

relief of heart failure symptoms C-Pulse system® reduces workload on heart minimally invasive Annual Report 2010 heart assist system C-Pulse system minimally invasive

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 15 November 2010 at 9 am.

## Chairman's Letter

#### Dear Shareholders,

I am pleased to report a year of significant achievement for Sunshine Heart. The Company has made excellent progress on a number of fronts under our CEO, Dave Rosa, since he took over at the end of 2009.

To give you a sense of the momentum building, let me recap the last couple of years. Two years ago at this time, our system for treating patients with moderate heart failure was a device with success in a first-in-human trial and we were then just starting the processes necessary to allow it to be sold in the most important market, the US. This meant winning the approval of the Food and Drug Administration ("FDA") and this has two main steps: firstly, demonstrate the safety of the device and secondly, prove the benefits that are claimed for the device.

At the end of 2008, we had just obtained FDA Investigational Device Exemption (IDE) approval to conduct the feasibility trial to implant 20 patients to prove the safety of the device in operation. Although this trial was not designed to demonstrate the effectiveness of the C-Pulse system in assisting heart failure patients as compared to other therapies, the performance of the system would, of course, be closely watched.

At the beginning, finding doctors who would recommend a new device like the C-Pulse and patients who would give their informed consent to have one implanted was, as expected, a challenge. The first couple of implants were done in April 2009 and the naturally cautious medical practitioners wanted to see how these patients fared before bringing their own patients forward. Fortunately, the benefits from a C-Pulse are felt by the patient immediately the device is activated. Our results were quickly seen and the effects were positive and so a few more patients were implanted.

The earliest implants were done by doctors using normal open-heart surgery. For the surgeon, this was a very simple operation. For the patient, it meant opening up the chest, quite a daunting prospect. As our trial progressed, what was interesting to us was that the surgeons, once they had done their first implant, were deciding they could use a less invasive surgical technique than opening the chest. This is one of the exciting developments that I referred to in my opening sentence. We have now worked with the surgeons to develop special tools to assist the less invasive implant operations and, at their suggestions, we have modified elements of the design of the device to make it easier to insert. This is a good example of how the surgeons, after actually working with the C-Pulse, have helped us evolve the product from its original experimental configuration to one that will be ready for larger scale introduction to the market. Not only have they now developed surgical techniques that can genuinely be called minimally invasive – and the CEO's report gives details on this – but they have also suggested improvements to adapt elements of the C-Pulse system to suit how it is used in practice. This represents a very significant progress for the Company on the medical front.

With this positive engagement by the medical practitioners and the very good results from the early implants, we have seen a rapid growth in the momentum as doctors and patients gain confidence in C-Pulse. In my report last year, we had implanted four patients. As at June 30th this year, we were up to nine. At the time of writing we have added four more and expect to complete enrolment in the 20-patient trial in the next few months.

The FDA IDE feasibility trial requires that we monitor the patients for six months. During this period we will prepare for the next stage of our development. Dave Rosa, in his report, talks about what he has already been doing in this regard. He is bringing in to the Company the people with the talent and experience necessary to handle the regulatory and clinical operations, he is moving our production from a small batch, single supplier basis to a more robust, larger scale operation and, most importantly, he and his team are working hard on refining the existing product as well as advancing development of the next generation products.

## Chairman's Letter continued

We are naturally keen to take the product to market as soon as we have the regulatory approvals. In parallel with our process to get FDA approval for the USA, in 2011 we intend to use the results of our US trial to apply for CE Mark approval. This approval would allow us to start marketing C-Pulse in a number of countries outside the USA, including Europe and parts of Asia.

