the board is appropriate as Dr Brooke and Mr Brennan are experienced venture capital managers who bring to the board particular expertise in the management and development of early stage medical device companies and Mr Marsh, a co-founder of the Company, offers substantial strategic foresight in commercialising the Company's technology. The Chairman, Mr Callinan, has extensive experience at board level in Australia and overseas working with high growth early stage companies.

#### 2.2 The chairman should be an independent director.

The Board Charter requires the chairman to be independent.

#### 2.3 The roles of chairman and chief executive officer should not be exercised by the same individual.

The Board Charter requires the chairman and the chief executive officer to be different individuals.

#### 2.4 The Board should establish a nomination committee.

The Company has a Remuneration and Nomination Committee comprising two non-executive directors. The combined role is considered appropriate for a company of this size. A copy of the Remuneration and Nomination Committee Charter is available on the Company's website.

#### 2.5 Disclose the process for evaluating the performance of the board, its committees and individual directors.

The Board undertakes an annual process of assessing both the performance of the board and its committees, as well as the individual performance of directors. To ensure this process is objective and constructive, external advisors may assist the board and provide independent advice to enhance and improve the process and the board's performance. During the year the performance of the board and each committee were assessed as well as the individual performance of directors. Areas for improvement were identified and strategies adopted to implement improvements.

#### 3 Promote ethical and responsible decision making

Actively promote ethical and responsible decision making

#### 3.1 Establish a code of conduct to guide and disclose the code or a summary of the code as to:

- the practices necessary to maintain confidence in the company's integrity;
- the responsibility and accountability of individuals for reporting and investigating reports of unethical practices.

A copy of the Code of Conduct is available on the Company's website.

#### 3.2 Establish a policy concerning trading in company securities by directors, officers and employees.

A copy of the Company's Share Trading Policy is available on the Company's website.

#### 4 Safeguard integrity in financial reporting

Have a structure to independently verify and safeguard the integrity of the company's financial reporting

#### 4.1 The board should establish an audit committee

The Company has an Audit, Compliance and Corporate Governance ("Audit") Committee.

#### 4.2 The audit committee should be structured so that it consists of:

- only non-executive directors
- majority of independent directors
- an independent chairman, who is not chairman of the board
- at least three members.

The Audit Committee has three non-executive members, a majority of independent directors and its chairman is not chairman of the board. The size of the Audit Committee is appropriate to the size of the Company.

#### 4.4 The audit committee should have a formal charter.

The Audit Committee Charter is available on the Company's website.

## Corporate Governance Statement continued

#### 5 Make timely and balanced disclosure

Promote timely and balanced disclosure of all material matters concerning the company

5.1 Establish written policies and procedures designed to ensure compliance with ASX Listing Rule disclosure requirements and to ensure accountability at a senior management level for that compliance and disclose those policies or a summary of those policies.

The Company has a Continuous Disclosure and Shareholder Communication Policy to ensure compliance with ASX Listing Rule disclosure requirements and to ensure accountability at a senior management level for that compliance. A copy of the Policy is available on the Company's website.

#### 6 Respect the rights of shareholders

Respect the rights of shareholders and facilitate the effective exercise of those rights

6.1 Design a communications policy to promote effective communication with shareholders and encouraging their participation at general meetings and disclose their policy or a summary of that policy.

Sunshine Heart provides shareholders with quarterly updates of the Company's progress across all areas of the business (in addition to continuous disclosure requirements), and utilises its website to disclose useful and relevant information about the Company. The Company's Continuous Disclosure and Shareholder Communication Policy is available on its website.

6.2 Request the external auditor to attend the annual general meeting and be available to answer shareholder questions about the conduct of the audit and the preparation and content of the auditor's report.

The Company's Continuous Disclosure and Shareholder Communication Policy requires that the external auditor be requested to attend annual general meetings and be able to answer shareholder questions.

#### 7 Recognise and manage risk

Establish a sound system of risk oversight and management and internal control

7.1 The board or appropriate board committee should establish policies for the oversight and management of material business risks and disclose a summary of those policies.

The Audit Committee is responsible to the Board for oversight in this area. The Company's Risk Management Statement which provides an overview of the Company's risk profile and management strategies is available on its website.

7.2 The board should require management to design and implement the risk management and internal control system to manage the company's material business risks and report to it on the effective management of those risks

The Company's Risk Management Statement which provides an overview of the Company's risk profile and management strategies is available on its website. The board requires a statement in writing from the chief executive officer and chief financial officer (or equivalent) attesting to the risk management and internal control system.

7.2 Assurance from the chief executive officer (or equivalent) and the chief financial officer (or equivalent) that the declaration provided in accordance with section 295A of the Corporations Act is founded on a sound system of risk management and internal control and that the system is operating effectively in all material respects.

The board requires a statement in writing from the chief executive officer and chief financial officer (or equivalent) attesting to the above requirements.

#### 8 Remunerate fairly and responsibly

Ensure that the level and composition of remuneration is sufficient and reasonable and that its relationship to corporate and individual performance is defined

#### 8.1 The board should establish a remuneration committee.

The Company has a Remuneration and Nomination Committee. A copy of the Remuneration and Nomination Committee Charter is available on the Company's website.

#### 8.2 Clearly distinguish the structure of non-executive Directors' remuneration from that of executives.

The Company's policy is to reward executives with a combination of fixed remuneration and short and long term incentives, structured to drive improvements in shareholder value. Non-executive directors receive no incentive cash payments other than their fixed fee. Non-executive directors have received shareholder approved share options which are normally issued at premium to the then share price. Any benefit to directors will only accrue from an increase in share price.

# Income Statement

For the year ended 30 June 2009

	NOTES	CONSOL	CONSOLIDATED		IEART, INC.
		2009	2008	2009	2008
		\$	\$	\$	\$
Revenue and other income	3	424,182	441,121	394,557	360,914
Write-down of investments	3	_	_	(7,678,347)	(9,357,218)
Depreciation and amortisation	3	(69,714)	(78,277)	_	_
Insurance		(208,925)	(110,945)	(174,472)	(77,874)
Listing fees		(25,781)	(36,112)	(25,781)	(36,112)
Office expenses	3	(193,365)	(177,259)	_	_
Professional fees		(425,100)	(413,968)	(384,927)	(347,152)
Salaries and employee benefits	3	(2,942,398)	(2,643,055)	_	_
Research and development	3	(3,121,406)	(5,351,482)	_	_
Travel		(492,679)	(529,479)	(45,015)	(8,257)
Patents		(147,828)	(151,364)	_	_
Other expenses		(876,041)	(687,363)	(165,070)	(272,484)
Loss before income tax		(8,079,055)	(9,738,183)	(8,079,055)	(9,738,183)
Income tax benefit	4	_	_	_	_
Loss after income tax		(8,079,055)	(9,738,183)	(8,079,055)	(9,738,183)
Loss for the year attributable to members					
of Sunshine Heart, Inc.	12(e)	(8,079,055)	(9,738,183)	(8,079,055)	(9,738,183)
Basic loss per share (cents per share)	18	(2.8)	(4.8)		
Diluted loss per share (cents per share)	18	(2.8)	(4.8)		

# Balance Sheet

#### At 30 June 2009

	NOTES	CONSOL	IDATED	SUNSHINE HEART, INC.	
		2009	2008	2009	2008
		\$	\$	\$	\$
ASSETS					
Current Assets					
Cash and cash equivalents	13(b)	2,013,816	9,772,617	30,674	8,998,841
Trade and other receivables	5	161,171	59,056	148,229	59,056
Other current assets	6	93,071	94,071	_	
Total Current Assets		2,268,058	9,925,744	178,903	9,057,897
Non-Current Assets					
Property, plant and equipment	9	188,962	252,710	-	_
Other financial assets	7	-	_	1,906,401	878,697
Total Non-Current Assets		188,962	252,710	1,906,401	878,697
Total Assets		2,457,020	10,178,454	2,085,304	9,936,594
LIABILITIES					
Current Liabilities					
Trade and other payables	10	344,415	152,447	56,454	1,692
Provisions	11	83,755	91,105	_	
Total Current Liabilities		428,170	243,552	56,454	1,692
Total Liabilities		428,170	243,552	56,454	1,692
Net Assets		2,028,850	9,934,902	2,028,850	9,934,902
EQUITY					
Contributed equity	12(a)	48,293,638	48,293,638	48,293,638	48,293,638
Accumulated losses	12(e)	(48,032,446)	(39,953,391)	(48,032,446)	(39,953,391)
Reserves	12(f)	1,767,658	1,594,655	1,767,658	1,594,655
Total Equity		2,028,850	9,934,902	2,028,850	9,934,902

# Statement of Recognised Income and Expense

For the year ended 30 June 2009

	CONSOL	IDATED	SUNSHINE HEART, INC.		
	2009	2008	2009	2008	
	\$	\$	\$	\$	
Net income recognised directly in equity	_	_	-	_	
Loss for the year	(8,079,055)	(9,738,183)	(8,079,055)	(9,738,183)	
Total recognised income and expense					
for the year	(8,079,055)	(9,738,183)	(8,079,055)	(9,738,183)	
Attributable to:					
Equity holders of Sunshine Heart, Inc.	(8,079,055)	(9,738,183)	(8,079,055)	(9,738,183)	

# Cash Flow Statement

For the year ended 30 June 2009

	NOTES	CONSOL	IDATED	SUNSHINE HEART, INC.	
		2009	2008	2009	2008
		\$	\$	\$	\$
Cash flows from operating activities					
Receipt of government grants		_	143,045	-	_
Payments to suppliers and employees		(8,070,160)	(9,717,518)	(723,395)	(806,855)
Interest received		322,787	422,611	293,163	342,404
Net cash flow used in					
operating activities	13(a)	(7,747,373)	(9,151,862)	(430,232)	(464,451)
Cash flows from investing activities					
Investment in subsidiary		-	_	(8,533,048)	(7,000,000)
Purchase of property, plant and equipment		(8,567)	(8,885)	-	
Net cash flows used in investing activities		(8,567)	(8,885)	(8,533,048)	(7,000,000)
Cash flows from financing activities					
Proceeds from issue of ordinary shares		-	11,445,542	_	11,445,542
Payment of share issue costs		-	(226,032)	_	(226,032)
Net cash flows from					
financing activities		_	11,219,510	_	11,219,510
Net increase in cash and cash equivalents		(7,755,940)	2,058,763	(8,963,280)	3,755,059
Net foreign exchange differences		(2,861)	(4,644)	(4,887)	(4,644)
Cash and cash equivalents					
at beginning of year		9,772,617	7,718,498	8,998,841	5,248,426
Cash and cash equivalents					
at end of year	13(b)	2,013,816	9,772,617	30,674	8,998,841

## Notes to the Financial Statements

For the year ended 30 June 2009

#### 1. Corporate Information

The annual report of Sunshine Heart, Inc. ("Company" or "Sunshine Heart") for the year ended 30 June 2009 was authorised for issue in accordance with a resolution of the directors on 21 August 2009.

Sunshine Heart, Inc. ("Company" or "Sunshine Heart") is a company limited by shares incorporated in Delaware, United States of America. Its shares are publicly traded on the Australian stock exchange, ASX code: SHC.

The nature of the operations and principal activities of the Company are to design and develop a heart assist device.

#### 2. Summary of Significant Accounting Policies

#### (a) Basis of Preparation

Sunshine Heart is a foreign company registered under Part 5B.2 of the Corporations Act 2001. The financial report is a general purpose financial report and has been prepared to satisfy the requirements of the Corporations Act 2001 and Australian Accounting Standards. The financial report is presented in Australian dollars and has been prepared on a historical cost basis.

#### (b) Statement of compliance

The financial report complies with Australian Accounting Standards and International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board.

Certain Australian Accounting Standards and UIG interpretations have been recently issued or amended but are not yet effective. These other standards have not been adopted by the Group for the year ended 30 June 2009. The Directors have yet to finalise their assessment of the impact of these new or amended standards (to the extent relevant to the Group) and interpretations.

#### (c) Going Concern

The Group's financial statements have been prepared and presented on a basis assuming it continues as a going concern.

During the years ended 30 June 2009 and 30 June 2008, the Group incurred an operating loss before tax and net cash outflows from operating activities as disclosed in the income statement and cash flow statement, respectively.

The Group's ability to continue as a going concern is dependent on the Group's ability to raise additional capital based on the achievement of its existing milestones as and when required. The directors, after due consideration, believe that the Group will be able to raise new equity capital as required to fund its business plan. Should the future capital raising not be successful, the Group may not be able to continue as a going concern. Furthermore, the ability of the Group to continue as a going concern is subject to the ability of the Group to develop and successfully commercialise the product being developed. If the Group is unable to obtain such funding of an amount and timing necessary to meet its future operational plans, or to successfully commercialise its intellectual property, the Group may be unable to continue as a going concern. No adjustments have been made relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Group not continue as a going concern.

#### (d) Basis of consolidation

The consolidated financial statements comprise the financial statements of Sunshine Heart, Inc. and its subsidiary as at 30 June each year (the Group). The financial statements of the subsidiary are prepared for the same reporting period as the parent Company, using consistent accounting policies. In preparing the consolidated financial statements, all intercompany balances and transactions, income and expenses and profit and losses resulting from intra-group transactions have been eliminated in full. Subsidiaries are fully consolidated from the date on which control is transferred to the Group and cease to be consolidated from the date on which control is transferred out of the Group.

#### (e) Significant accounting estimates and assumptions

The carrying amounts of certain assets and liabilities are often determined based on estimates and assumptions of future events. The key estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of certain assets and liabilities within the next annual reporting period are:

#### Share-based payment transactions

The consolidated Group provides benefits to employees, consultants and directors in the form of share-based payment transactions, whereby employees render services in exchange for share options ('equity-settled transactions') under the 2002 Stock Plan ('the Plan'). The Group measures the cost of equity-settled transactions by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is determined by using the Black-Scholes formula taking into account the terms and conditions upon which the instruments were granted, as discussed in Note 15.

#### Impairment of investment in subsidiary

The Group assesses impairment of its investment in its subsidiary at each reporting date by evaluating conditions specific to the Group and to the subsidiary that may lead to impairment. This includes product performance, technology, economic and political environment and future product expectations. If an impairment trigger exists the recoverable amount of the asset is determined. The assumptions used in determining the recoverable amount are discussed in Note 8.

#### (f) Revenue recognition

Revenue is recognised to the extent that it is probable that the economic benefits will flow to the Group and the revenue can be reliably measured. The following specific recognition criteria must also be met before revenue is recognised:

#### (i) Clinical trial implant reimbursement

Revenue from product sales is only recognised when substantially all the risks and rewards of ownership have transferred to our customers (which generally occurs on the date the product is implanted), the selling price is fixed and collection is reasonably assured. Revenue recognised to date is from sales of devices in connection with our US clinical trial.

#### (ii) Interest income

Interest revenue is recognised as it accrues, taking into account the effective yield on the financial asset.

#### (iii) Grant income

Grants from the government are recognised at their fair value where there is reasonable assurance that the grant will be received and the Group will comply with all attached conditions.

Where the grant relates to an expense item, it is recognised as income over the periods necessary to match the grant on a systematic basis to the costs it intends to compensate. When the grant relates to an asset, the fair value is credited to a deferred income account and is released to the income statement over the expected useful life of the relevant asset by equal annual instalments. Where government payments are received in advance of expenditure, a present obligation exists to repay the government under the conditions of the grant. This is recognised as deferred income. Where government grants are received in arrears of expenditure, a future economic benefit exists with funds owed by the government under the conditions of the grant.

### Notes to the Financial Statements continued

For the year ended 30 June 2009

#### 2. Summary of Significant Accounting Policies continued

#### (g) Borrowing costs

Borrowing costs are recognised as an expense when incurred. The Group does not currently hold qualifying assets but, if it did, the borrowing costs directly associated with this asset would be capitalised (including any other associated costs directly attributable to the borrowing and temporary investment income earned on the borrowing).

#### (h) Leases

The determination of whether an arrangement is or contains a lease is based on the substance of the arrangement and requires an assessment of whether the fulfilment of the arrangement is dependent on the use of a specific asset or assets and the arrangement conveys a right to use the asset.

#### Group as a lessee

Operating lease payments are recognised as an expense in the income statement on a straight-line basis over the lease term. Lease incentives are recognised in the income statement as an integral part of the total lease expense.

#### (i) Cash and cash equivalents

Cash and short term deposits in the balance sheet comprise cash at bank and in hand and short term deposits with an original maturity of three months or less. For the purposes of the cash flow statement, cash and cash equivalents consist of cash and cash equivalents as defined above, net of outstanding bank overdrafts.

#### (j) Other receivables

Other receivables generally have 30-90 day terms and are recognised and carried at nominal contractual amounts less an allowance for any uncollectible amounts. The doubtful debts allowance is made when objective evidence suggests the Group will be unable to collect the debts and bad debts are written off when identified.

#### (k) Foreign currency translation

Both the functional and presentation currency of Sunshine Heart, Inc. and it Australian subsidiary is Australian dollars (A\$). Each entity in the Group determines its own functional currency and items included in the financial statements of each entity are measured using that functional currency.

Transactions in foreign currencies are initially recorded in the functional currency at the exchange rates ruling at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are retranslated at the rate of exchange ruling at the balance sheet date. All exchange differences in the consolidated report are taken to the income statement. Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rate as at the date of the initial transaction.

#### (I) Income tax

Current tax assets and liabilities for the current and prior periods are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted by the balance sheet date.

Deferred income tax liabilities are recognised for all taxable differences except when the taxable temporary difference is associated with an investment in a subsidiary and the timing of the reversal of the temporary difference can be controlled and it is probable that the temporary difference will not reverse in the foreseeable future.

Deferred income tax assets are recognised for all deductible temporary differences, carry-forward of unused tax assets and unused tax losses to the extent that it is probable that taxable profit will be available against which the deductible temporary differences and the carry-forward of unused tax credits and unused tax losses can be utilised except when the deferred income tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss.

The carrying amount of deferred income tax assets is reviewed at each balance sheet date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred income tax asset to be utilised.

Unrecognised deferred income tax assets are reassessed at each balance sheet date and are recognised to the extent that it has become probable that future taxable profit will allow the deferred tax asset to be recovered.

Deferred income tax assets and liabilities are measured at the tax rates that are expected to apply to the year when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the balance sheet date.

Income taxes relating to items recognised directly in equity are recognised in equity and not in the income statement.

Deferred tax assets and deferred tax liabilities are offset only if a legally enforceable right exists to set off current tax assets against current tax liabilities and the deferred tax assets and liabilities relate to the same taxable entity and the same taxation authority

#### (m) Other taxes

Revenues, expenses and assets are recognised net of the amount of GST except:

- when the GST on a purchase of goods and services is not recoverable from the taxation authority, in which
  case the GST is recognised as part of the cost of acquisition of the asset or as part of the expense item as
  applicable; and
- receivables and payables, which are stated with the amount of GST included.

The net amount of GST recoverable from, or payable to, the taxation authority is included as part of receivables or payables in the balance sheet.

Cash flows are included in the cash flow statement on a gross basis and the GST component of cash flows arising from investing and financing activities, which is recoverable from, or payable to, the taxation authority, are classified as operating cash flows.

Commitments and contingencies are disclosed net of the amount of GST recoverable from, or payable to, the taxation authority.