On the financial side of our operations, we are well positioned in the USA for when we start to sell the C-Pulse device. The current insurance reimbursement arrangements we have been able to win, if carried into our stage two "pivotal" trial, would start to produce income for the Company. We will, however, still be dependent on our investors until we have full marketing approval in the USA. With this in mind, over recent months the Board has been working to introduce the Company to US investors. We have recently asked you, our shareholders, to approve a placement of shares to institutions, mainly in the US. As we have previously foreshadowed, we will need to raise additional capital later in 2011 for the larger FDA trial we hope to have approved and launched by then. Our hope and intention is that the investors who participate in this year's placement will support us further in next year's capital raising. I am pleased to report we have been receiving very encouraging responses from US investors who, for understandable reasons have urged us to have our shares listed on the NASDAQ. There are a number of successful models of Australian-listed companies with NASDAQ listings and the Board has committed itself to working towards a NASDAQ IPO as a goal in 2011.

As well as the placement of shares to US institutions, the Board has announced a rights issue to existing shareholders so they can participate in the new issue on similar terms and conditions as the placement. I am very pleased that our two largest shareholders, the venture capital funds GBS Ventures and CM Capital, have indicated their intention to take up their full entitlement in the rights issue. The Company is most fortunate to have these leading investors who have patiently supported us over the years and contributed at board-level to our development.

My comments on this fund raising must not be taken as legal descriptions of the proposed transactions. Those are set out in other documents sent to you separately.

I hope my report and that of our CEO, Dave Rosa, which follows, will help you get a sense that significant momentum is building in Sunshine Heart. The device is showing safety and performance data in line with our positive expectations, the rate of implants is accelerating, the team is building, and the Company is closer to being able to tap into the very large market of moderate heart failure patients around the world for whom there are very few alternatives.

I thank all shareholders for their support over the past years and I invite you to attend the Company's Annual General Meeting to hear first hand from the CEO and other executives the most up to date reports on our rapidly developing position. It will be held at 9am on Monday 15 November 2010.

Yours sincerely

Nicholas Callinan

Chairman

17 September 2010

## Chief Executive Officer's Review

#### Dear Shareholders,

On November 1, 2009, I joined Sunshine Heart Inc. as Chief Executive Officer. Through my travels to Australia, I have had the pleasure of meeting some of you. One of the frequent questions I have been asked is why I was interested in joining Sunshine Heart. While there were numerous reasons, the primary one was the potential to offer a meaningful heart failure therapy to a broad number of patients that have failed other treatment options such as medical therapy and/or cardiac resynchronization therapy. I have been motivated by the feedback we have received from customers and physicians. It is truly rewarding to hear a patient describe how the C-Pulse technology helped them "get their life back".

As I look to the future, I see many reasons to be excited about Sunshine Heart Inc. Completing our feasibility trial, improving our core technology, offering tools to enable a minimally invasive procedure, initiating our US pivotal trial and receiving CE Mark are all milestones we have targeted through 2011. 2010 was a transition year for the Company from a design and development stage to a clinical, system improvement and commercialization execution phase. While there are many challenges along the way, I believe the Company has the right people, plan and investor support we need to accomplish our objectives.

#### 2010 Key Achievements

The over-riding goal for the Company has been to complete the US 20 patient FDA feasibility trial. To achieve this, we added four new centers during the year who are now fully trained and approved for implants. Through the end of August, I am pleased to report that we have completed 13 implants. As well as these achievements, there were a number of other key milestones achieved:

- Development of tools to allow minimally invasive implants.
- Exceeding our milestone of having one implant done minimally invasively before the end of 2010. As of August 31, two patients have been implanted via a mini-thoracotomy (through ribs) and two have been completed via a mini-sternotomy.
- Launch of program to reduce the size, weight and cost of the system's driver.
- Demonstration of feasibility of our Sync-Pulse concept, which links the C-Pulse to existing pacemaker technology creating a potential new therapy.
- Development of our human resources by adding to our team experienced clinical, regulatory and research and development personnel.
- Relocation of our US headquarters to Minneapolis, Minnesota, where we are part of a recognised medical technology precinct with a full range of support services.