### Notes to the Financial Statements continued

For the year ended 30 June 2009

#### 2. Summary of Significant Accounting Policies continued

#### (n) Property, plant and equipment

Plant and equipment is stated at cost less accumulated depreciation and any impairment in value. Depreciation is calculated on a straight line basis over the estimated useful life of the asset. The depreciation rates used for each class of asset are as follows (applicable for 2009/2008):

Office furniture and equipment 10 - 15 years Computer equipment 3 - 4 years Laboratory and research equipment 3 - 15 years.

Leasehold improvements are stated at cost less accumulated amortisation and any impairment in value. Amortisation is calculated on a straight line basis over the shorter of the estimated useful life of the asset or the lease term.

#### (i) Impairment

The carrying values of plant and equipment are reviewed for impairment when events or changes in circumstances indicate the carrying value may not be recoverable. For an asset that does not generate largely independent cash inflows, the recoverable amount is determined for the cash generating unit to which the asset belongs. If any such indication exists and where the carrying values exceed the estimated recoverable amount, the assets or cash generating units are written down to their recoverable amount.

The recoverable amount of plant and equipment is the greater of fair value less costs to sell and value in use. In assessing value in use, the estimated future cash flows are discounted to their present value using a pretax discount rate that reflects current market assessments of the time value of money and risks specific to the asset.

#### (ii) Derecognition and disposal

An item of property, plant and equipment is derecognised upon disposal or when no future economic benefits are expected to arise from the continued use of the asset.

#### (o) Other financial assets

Investment in a controlled entity is carried at the lower of cost or recoverable amount and reviewed at each balance date to reflect the Company's interest in the underlying net asset value of the controlled entity.

#### **Impairment**

The carrying value is reviewed for impairment when events or changes in circumstances indicate the carrying value may not be recoverable. If any such indication exists and where the carrying values exceed the estimated recoverable amount, the assets or cash generating units are written down to their recoverable amount. The amount of the loss is recognised in the Income Statement.

#### (p) Intangible assets

Intangible assets acquired separately or in a business combination are initially measured at cost. The cost of an intangible asset acquired in a business combination is its fair value as at the date of acquisition. Following initial recognition, intangible assets are carried at cost less any accumulated amortisation and any accumulated impairment losses. Internally generated intangible assets, excluding capitalised development costs, are not capitalised and expenditure is charged to the income statement in the year in which the expenditure is incurred. The amortisation period and method are reviewed annually, to ensure that they reflect the expected pattern of consumption of embodied, future economic benefits.

#### (i) Research and development expenditure

The consolidated Group expenses all research expenditure as incurred including expenditure made on the C-Pulse and other related technologies. Development expenditure is carried forward when its future recoverability can be regarded as assured.

#### (ii) Patents and trademarks

All patent, licence and trademarks expenditure is expensed as incurred as the Group has not yet developed a commercial product.

The useful lives of intangible assets are assessed to be either finite or indefinite. Intangible assets with finite lives are amortised over the useful life and tested for impairment whenever there is an indication that the intangible asset may be impaired. The amortisation period and the amortisation method for an intangible asset with a finite useful life is reviewed at least each financial year-end. Changes in the expected useful life or the expected pattern of consumption of future economic benefits embodied in the asset are accounted for prospectively by changing the amortisation period or method, as appropriate which is a change in accounting estimate. The amortisation expense on intangible assets with finite lives is recognised in profit or loss in the expense category consistent with the function of the intangible asset.

Intangible assets with indefinite useful lives are tested for impairment annually either individually or at the cash generating unit level. Such intangibles are not amortised. The useful life of an intangible asset with an indefinite life is reviewed each reporting period to determine whether indefinite life assessment continues to be supportable. If not, the change in the useful life assessment from indefinite to finite is accounted for as a change in an accounting estimate and is thus accounted for on a prospective basis.

#### (q) Trade and other payables

Trade payables and other payables are carried at amortised costs and represent liabilities for goods and services provided to the Group prior to the end of the financial year that are unpaid and arise when the Group becomes obliged to make future payments in respect of the purchase of these goods and services.

#### (r) Provisions

Provisions are recognised when the Group has a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation.

When the Group expects some or all of a provision to be reimbursed, for example under an insurance contract, the reimbursement is recognised as a separate asset but only when the reimbursement is virtually certain. The expense relating to any provision is presented in the income statement net of any reimbursement.

If the effect of the time value of money is material, provisions are discounted using a current pre-tax rate that reflects the risks specific to the liability. When discounting is used, the increase in the provision due to the passage of time is recognised as a borrowing cost.

### Notes to the Financial Statements continued

For the year ended 30 June 2009

#### 2. Summary of Significant Accounting Policies continued

#### (s) Employee leave benefits

#### (i) Wages, salaries, annual leave and sick leave

Liabilities for wages and salaries, including non-monetary benefits and annual leave expected to be settled within 12 months of the reporting date are recognised in provisions in respect of employees' services up to the reporting date. They are measured at the amounts expected to be paid when the liabilities are settled.

#### (ii) Long service leave

The liability for long service leave is recognised in the provision for employee benefits and measured as the present value of expected future payments to be made in respect of services provided by employees up to the reporting. Consideration is given to expected future wage and salary levels, experience of employee departures, and periods of service. Expected future payments are discounted using market yields at the reporting date on national government bonds with terms to maturity and currencies that match, as closely as possible, the estimated future cash outflows.

#### (t) Pensions and other post employment benefits

All Australian employees are entitled to varying levels of benefits on retirement, disability or death. The superannuation plans provide accumulated benefits. Employees contribute to the plans at various percentages of their wages and salaries. Contributions by the consolidated entity of up to 9% of employees' wages and salaries are legally enforceable in Australia.

#### (u) Share-based payment transactions

#### **Equity settled transactions**

The Group provides benefits to employees (including Directors) in the form of share-based payments, whereby employees render services in exchange for options over shares (equity settled transactions) under Sunshine Heart's 2002 Stock Plan ("the Plan").

The cost of these equity-settled transactions with employees is measured by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is determined using a Black-Scholes model, details of which are given in Note 15. In valuing equity-settled transactions, no account is taken of any performance conditions, other than conditions linked to the price of the shares of Sunshine Heart (market conditions).

The cost of equity-settled transactions is recognised, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled, ending on the date on which the relevant employees become entitled to the award (the vesting period).

The cumulative expense recognised for equity-settled transactions at each reporting date until vesting date reflects (i) the extent to which the vesting period has expired and (ii) the Group's best estimate of the number of equity instruments that will ultimately vest. No adjustment is made for the likelihood of market performance conditions being met as the effect of these conditions is included in the determination of fair value at grant date. The income statement charge or credit for a period represents the movement in cumulative expense recognised as at the beginning and end of that period.

No expense is recognised for awards that do not ultimately vest, except for awards where vesting is only conditional upon a market condition.

If the terms of an equity-settled award are modified, as a minimum an expense is recognised as if the terms had not been modified. In addition, an expense is recognised for any modification that increases the total fair value of the share based payment arrangement, or is otherwise beneficial to the employee, as measured at the date of modification.

If an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognised for the award is recognised immediately. However, if a new award is substituted for the cancelled award and designated as a replacement award on the date that it is granted, the cancelled and new award are treated as if they were a modification of the original award, as described in the previous paragraph.

The dilutive effect, if any of options is reflected as additional share dilution in the computation of earnings per share.

#### (v) Contributed equity

Ordinary shares are classified as equity. Incremental costs directly attributable to the issue of new equity instruments are shown in equity as a deduction, net of tax, from the proceeds.

#### (w) Warrants

Warrants are classified as equity as the number of ordinary shares that will be issued upon their exercise is fixed. The fair value was determined using the Black-Scholes model.

#### (x) Earnings Per Share

Basic EPS is calculated as a net loss attributable to members, adjusted to exclude costs of servicing equity (other than dividends), divided by the weighted average number of ordinary shares.

Diluted EPS is calculated as net loss attributable to members, adjusted for:

- Costs of servicing equity (other than dividends);
- The after-tax effect of dividends and interest associated with dilutive potential ordinary shares that have been recognised as expenses; and
- Other non-discretionary changes in revenues or expenses during the period that would result from the dilution of potential ordinary shares

divided by the weighted average number of ordinary shares and dilutive potential ordinary shares.

At present the potential ordinary shares are anti-dilutive and have not been included in the dilutive earnings per share calculation.

# Notes to the Financial Statements continued

For the year ended 30 June 2009

1	NOTES	CONSOLIDATED		SUNSHINE HEART, INC.	
		2009	2008	2009	2008
		\$	\$	\$	\$
3. Revenues and Expenses					
(a) Revenue and other Income					
Finance revenue – bank interest		289,987	441,121	260,362	360,914
Clinical implant reimbursement		134,195	_	134,195	-
		424,182	441,121	394,557	360,914
(b) Write-down of investments in					
subsidiary		_	_	7,678,347	9,357,218
(c) Depreciation and amortisation					
Depreciation – plant and equipment		54,766	63,289	-	_
Amortisation – leasehold improvements		14,948	14,988	_	_
		69,714	78,277	_	_
(d) Operating lease rental					
Lease payments		193,365	177,259	_	_
(e) Employee benefits expense					
Share based payments 1	2(f)	173,003	329,827	-	_
Employee benefits		46,103	75,978	-	_
Superannuation		106,957	116,840	-	_
Salaries and consultancy fees		2,616,335	1,637,097	_	_
		2,942,398	2,159,742	_	_
(f) Research and development expenses		3,121,406	5,834,795	_	_
(g) Foreign exchange differences					
Net foreign exchange (gain)/loss		392,450	(4,644)	(4,885)	(4,644)

CONSOLIDATED		SUNSHINE I	HEART, INC.
2009	2008	2009	2008
\$	Ś	\$	Ś

### 4. Income Tax

A reconciliation between tax expense and the product of accounting loss before income tax multiplied by the Group's applicable income tax rate is as follows:

Accounting loss before tax from continuing				
operations	(8,079,055)	(9,738,183)	(8,079,055)	(9,738,183)
At the Group statutory income tax rate of 39%				
(2008: 39%)	(3,150,831)	(3,797,891)	(3,150,831)	(3,797,891)
Expenditure not allowed for income tax purposes				
– share based payments	67,471	128,633	_	-
- write-down of investment in subsidiary	_	_	2,994,558	3,649,315
Difference in overseas tax rates	640,896	750,480	_	_
Other	171,889	271,111	22,017	2,509
Current year tax losses not booked as a future tax				
benefit, as realisation of benefit is not probable	2,270,575	2,647,667	134,256	146,067
Income tax benefit reported in the				
consolidated income statement	_	_	-	
Income Tax Losses				
Future deferred tax asset arising from tax losses not				
recognised at reporting date as realisation of the				
benefit is not regarded as probable	12,613,625	10,353,613	839,452	626,360

The unrecognised deferred tax assets relating to deductible temporary differences at 30 June 2009 is \$87,674 (2008:\$46,558). The unrecognised deferred tax liabilities relating to assessable temporary differences at 30 June 2009 is nil (2008: nil). The aggregate temporary differences associated with the investment in Sunshine Heart Company Pty Limited at 30 June 2009 are nil (2008: nil).

Consolidated franking account balance at 30 June 2009 are nil (2008: nil).

For the year ended 30 June 2009

	CONSOLIDATED		SUNSHINE HEART, INC.	
	2009	2008	2009	2008
	\$	\$	\$	\$
5. Trade and Other Receivables				
Clinical implant reimbursement – receivable	134,195	_	134,195	_
Other receivables	26,976	26,256	14,034	26,256
Finance revenue receivables – bank interest	_	32,800	-	32,800
	161,171	59,056	148,229	59,056

Clinical implant reimbursement –receivable has a 30 day term.

Other receivables are non-interest bearing and generally on 30-90 day terms.

Financial revenue receivable relates to a 30 day term deposit.

No receivables are impaired.

### 6. Other Current Assets

**Total investments (Note 8)** 

Prepayments and deposits	93,071	94,071	-	_
7. Other Financial Assets (non-current)				
Investments at cost comprise:				
Investment in controlled entity	_	_	43,296,292	34,763,244
Share based payments – options issued *	_	_	1,767,658	1,594,655
Less provision for write-down in investment	_	_	(43,157,549)	(35,479,202)

- 1,906,401

878,697

Share options issued to employees in Sunshine Heart Company Pty Limited. Refer to Note 12.

#### 8. Interests in Subsidiaries

NAME	COUNTRY OF INCORPORATION	CONSOLIDATED ENTITY	INVEST	MENT
		2009,2008	2009	2008
		%	\$	\$
Sunshine Heart Company Pty Limited	Australia	100	1,906,401	878,697

EQUITY INTEREST

During the year ended 30 June 2009, Sunshine Heart, Inc. subscribed for an additional 8,533,048 ordinary fully paid shares in Sunshine Heart Company Pty Limited. The cost of acquisition was \$8,533,048. Furthermore, Sunshine Heart, Inc. made additional non-cash investments into its wholly owned subsidiary during the year in recognition of the share based payments expense (options remuneration) that was charged to the subsidiary's income statement for \$173,003 and accumulated amount for prior years for \$1,594,655. The carrying value of this investment has been written down to its recoverable amount, as regulatory approval to market CPulse has not yet been obtained. The Directors have determined the recoverable amount to be the fair value by reference to the stage of development of the Company being the net asset position of the subsidiary at balance date.

	NOTES	CONSOL	CONSOLIDATED		SUNSHINE HEART, INC.	
		2009	2008	2009	2008	
		\$	\$	\$	\$	
9. Property, Plant and Equipment						
Leasehold improvements						
At cost		77,241	77,241	_	_	
Accumulated amortisation		(40,034)	(25,086)	-	-	
	9(a)	37,207	52,155	-	_	
Office furniture and equipment						
At cost		88,443	88,443	-	_	
Accumulated depreciation		(22,330)	(15,849)	-	_	
	9(a)	66,113	72,594	-	-	
Computer equipment						
At cost		79,561	75,348	-	-	
Accumulated depreciation		(53,546)	(36,538)	-	_	
	9(a)	26,015	38,810	-	_	
Laboratory and research equipment						
At cost		177,083	177,083	-	_	
Accumulated depreciation		(117,456)	(87,932)	-	_	
	9(a)	59,627	89,151	-	-	
Total property, plant and equipment						
At cost		422,328	418,115	_	_	
Accumulated depreciation and amortisation		(233,366)	(165,405)	_		
Total written down amount		188,962	252,710			

For the year ended 30 June 2009

# 9. Property, Plant and Equipment continued

### (a) Reconciliations

Reconciliations of the carrying amounts of property, plant and equipment at the beginning and end of the current financial year.

	2009	2008
	\$	\$
Leasehold improvements		
Carrying amount at beginning	52,155	67,143
Amortisation expense	(14,948)	(14,988)
Net Carrying Amount	37,207	52,155
Office furniture and equipment		
Carrying amount at beginning	72,594	78,585
Additions	_	500
Depreciation expense	(6,481)	(6,491)
Net Carrying Amount	66,113	72,594
Computer equipment		
Carrying amount at beginning	38,810	60,748
Additions	8,567	8,385
Depreciation expense	(18,761)	(20,499)
Disposals	(2,601)	(9,824)
Net Carrying Amount	26,015	38,810
Laboratory and research equipment		
Carrying amount at beginning	89,151	152,423
Depreciation expense	(29,524)	(36,299)
Disposals	-	(26,973)
Net Carrying Amount	59,627	89,151
Total property, plant and equipment		
Carrying amount at beginning	252,710	358,899
Additions	8,567	8,885
Depreciation expense	(69,714)	(78,277)
Disposals	(2,601)	(36,797)
Net Carrying Amount	188,962	252,710

No property, plant and equipment is impaired.

	CONSOLIDATED		SUNSHINE HEART, INC.	
	2009	2008	2009	2008
	\$	\$	\$	\$
10. Trade and Other Payables (current)				
Sundry creditors	344,415	152,447	56,454	1,692
Sundry creditors are non-interest bearing and are normally settled on 30 day terms.				
11. Provisions (current)				
Annual leave	71,015	84,705	-	_
Long service leave	12,740	6,400	_	_
	83,755	91,105	_	_
Movement in annual leave provision				
Balance 1 July 2008	84,705	66,517	-	_
Arising during the year	89,845	95,784	-	_
Utilised	(103,535)	(77,596)	-	_
Balance at 30 June 2009	71,015	84,705	-	_
Movement in long service leave provision				
Balance 1 July 2008	6,400	2,000	-	_
Arising during the year	6,340	4,400	_	_
Balance at 30 June 2009	12,740	6,400	_	_

For the year ended 30 June 2009

	CONSO	LIDATED	SUNSHINE	SUNSHINE HEART, INC.	
	2009	2008	2009	2008	
	\$	\$	\$	\$	
12. Contributed Equity and Reserves					
(a) Issued and paid up capital					
Shares, fully paid	46,914,438	46,914,438	46,914,438	46,914,438	
Warrants	1,379,200	1,379,200	1,379,200	1,379,200	
	48,293,638	48,293,638	48,293,638	48,293,638	
		009	\$ \$  46,914,438		
	NUMBER OF SHARES	\$		\$	
(b) Movement in shares on issue					
Shares, fully paid					
Beginning of the financial year	291,724,429	46,914,438	173,950,969	35,694,928	
Issued on 1 October 2007 for cash as second					
tranche of placement	-	-	20,000,000	3,000,000	
Issued on 15 November 2007 for cash as second					
tranche of placement	-	_	20,000,000	3,000,000	
Issued on 16 and 19 June 2008 for cash					
– rights issue	-	_	77,793,460	5,445,542	
Transaction costs on share issue	_	_	_	(226,032)	
End of the financial year	291,724,429	46,914,438	291,724,429	46,914,438	
	NUMBER OF WARRANTS	\$	NUMBER OF WARRANTS	\$	
Warrants					
Beginning of the financial year	800	1,379,200	800	1,379,200	
Issued during the year	_	_	_	_	
End of the financial year	800	1,379,200	800	1,379,200	

#### (c) Share Options

### **Employee Options**

During the financial year Sunshine Heart, Inc. issued 10,315,277 options over ordinary shares with an issue term of 10 years. The options had an average exercise price of \$0.09 and average vesting period of three years. During the year 3,480,228 options were forfeited.

At the end of the year there were 26,730,393 (2008: 19,895,344) unissued ordinary shares in respect of which employee options were outstanding as remuneration to directors, consultants and employees of the Company (refer Note 15).

#### **Placement Options**

No placement options were issued during the year.

At the end of the year there were 43,604,079 (2008: 43,604,079) unissued ordinary shares in respect of which placement options were outstanding.

# (d) Terms and conditions of contributed equity

#### **Ordinary shares**

Holders of shares have the right to receive dividends as and when declared and, in the event of a winding up of the Company, to participate in proceeds from the sale of all surplus assets in proportion to the number of and amounts paid up on shares held. Shares entitle their holder to one vote, either in person or by proxy, at a meeting of the Company.

#### Warrants

Warrants to purchase ordinary shares were issued in connection with an \$800,000 convertible promissory note dated 29 June 2004 issued as a bridging loan prior to the Initial Public Offer. These warrants were issued to related party entities affiliated with directors Dr Geoff Brooke, Crispin Marsh and Dr William Peters and to one unrelated party. The Warrants entitle the holders to subscribe for a total of 3,200,000 shares at \$0.25. The warrants have an exercise period of ten years and expire on 20 June 2014. No warrants were exercised during the year.