## **US Feasibility Trial**

When we started the US feasibility trial, there were six approved centers: University of Alabama, Jewish Hospital, Ohio State University, Penn State University, University of Florida, and Northwestern University. Inevitably, personnel changes and other developments resulted in slower than expected enrolment so, early in the year, we launched a program to find additional centers and bring them to "implant ready" status. As of July 31st, four new centers had been added: St. Luke's Hospital (US), United Hospital (US), Royal Victoria (Canada) and St. Vincent's (Australia). These new centers have contributed quickly, implanting four patients to date with more expected. We expect to add to our current 13 patients and complete the 20-patient trial in the next few months.

Supporting these new centers required us to restructure our management team. To oversee the field operations, manage the Company relationship with FDA, and develop our pivotal trial protocol, we hired Debra Kridner as Vice President of regulatory and clinical affairs. Debra previously held this position at St. Jude Medical's Cardiovascular Division. We also added an experienced field clinical manager to support the centers. These changes contributed to the enrolment progress we have seen in recent months.

## Chief Executive Officer's Review continued

It is particularly pleasing to report how patients describe their experience with the C-Pulse System. They note improved breathing functions, and increased mobility and quality of life. These effects are consistent with and in some cases better than what is typically achieved with traditional intra-aortic balloon pump therapy. Patients have also been enthusiastic about being able to temporarily disconnect from the system, leaving them free to shower or perform other functions.

We have also received a great deal of feedback from our participating physicians and patients on the C-Pulse system regarding areas for improvement. We particularly value these as we continue to develop the product for the next phase. One key factor is clear, patients and physicians are keen to see implant procedures that are less invasive than the full open chest procedures used by doctors in the early implants. Doctors point to smaller incisions reducing the likelihood for infection, recovery time, overall cost and pain reduction. Patients like the idea of "minimally invasive" surgery and prefer smaller incisions for aesthetic reasons. During the year, in discussions with doctors at all of our centers, it became clear that a minimally invasive C-Pulse procedure was a key new Company objective. Having set ourselves this target, I am pleased to report we have met this milestone and that four of our last five implants have been performed through a small incision.

We will continue to develop tools for physicians to facilitate the new procedures. Patients and physicians are enthusiastically supportive of these developments. The other request relates to the miniaturizing of the system. To this end, we have now initiated a joint development program with two Australian design firms to reduce the current two unit system consisting of a driver and separate battery to one integrated, smaller, lighter unit. This new design is planned to be available for our pivotal trial. Our objective for next year is to provide Class III heart failure patients with a device implanted incorporating a minimally invasive procedure and connected to a small single external unit. This is what our patients and physicians have requested and this is what we are committed to deliver.

### **Technology Progress**

As well as the improvements to the existing product I have described above, we are also working on a significant new product which would connect the C-Pulse with a pacemaker in what we call the Sync-Pulse System. We have demonstrated the early feasibility of this combination and we will be working on this in the coming year. The reason we see this as a significant area for development is that:

Every one of the thirteen patients we have implanted to date has had a pacemaker, an ICD or both. These devices had been either ineffective or provided only minimal improvement for the patients. The Sync-Pulse may offer a more effective potential solution. Interestingly enough, physicians have suggested that combining the devices may actually provide a new therapy altogether. We will be exploring this in more detail and have hired an experienced former Boston Scientific research and development executive to spearhead the development effort of the completely implantable C-Pulse system and the Sync-Pulse System. We believe the ability to offer a pacemaker like procedure and system for mechanical heart failure is truly exciting.

## **Manufacturing and Operations**

The Company currently has operations in Sydney, Australia and Eden Prairie, Minnesota. Minnesota is home to Medtronic Inc., St. Jude Medical and Boston Scientifics' cardiovascular operations. All of Sunshine Heart's US employees have worked for at least one of these three firms. As the Company's objectives require the hiring of additional personnel in the US, our location enables us to easily recruit qualified personnel.

During the year, a part of the transition from producing an experimental device to preparing for our larger pivotal trial device required modifications to our existing supplier agreements. I am pleased to report that we have solidified our key supplier relationships, signing longer term manufacturing agreements to ensure an uninterrupted supply of product for pivotal clinical trial and potentially beyond.