	CONSOLIDATED		SUNSHINE HEART, INC.	
	2009	2008	2009	2008
	\$	\$	\$	\$
(e) Accumulated Losses				
Movement in accumulated losses were as follows:				
Balance 1 July	(39,953,391)	(30,215,208)	(39,953,391)	(30,215,208)
Net loss attributable to members of				
Sunshine Heart, Inc.	(8,079,055)	(9,738,183)	(8,079,055)	(9,738,183)
Balance 30 June	(48,032,446)	(39,953,391)	(48,032,446)	(39,953,391)

#### (f) Reserves

### Movement in reserves were as follows:

	CONSOLIDATED		SUNSHINE HEART, INC.		
	EMPLOYEE EQUITY BENEFITS RESERVE	TOTAL	EMPLOYEE EQUITY BENEFITS RESERVE	TOTAL	
At 1 July 2007	1,264,828	1,264,828	1,264,828	1,264,828	
Share-based payments	329,827	329,827	329,827	329,827	
At 30 June 2008	1,594,655	1,594,655	1,594,655	1,594,655	
Share-based payments	173,003	173,003	173,003	173,033	
At 30 June 2009	1,767,658	1,767,658	1,767,658	1,767,658	

#### (g) Dividends

No dividends were paid or recommended to be paid during the year (2008: Nil).

For the year ended 30 June 2009

	NOTES	CONSOLI	DATED	SUNSHINE HEART, INC.	
		2009	2008	2009	2008
		\$	\$	\$	\$
13. Cash and Cash Equivalents					
(a) Reconciliation of the net loss after tax					
to the net cash flows from operations					
Net loss		(8,079,055)	(9,738,183)	(8,079,055)	(9,738,183)
Non-Cash items					
Write down of investments in subsidiaries	3(b)	_	_	7,678,347	9,357,218
Depreciation and amortisation of					
non-current assets	3(c)	69,714	78,277	_	_
Loss on disposal of non-current assets		-	36,796	_	_
Share based payments expense		173,003	329,827	-	_
Unrealised net foreign exchange differences		5,462	4,644	4,886	4,644
Changes in assets and liabilities					
(Increase)/decrease in prepayments and					
other receivables		(101,115)	150,984	(89,172)	(9,867)
(Decrease)/increase in trade and other					
payables		191,968	(36,795)	54,762	(78,263)
Increase in provisions		(7,350)	22,588	_	
Net cash outflow from operating activities		(7,747,373)	(9,151,862)	(430,232)	(464,451)
(b) Reconciliation of cash					
Cash balance comprises:					
– cash at bank		2,013,816	2,320,313	30,674	1,446,537
- term deposits		_	7,452,304	_	7,452,304
Closing cash balance		2,013,816	9,772,617	30,674	8,898,841
(c) Non-cash financing and investing					
activities		470.000	222.027		
Share based payments		173,003	329,827	-	

# (d) Terms and conditions

For the purposes of the cash flow statement, cash comprises short term deposits with an original maturity of three months or less and cash at bank.

	CONSOLIDATED		SUNSHINE H	EART, INC.
	2009	2008	2009	2008
	\$	\$	\$	\$
14. Commitments				
(a) Lease expenditure commitments –				
Group as lessee				
(i) Operating leases (non-cancellable)				
Minimum lease payments				
– not later than one year	141,357	176,850	-	_
- later than one year and not later than five years	-	136,379	-	
Aggregate lease expenditure contracted for				
at reporting date	141,357	313,229	-	

Operating lease expenditure commitments include two property leases. The St Leonards property lease expires on 31 March 2010. The Orange County, California property lease expires on 2 April 2010. Both property leases are expected to be renewed on similar terms at expiration.

#### (b) Other expenditure commitments

Commitments contracted for at reporting date but not recognised as liabilities are as follows:

– not later than one year	394,725	387,916	_	_
- later than one year and not later than five years	_	_	-	_
Aggregate other expenditure contracted for				
at reporting date	394,725	387,916	_	_

# 15. Share-based Payments Plan Employee Share Incentive Scheme

The 2002 Stock Plan ("the Plan") has been established, pursuant to which Sunshine Heart may, at the discretion of the Board or a committee appointed by the Board to administer the Plan, grant options to purchase Shares of Sunshine Heart to directors, employees, advisors and consultants ("employees") of the consolidated entity.

The options are issued for a term stated in the option agreement, not exceeding ten years from the date of the grant. The options are not quoted on the ASX.

At 30 June 2009 there were 8 retained Key Management Personnel and 4 staff members eligible for the Plan. Any vesting requirements are set out in the option agreements and are determined at the discretion of the Board or a Board-appointed administration committee.

Information with respect to the number of options granted under the Plan is as follows. It is noted that where the exercise price is dominated in US dollars, it has been translated to Australian dollars using the exchange rate applicable on 30 June 2009, being \$0.8048. All options issued and outstanding under the Plan do not carry dividend and/or voting rights.

For the year ended 30 June 2009

# 15. Share-based Payments Plan continued **Employee Share Incentive Scheme** continued

	2009		2008	
	NUMBER OF OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE	NUMBER OF OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE
		\$		\$
Balance at beginning of year	19,895,344	0.24	26,810,202	0.26
– granted	10,315,277	0.09	691,000	0.30
– cancelled	_	-	(1,104,858)	0.39
– forfeited	(3,480,228)	0.19	(6,501,000)	0.28
Balance at end of year	26,730,393	0.19	19,895,344	0.24

# Options held as at the end of the reporting period

The following table summarises information about options held by the employees as at 30 June 2009. The options granted do not provide dividend and or voting rights. No consideration was paid to the entity from employees on granting of the options.

NUMBER OF OPTIONS	GRANT DATE	VESTING	EXPIRY DATE	WEIGHTED AVERAGE EXERCISE PRICE
				\$
2,033,238	19 Dec 02 to 13 Oct 03	19 Dec 02 to 1 Nov 03	18 Dec 12 to 12 Oct 13	0.01
1,783,282	31 Jan 03	31 Jan 03	30 Jan 13	0.07
38,800	29 Apr 03	31 Jan 03	28 Apr 13	0.12
795,400	19 May 04	30 Mar 04	18 May 14	0.08
3,691,490	23 Jun 04	28 Sep 04	23 Jun 14	0.28
485,000	20 Jul 04	28 Sep 04	20 Jul 14	0.50
19,400	31 May 05	31 May 05	30 May 10	0.60
179,000	21 Jun 05	10 Jan 05 to 21 Jun 05	20 June 10	0.48
660,666	9 Feb 06	7 Nov 05 to 3 Jan 06	8 Feb 16	0.35
330,417	21 Apr 06	31 Mar 06	20 Apr 16	0.37
58,200	2 Jun 06	1 Jun 06	1 Jun 16	0.25
1,338,784	1 Nov 06	1 Nov 06	31 Oct 16	0.20
1,376,125	31 Jan 07	31 Jan 07	30 Jan 17	0.29
927,500	16 Apr 07	30 Jun 07	15 Apr 17	0.30
3,786,000	18 Apr 07	30 Jun 07	17 Apr 17	0.30
50,000	24 May 07	24 May 07	23 May 17	0.20
400,000	10 Oct 07	10 Oct 08	9 Oct 17	0.30
291,000	18 Dec 07	18 Dec 08	18 Dec 17	0.30
574,813	14 Feb 08	14 Feb 08	13 Feb 18	0.18
2,325,000	10 Jul 08	10 Jul 08 to 30 Oct 08	9 Jul 18	0.11
5,586,278	21 Aug 08	21 Aug 09	20 Aug 18	80.0

Options granted as part of employee remuneration have been valued using the Black-Scholes option pricing methodology, to provide the fair value of the options. This methodology takes into account factors such as the share price at grant date, the exercise price, the term of the option, the expected price volatility of the underlying share, the expected dividend yield and the risk-free interest rate for the term of the option. With regards to the performance conditions, options to individuals are assumed to vest, and therefore it is not appropriate to reduce fair value estimates of options that may not vest.

#### Fair value of options

The fair value of each option is estimated on the grant date using a Black-Scholes option pricing model with the following weighted average assumptions used:

	2009	2008
Dividend yield (%)	0%	0%
Risk-free Interest rate (%)	5.84%	6.33%
Expected volatility (%)	45%	45%
Expected life of option (years)	5 years	5 years
Weighted average exercise price	\$0.09	\$0.24

Historical data is used as the main component to determine expected volatility

The amount of options remuneration is determined on a pro-rata basis, by amortising the fair value estimate of each option, over the vesting period of the individual option grant. The fair value of options granted as compensation is recognised as an expense on a pro-rata basis over the vesting period in the income statement with a corresponding adjustment to equity.

#### Weighted average fair value

The weighted average fair value of options granted during the year was \$0.016 (2008: \$0.05).

#### Weighted average remaining contractual life

The weighted average remaining contractual life for the share options outstanding as at 30 June 2009 is 7.02 years (2008: 7.18 years).

#### 16. Contingent Liabilities

#### **Commercial Ready Grant**

On 21 October 2005, Sunshine Heart Company Pty Limited (SHCP) received a Commercial Ready Grant from the Australian Government through AusIndustry. The grant contributed fifty cents for each dollar spent on eligible project spends, to a maximum funding of \$2.23 million.

On 13 June 2006, SHCP received a further Commercial Ready Grant from the Australian Government through AusIndustry. The grant contributes fifty cents for each dollar spent on eligible project spends, to a maximum funding of \$2.16 million.

Under the terms of both agreements, the government may require SHCP to repay all or some of the amount, including interest, in any of the following circumstances:

- (a) SHCP fails to use its best endeavours to commercialise the relevant grant project within a reasonable time of completion of the project; or
- (b) Upon termination of a grant due to breach or insolvency; or
- (c) At any time for up to five years, a change in control occurs whereby either Sunshine Heart, Inc.'s ownership of the subsidiary (grant recipient) falls below fifty percent or Australian ownership of Sunshine Heart, Inc falls below fifty per cent.

SHCP continues the development and commercialisation of all projects funded by the Commercial Ready program. The total amount received under the Commercial Ready Programs as at 30 June 2009 was \$4.07 million.

For the year ended 30 June 2009

# 17. Subsequent Events

On 10 August 2009 the Company announced the successful completion of a private placement to raise \$1.75 million. The Company also announced it intends to offer eligible Sunshine Heart shareholders the opportunity to participate in a non-renouncable rights issue, to raise up to an additional \$8.1 million. This includes \$4.2 million from major shareholders GBS Venture Partners and CM Capital who have committed to take up their pro rata entitlement of new shares under the offer.

## 18. Earnings Per Share

	2009	2008
	\$	\$
The following reflects the income and share data used in the calculations of basic and diluted loss per share:		
Net loss	(8,079,055)	(9,738,183)
Weighted average number of ordinary shares used in calculating basic and dilutive earnings per share (Note that, had the dilutive shares been factored, this would		
have reduced the net loss per share):	291,724,429	204,203,178

The following type and number of shares are not included in the weighted average number of ordinary shares noted above as they are anti-dilutive in nature:

■ Warrants 3,200,000

Options 70,334,472

	CONSOLIDATED		SUNSHINE HEART, INC.	
	2009	2008	2009	2008
	\$	\$	\$	\$
19. Auditors' Remuneration				
Amounts received or due and receivable by Ernst &				
Young Australia for:				
<ul> <li>an audit or review of the financial report of the entity and any other entity in the consolidated entity</li> </ul>	106,605	111,662	106,605	111,662
<ul> <li>other services in relation to the entity and any other entity in the consolidated entity</li> </ul>				
- Tax compliance services	8,496	8,383	_	_
- Advisory services	4,060	17,140	-	_
	119,161	137,185	106,605	111,662
<ul> <li>other services in relation to the entity and any other entity in the consolidated entity</li> <li>- Tax compliance services</li> </ul>	4,060	17,140	- - 106,605	- - 111,662

#### 20. Director and Executive Disclosures

### (a) Details of Key Management Personnel

#### **Directors**

Mr Nicholas Callinan Chairman (non-executive)

(appointed Director 10 July 2008, appointed Chairman 30 October 2008)

Mr Malcolm McComas Chairman (non-executive)

(resigned Chairman 30 October 2008, resigned Director 16 December 2008)

Dr Geoff Brooke Director (non-executive)
Mr Crispin Marsh Director (non-executive)
Mr Donal O'Dwyer Director (non-executive)

Dr William Peters Medical Director and Chief Technology Officer

Mr John Brennan Director (non-executive)
Mr Donald Rohrbaugh Chief Executive Officer

Dr Conrad Wang Director (non-executive) (resigned 10 July 2008)

**Executives** 

Mr Victor Windeyer Chief Operating Officer to 31 October 2008

Mr Brian Bolton Chief Financial Officer and Company Secretary to 15 May 2009
Ms Mary Beth Kepler Director of Regulatory and Quality Affairs to 27 April 2009

Mr John Weitzner Vice President of Operations
Mr Scott Miller Director of Australian Operations
Mr Rodney Parkin Director of Clinical Engineering

# (b) Compensation of Key Management Personnel

	CONSOLIDATED		SUNSHINE HEART, INC.	
	2009	2008	2009	2008
	\$	\$	\$	\$
Short-Term	2,305,444	1,434,783	215,322	175,000
Post Employment	65,997	39,996	_	_
Share-based Payment	155,786	289,893	19,230	5,688
	2,527,227	1,764,672	234,552	180,688

For the year ended 30 June 2009

# 20. Director and Executive Disclosures continued (c) Option holdings of Key Management Personnel

June 2009	BALANCE AT BEGINNING OF			BALANCE	VESTED AT 3	80 JUNE 2009
	PERIOD 1 JULY 2008	OPTIONS GRANTED	OPTIONS FORFEITED <sup>3</sup>	AT END OF PERIOD 30 JUNE 2009	NOT EXERCISABLE	VESTED AND EXERCISABLE
Directors						
N Callinan	_	2,000,000	_	2,000,000	1,037,037	962,963
M McComas	388,000	_	_	388,000	_	388,000
G Brooke 1	15,963,667	_	_	15,963,667	_	15,963,667
C Marsh	2,106,665	_	_	2,106,665	86,261	2,020,404
D O'Dwyer	97,000	_	_	97,000	_	97,000
W Peters	2,669,881	1,042,601	_	3,712,482	1,366,768	2,345,714
J Brennan <sup>2</sup>	18,133,333	_	_	18,133,333	_	18,133,333
D Rohrbaugh	7,654,923	1,113,418	_	8,768,341	2,604,251	6,164,090
Executives						
V Windeyer <sup>3</sup>	1,880,000	192,500	(716,667)	1,355,833	_	1,355,833
B Bolton <sup>3</sup>	1,690,000	1,052,752	(1,622,752)	1,120,000	_	1,120,000
M Kepler <sup>3</sup>	286,000	829,730	(920,709)	195,021	_	195,021
J Weitzner	400,000	715,730	_	1,115,730	864,063	251,667
S Miller	707,135	408,595	_	1,115,730	517,762	597,968
R Parkin	704,200	411,530	_	1,115,730	516,634	599,096
Total	52,680,804	7,766,856	(3,260,128)	57,187,532	6,992,776	50,194,756

No options were exercised during the year.

June 2008	BALANCE			DALANCE	VESTED AT 3	80 JUNE 2008
	AT BEGINNING OF PERIOD 1 JULY 2007	GRANTED UNDER CAPITAL RAISING,	OPTIONS FORFEITED <sup>4</sup>	BALANCE AT END OF PERIOD 30 JUNE 2008	NOT EXERCISABLE	VESTED AND EXERCISABLE
Directors						
M McComas	388,000	_	_	388,000	_	388,000
G Brooke 1	8,497,000	7,466,667	_	15,963,667	_	15,963,667
R Lin/C Wang	2,116,400	_	_	2,116,400	2,000,000	116,400
C Marsh	2,106,665	_	_	2,106,665	1,156,349	950,316
D O'Dwyer	97,000	-	_	97,000	_	97,000
W Peters	4,013,881	-	(1,344,000)	2,669,881	690,833	1,979,048
J Brennan <sup>2</sup>	9,600,000	8,533,333	_	18,133,333	_	18,133,333
D Rohrbaugh	9,574,923	_	(1,920,000)	7,654,923	2,197,408	5,457,515
Executives						
V Windeyer	2,840,000	_	(960,000)	1,880,000	937,500	942,500
B Bolton	1,800,000	-	(110,000)	1,690,000	1,080,208	609,792
G Frugard	1,141,490	-	(340,800)	800,690	180,625	620,065
M Kepler	550,000	_	(264,000)	286,000	166,146	119,854
Total	42,725,359	16,000,000	(4,938,800)	53,786,559	8,409,069	45,377,490

No options were exercised during the year.

<sup>1</sup> Options issued to GBS Venture Partners Limited in its capacity as manager and trustee of the GBS Bioventures II and III Trusts. Dr G Brooke has an indirect interest as a member and the Managing Director of GBS Venture Partners Limited.

<sup>2</sup> Options issued to CM Capital Investments in its capacity as trustee of CM Capital Venture Trust 4A and CM Capital Venture Trust 4B. Mr J Brennan has an indirect interest as a member and Partner of CM Capital Investments.

<sup>3</sup> Options forfeited due to termination of employment.

<sup>4</sup> Options forfeited due to milestones not being achieved.

### (d) Ordinary Shareholdings of Key Management Personnel in Sunshine Heart, Inc.

	BALANCE 1 JULY 2007	PURCHASED 1 JULY 2007 TO 30 JUNE 2008	BALANCE 30 JUNE 2008	PURCHASED/SOLD 1 JULY 2008 TO 30 JUNE 2009	BALANCE 30 JUNE 2009
Directors					
N Callinan	_	_	_	_	_
M McComas	100,000	36,364	136,364	_	136,364
G Brooke <sup>1</sup>	41,184,835	50,963,074	92,147,909	_	92,147,909
C Marsh	7,263,568	735,714	7,999,282	_	7,999,282
D O'Dwyer	625,000	_	625,000	_	625,000
W Peters	7,001,161	500,000	7,501,161	319,991	7,821,152
J Brennan <sup>2</sup>	32,000,000	50,112,479	82,112,479	_	82,112,479
Executives					
B Bolton	_	290,608	290,608	50,000	340,608
V Windeyer	28,825	71,429	100,254	_	100,254
S Miller	38,800	_	38,800	_	38,800
R Parkin	100,000	36,364	136,364	_	136,364
Total	88,342,189	102,746,032	191,088,221	369,991	191,458,212

<sup>1</sup> Shares are held by GBS Venture Partners Limited in its capacity as manager and trustee of the GBS Bioventures II and III Trusts. Dr G Brooke has an indirect interest as a member and the Managing Director of GBS Venture Partners Limited.

### (e) Other transactions and balances with Key Management Personnel

During the year ended 30 June 2009, Sunshine Heart Company Pty Limited paid \$10,875 (2008: \$27,125) to SCP Technology and Growth Pty Limited, a company controlled by C Marsh, for the provision of intellectual property and patent services. As at 30 June 2009, there were no monies outstanding with Key Management Personnel (2008: \$nil).

<sup>2 32,000,000</sup> shares are held by CM Capital Investments. Mr J Brennan has an indirect interest as a member and Partner of CM Capital Investments.

For the year ended 30 June 2009

## 21. Related Party Disclosures

#### **Ultimate parent**

Sunshine Heart, Inc. (incorporated in Delaware, USA) is the ultimate parent entity.

The following related party transactions occurred with the wholly-owned group during the financial year:

During the year ended 30 June 2009, Sunshine Heart, Inc. subscribed for an additional 8,533,048 ordinary fully paid shares in Sunshine Heart Company Pty Limited. The cost of acquisition was \$8,533,048. Furthermore, Sunshine Heart, Inc. made additional non-cash investments into its wholly owned subsidiary during the year in recognition of the share based payments expense (options remuneration) of \$173,003 (2008: \$329,827), refer Note 12.

All transactions with Key Management Personnel other than those arising from the exercise of remuneration options have been entered into under terms and conditions no more favourable than those the entity would have adopted if dealing at arm's length.

## 22. Segment Information

### (a) Segment products and locations

The consolidated entity operates in one industry segment, which is the research and development of heart assist devices, and in two geographical segments, which are Australia and the United States.

## (b) Segment accounting policies

Segment accounting policies are the same as the consolidated entity policies described in note 2. During the year there have been no changes in segment accounting policies that had a material effect on the segment information.

#### (c) Geographic Segments

2009	AUSTRALIA	UNITED STATES	UNALLOCATED	ELIMINATION	CONSOLIDATION
	\$A	\$A	\$A	\$A	\$A
Segment Revenue	_	134,195	289,987	_	424,182
Segment Results	(8,079,055)	(7,986,341)	289,987	7,678,354	(8,079,055)
Other segment information:					
Depreciation	54,766	_	_	_	54,766
Amortisation	14,948	_	_	_	14,948
Investments write-down	_	7,678,354	_	(7,678,354)	_
Segment assets	1,547,455	2,815,966	_	(1,906,401)	2,457,020
Segment liabilities	371,716	56,454	_	_	428,170
Acquisition of plant and equipment	8,567	_	_	-	8,567
Net Cash flow information:					
Used in operating activities	(5,352,566)	(2,717,594)	322,787	_	(7,747,373)
Used in investing activities	(8,567)	_	_	_	(8,567)
From financing activities	_	_	_	_	_

## 22. Segment Information continued

# (c) Geographic Segments continued

2008	AUSTRALIA	UNITED STATES	UNALLOCATED	ELIMINATION	CONSOLIDATION
	\$A	\$A	\$A	\$A	\$A
Segment Revenue	_	_	441,121	_	441,121
Segment Results	(9,357,218)	(10,179,304)	441,121	9,357,218	(9,738,183)
Other segment information:					
Depreciation	63,289	_	_	_	63,289
Amortisation	14,988	_	_	_	14,988
Investments write-down	_	9,357,218	_	(9,357,218)	_
Segment assets	10,120,593	903,759	32,800	(878,697)	10,178,454
Segment liabilities	241,849	1,703	_	_	243,552
Acquisition of plant and equipment	8,885	_	_	_	8,885
Net Cash flow information:					
Used in operating activities	(7,358,369)	(2,216,099)	422,611	_	(9,151,857)
Used in investing activities	(8,885)	_	_	_	(8,885)
From financing activities	11,219,505	_	_	_	11,219,505

#### 23. Financial Instruments

#### (a) Financial risk management objectives and policies

The Board determines and regularly reviews the Groups's financial instrument policy and performance. The Group's principal financial instruments comprise cash and short-term bank deposits. The Group does not utilise derivatives, holds no debt and does not trade in financial instruments. The Group has other financial assets and liabilities such as other receivables and other payables, which arise directly from its operations.

The main risks arising from the Groups financial instruments are foreign currency risk and liquidity risk. The Board policies for managing these risks are summarised below.

Details of the significant accounting policies and methods adopted, including the criteria for methods adopted, including the criteria for recognition, the basis of measurement and the basis on which income and expenses are recognised, in respect of each class of financial asset, financial liability and equity instrument are disclosed in Note 2 to the financial statements.

#### Interest rate risk

The Group is only exposed to interest rate risk in the area of cash at bank as it has no borrowings.

#### Credit risk management

Credit risk arises from the cash and cash equivalents of the Group. Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in financial loss to the Group. The consolidated entity measures credit risk on a fair value basis. The Group policy is only to deal with accredited teaching hospitals so the credit risk is minimal. The maximum exposure to credit risk at balance date is the clinical implant reimbursement receivable, refer Note 5.

For the year ended 30 June 2009

#### 23. Financial Instruments continued

#### (b) Risk exposures and responses

The credit risk on liquid funds is limited because the counterparties are banks with high credit-ratings assigned by international credit-rating agencies.

The carrying amount of financial assets recorded in the financial statements, net of any allowances for losses, represents the consolidated entity's maximum exposure to credit risk without taking account of the value of any collateral obtained.

At balance date, the Group has the following financial assets (no financial liabilities at 30 June 2009 or 30 June 2008) exposed to Australian variable interest rate not designated in cash flow hedges

	CONSOLIDATED		SUNSHINE HEART, INC.	
	2009	2008	2009	2008
	\$	\$	\$	\$
Financial Assets				
Cash and cash equivalents	2,013,816	9,772,617	30,674	8,998,841
	2,013,816	9,772,617	30,674	8,998,841

The following sensitivity analysis is based on the interest rate risk exposures in existence at the balance sheet date. At 30 June 2009, if interest rates moved, as illustrated in the table below, with all other variables held constant, post tax profit and equity would have been affected as follows::

	POST TAX PROFIT HIGHER/(LOWER)			EQUITY HIGHER/(LOWER)	
	2009	2008	2009	2008	
	\$	\$	\$	\$	
Consolidated					
+1% (100 basis points)	20,138	97,726	20,138	97,726	
-0.5% (50 basis points)	(10,069)	(48,863)	(10,069)	(48,863)	
Parent					
+1% (100 basis points)	307	89,988	307	89,988	
-0.5% (50 basis points)	153	(44,994)	153	(44,994)	

The movements in profit are due to the higher/lower interest income from variable rate term deposits and cash balances. There is no equity movement as there are no financial assets or financial liabilities which are designated as cash flow hedges.

#### Foreign Currency Risk

The Group is exposed to a small amount of foreign currency risk as a result of holding a US bank account and paying some expenses in US dollars. The Group purchased US dollars during the period to hedge the falling exchange rate. Where the Group can reasonably forecast likely future US Dollar denominated expenses being incurred in advance, it may consider holding a similar magnitude of funds in the US dollar bank account for ease of administration. The Board reviews the ongoing appropriateness of the Group's policy on managing foreign currency risk based on the level of foreign operations.

At 30 June 2009, the group had the following exposure to US\$ foreign currency that is not designated in cash flow hedges:

	CONSOLIDATED		SUNSHINE H	SUNSHINE HEART, INC.	
	2009	2008	2009	2008	
	\$	\$	\$	\$	
Financial Assets					
Cash and cash equivalents	909,595	25,062	20,580	25,062	
Clinical implant reimbursement receivable	134,195	_	134,195	_	
Financial Liabilities					
Sundry creditors	238,782	472,790	_	472,790	

#### Net exposure

The following sensitivity is based on the foreign currency risk exposures in existence at the balance sheet date. At 30 June 2009, had the Australian dollar moved, as illustrated in the table below, with all other variables held constant post tax profit and equity would have been affected as follows:

	POST TAX PROFIT HIGHER/(LOWER)		EQUITY HIGHER/(LOWER)	
	2009	2008	2009	2008
	\$	\$	\$	\$
Consolidated				
AUS/USD +10%	104,379	49,786	104,379	49,786
AUS/USD -5%	(52,190)	(24,893)	(52,190)	(24,893)
Parent				
AUS/USD +10%	15,478	49,786	15,478	49,786
AUS/USD -5%	(7,739)	(24,893)	(7,739)	(24,893)

Management believe the balance date risk exposures are representative of the risk exposure inherent in the financial instruments.

#### Liquidity risk exposure

The Group's objective is to maintain a balance between continuity of funding for meeting its operating costs and maximising financing revenue through at call bank deposits in line with budget requirements. The Group's policy is to minimise its forward commitments in achieving this objective.

All liquid assets are less than 60 days represented by cash and cash equivalents, other current assets and other receivables. All liquid liabilities contractual maturities are less than 60 days represented by trade and other payables. The contractual maturity amounts are the current carrying value. The group monitors its liquidity by reviewing a 12 month rolling forecast in conjunction with its overall strategy and capital raising.

#### Fair value of financial instruments

The fair value of assets and liabilities approximates the carrying amount.

#### Capital management

When managing capital, the Board's objective is to ensure the Company continues as a going concern and to optimise the returns to shareholders and benefits to other stakeholders. The Company is in early stage development and its primary source of funding is via the equity market. The Company continually reviews market trends and the impact that this may have on the capital markets and the ability to raise capital when managing its risk cashflow. The directors will continue to raise capital as and when needed to meet its ongoing capital commitments.

# Directors' Declaration

In accordance with a resolution of the directors of Sunshine Heart, Inc. I state that:

In the opinion of the directors:

- (a) the financial statements and notes of the Company and the consolidated entity are in accordance with the Corporations Act 2001, including:
  - (i) giving a true and fair view of the Company's and consolidated entity's financial position as at 30 June 2009 and of their performance for the year ended on that date; and
  - (ii) complying with Accounting Standards and the Corporations Regulations 2001; and
- (b) there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.
- (c) this declaration has been made after receiving the declarations required to be made to the Directors in accordance with section 295A of the Corporations Act 2001 for the financial year ending 30 June 2009.

On behalf of the Board

D.G. Robelle

Donald Rohrbaugh

Director

Sydney, 21 August 2009

# **Auditor Independence**



Ernst & Young Centre 680 George Street Sydney NSW 2000 Australia GPO Box 2646 Sydney NSW 2001

Tel: +61 2 9248 5555 Fax: +61 2 9248 5959 www.ey.com/au

#### Auditor's Independence Declaration to the Directors of Sunshine Heart, Inc.

In relation to our audit of the financial report of Sunshine Heart, Inc for the financial year ended 30 June 2009, to the best of my knowledge and belief, there have been no contraventions of the auditor independence requirements of the *Corporations Act 2001* or any applicable code of professional conduct.

Ernst & Young

Canini Nathray

Gamini Martinus Partner Sydney 21 August 2009

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# Independent Audit Report



Ernst & Young Centre 680 George Street Sydney NSW 2000 Australia GPO Box 2646 Sydney NSW 2001

Tel: +61 2 9248 5555 Fax: +61 2 9248 5959 www.ey.com/au

#### Independent auditor's report to the members of Sunshine Heart, Inc.

#### Report on the Financial Report

We have audited the accompanying financial report of Sunshine Heart, Inc., which comprises the balance sheet as at 30 June 2009, and the income statement, statement of recognised income and expense and cash flow statement for the year ended on that date, a summary of significant accounting policies, other explanatory notes and the directors' declaration of the consolidated entity comprising the company and the entities it controlled at the year's end or from time to time during the financial year.

#### Directors Responsibility for the Financial Report

The directors of the company are responsible for the preparation and fair presentation of the financial report in accordance with the Australian Accounting Standards (including the Australian Accounting Interpretations) and the *Corporations Act 2001*. This responsibility includes establishing and maintaining internal controls relevant to the preparation and fair presentation of the financial report that is free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting policies; and making accounting estimates that are reasonable in the circumstances. In Note 2, the directors also state that the financial report, comprising the financial statements and notes, complies with International Financial Reporting Standards as issued by the International Accounting Standards Board.

#### Auditor's Responsibility

Our responsibility is to express an opinion on the financial report based on our audit. We conducted our audit in accordance with Australian Auditing Standards and International Standards on Auditing. These Auditing Standards require that we comply with relevant ethical requirements relating to audit engagements and plan and perform the audit to obtain reasonable assurance whether the financial report is free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial report. The procedures selected depend on our judgment, including the assessment of the risks of material misstatement of the financial report, whether due to fraud or error. In making those risk assessments, we consider internal controls relevant to the entity's preparation and fair presentation of the financial report in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal controls. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the financial report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

#### Independence

In conducting our audit we have met the independence requirements of the *Corporations Act 2001*. We have given to the directors of the company a written Auditor's Independence Declaration, a copy of which is included on Page 55. In addition to our audit of the financial report, we were engaged to undertake the services disclosed in the notes to the financial statements. The provision of these services has not impaired our independence.

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#### Auditor's Opinion

#### In our opinion:

- 1. the financial report of Sunshine Heart, Inc. is in accordance with the *Corporations Act 2001*, including:
  - i giving a true and fair view of the financial position of Sunshine Heart, Inc. and the consolidated entity at 30 June 2009 and of their performance for the year ended on that date; and
  - ii complying with Australian Accounting Standards (including the Australian Accounting Interpretations) and the *Corporations Regulations 2001*.
- 2. the financial report also complies with International Financial Reporting Standards as issued by the International Accounting Standards Board.

#### Inherent Uncertainty Regarding Continuation of Going Concern

Without qualification to the opinion expressed above, attention is drawn to the following matter. As a result of the matters described in Note 2 (c) "Going Concern" to the financial statements, there is significant uncertainty whether the company and/or the consolidated entity will be able to continue as going concerns and therefore whether they will be able to pay their debts as and when they fall due and realise their assets and extinguish their liabilities in the normal course of business and at the amounts stated in the financial report. The financial report does not include any adjustments relating to the recoverability and classification of recorded asset amounts or to the amounts and classification of liabilities that might be necessary should the company and/or the consolidated entity not continue as going concerns.

#### Report on the Remuneration Report

We have audited the Remuneration Report included in pages 10 to 16 of the directors' report for the year ended 30 June 2008. The directors of the company are responsible for the preparation and presentation of the Remuneration Report in accordance with section 300A of the *Corporations Act 2001*. Our responsibility is to express an opinion on the Remuneration Report, based on our audit conducted in accordance with Australian Auditing Standards.

#### Auditor's Opinion

In our opinion the Remuneration Report of Sunshine Heart, Inc. for the year ended 30 June 2009, complies with section 300A of the *Corporations Act 2001*.

Ernst & Young

Ernst + Young

Gamini Mastrus

Gamini Martinus Partner Sydney 21 August 2009

# **ASX Additional Information**

Additional information required by the Australian Stock Exchange Ltd and not shown elsewhere in this report is as follows.

For the purposes of this report, Chess Depository Instrument (CDI) holders and certificated shareholders are shown as one class of shareholder, notwithstanding CDI holders having beneficial interests in the underlying shares, rather than legal title.

Chess Depository Nominees Pty Ltd (CDN) as a subsidiary of the Australian Stock Exchange Ltd holds the legal title in the Company's shares, for and on behalf of CDI holders, to effect broker-to-broker settlement of trading in the underlying shares. Holders of CDIs are entitled to all the economic benefits of the underlying shares as though they were holders of the legal title. For the purposes of the information below, CDN has been excluded and the terms CDI/fully paid ordinary shares or shares are interchangeable.

This information is current as at 11 August 2009.

#### (a) Distribution of equity securities

#### (i) Ordinary share capital

291,724,429 fully paid ordinary shares are held by 783 individual security holders.

CDI holders are not entitled to vote at shareholder meetings as CDN holds legal title to the Company's shares, for and on their behalf. CDI holders should direct CDN on how to vote on proposed resolutions at shareholder meetings. CDN must exercise its right to vote by proxy at shareholder meetings in accordance with the directions of CDI holders.

All issued ordinary shares carry one vote per share without restriction.

#### (ii) Warrants

 3,200,000 unquoted warrants over ordinary shares are held by 4 individual security holders. Warrants do not carry a right to vote.

#### (iii) Options

 70,334,472 unquoted options over ordinary shares are held by 97 individual security holders. Options do not carry a right to vote.

The number of security holders, by size of holding, in each class are:

	FULLY PAID ORDINARY SHARES	WARRANTS	OPTIONS
1 – 1,000	8	-	_
1,001 - 5,000	115	-	4
5,001 - 10,000	170	_	3
10,001 – 100,000	384	_	44
100,001 and over	106	4	46
	783	4	97
Holding less than a marketable parcel of shares are:	186	_	

# (b) Substantial shareholders

	FULLY PAID		
	NUMBER	PERCENTAGE	
GBS Venture Partners Limited (GBS Bioventures III A/C)	55,986,769	19.19	
Australian Executor Trustees Ltd (CM Capital Venture 4A A/C)	41,056,240	14.07	
Australian Executor Trustees Ltd (CM Capital Venture 4B A/C)	41,056,239	14.07	
GBS Venture Partners Limited (GBS Bioventures II A/C)	36,161,140	12.40	
	174,260,388	59.73	

# (c) Twenty largest holders of quoted equity securities

	FULLY PAID		
	NUMBER	PERCENTAGE	
Ordinary shareholders			
GBS Venture Partners Limited (GBS Bioventures III A/C)	55,986,769	19.19	
Australian Executor Trustees Ltd (CM Capital Venture 4A A/C)	41,056,240	14.07	
Australian Executor Trustees Ltd (CM Capital Venture 4B A/C)	41,056,239	14.07	
GBS Venture Partners Limited (GBS Bioventures II A/C)	36,161,140	12.40	
Three Arch Partners III LP	15,062,652	5.16	
Phillip Asset Management Ltd (IB Aus Bioscience Fund I A/C)	13,000,000	4.46	
J P Morgan Nominees Australia Limited	9,450,727	3.24	
PCLM Investments Pty Ltd	5,572,716	1.91	
WSP Holdings Limited	5,061,161	1.73	
Asia Union Investments Pty Ltd	5,003,000	1.71	
ANZ Nominees Limited	4,564,500	1.56	
HSBC Custody Nominees (Australia) Limited – A/C 2	3,961,687	1.36	
Australian Biotechnology and Healthcare Fund No 3 Limited	2,672,889	0.92	
Szigetvary Trustee Services Ltd	1,940,000	0.67	
Riverdwell Pty Ltd	1,827,718	0.63	
Australian Biomedical Fund No 2 Limited	1,447,972	0.50	
SCP Investments Pty Limited	1,399,450	0.48	
National Nominees Limited	1,240,000	0.43	
Maryfair Pty Ltd	1,200,000	0.41	
Superluminal Pty Ltd	1,200,000	0.41	
	248,864,860	85.31	

# **Corporate Directory**

#### ABN 79 109 440 888

#### **Directors**

Mr Nicholas Callinan (Chairman)

Mr John Brennan

Dr Geoff Brooke

Mr Crispin Marsh

Mr Donal O'Dwyer

**Dr William Peters** 

Mr Donald Rohrbaugh (Chief Executive Officer)

# **Company Secretary**

Mrs Rowena Hubble

# **Registered Office in Australia**

3/12 Frederick Street St Leonards NSW 2065 Phone: 61 2 8424 7717

#### **Internet Address**

www.sunshineheart.com

#### **Australian Solicitors**

Henry Davis York 44 Martin Place Sydney NSW 2000

### **Bankers**

National Australia Bank

# **Share Registry**

Link Market Services Limited Level 12 680 George Street Sydney NSW 2000

## **Auditors**

Ernst & Young 680 George Street Sydney NSW 2000