#### **Capital Raising**

In May 2010, the Company started the process of seeking additional capital in the fourth quarter of 2010 to finance the 2011 corporate objectives. To assist with raising the capital, we appointed Summer Street Research Partners in the US and RBS Morgans as the Australian brokers for the financing.

### 2011 targeted milestones

In 2011, the Company will focus on a number of key milestones which have the potential to bring meaningful value. They are as follows:

- 1) FDA submission and publication of six-month follow up for feasibility trial.
- 2) FDA approval and initiation of pivotal trial.
- 3) Introduction of minimally invasive tools.
- 4) Introduction of single unit C-Pulse system for pivotal trial.
- 5) Submission for CE Mark approval.
- 6) Advancement of implantable system program.
- 7) Additional personnel to support objectives.
- 8) Continued development of Sync-Pulse program.
- 9) Launch of new website.
- 10) Raise capital to complete the pivotal trial.

#### Summary

After personally hearing and witnessing the impact that the C-Pulse System has had on our patient's lives, I am truly convinced that there is a tremendous opportunity for Sunshine Heart Inc. Patients whose lives are impaired by shortness of breath and severe fatigue presently have limited treatment options, none of which have demonstrated meaningful improvement. C-Pulse offers the potential to reduce or eliminate these symptoms and its effects are immediate. When you also consider that there are nearly four times more patients in this market than those with Class IV heart failure, it is clear there is a great opportunity for Sunshine Heart. In 2011, we will offer a minimally invasive, portable single unit mechanical system that is non-blood contacting for Class III heart failure. Our primary challenge is now the execution of our Company plan.

Your support will continue to be vital to our ability to achieve this.

Best regards

Dave Rosa

Chief Executive Officer

17 September 2010

## 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

Mr Callinan was appointed Chairman of Sunshine Heart on 30 October 2008. He is a member of the Audit Committee. 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 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 Dave Rosa MSCE MBA (appointed Director and Chief Executive Officer 1 November 2009)

With more than 20 years' experience in the medical device industry, Mr. Rosa has spent more than fifteen years with Boston Scientific (Director of WW Marketing for IVUS), St. Jude Medical (VP of WW Marketing, Cardiovascular Division), A-Med Systems (VP of Marketing and Sales, CEO) and Sunshine Heart Inc. (CEO). He has also held roles in sales with Stryker Instruments and marketing with C.R. Bard Inc. in their Patient Care Division.

#### 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 technology 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 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. Dr Brooke sits on the board of a number of GBS private companies, as well as the Victorian WorkSafe Authority. 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).

#### **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, Compliance and Corporate Governance 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 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. 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.

## Directors' Report continued

#### Mr Donald Rohrbaugh MSME (resigned as Chief Executive Officer and Director 31 October 2009)

Mr Rohrbaugh was a Director and Chief Executive Officer of Sunshine Heart from January 2003 until his resignation in October 2009. 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.

## **Company Secretary**

#### Mrs Rowena Hubble B Bus CPA

Mrs Hubble was appointed Company Secretary of Sunshine Heart in May 2009 and Chief Financial Officer in December 2009. Mrs Hubble 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.

### **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 19. There has been no change in director's interests post year end.

## **Earnings per Share**

Basic Earnings per Share (1.4) cents
Diluted Earnings per Share (1.4) cents.

#### Dividends

No dividends were paid or recommended to be paid during the year (2009: 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 11 employees and 5 consultants as at 30 June 2010 (2009: 6 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 United States.

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

The Group incurred a net loss for the year of \$6,532,720 (2009 loss - \$8,079,055). 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 2011 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 \$7,266,912 (2009: \$7,747,373).

### **Liquidity and Funding**

The Company is seeking to raise additional capital through a placement to institutional investors and a rights issue, announced on 16 September 2010. Further funding will be required in order to commercialise C-Pulse.

## **Significant Events After Balance Date**

On 16 September 2010 the Company announced a placement, subject to Shareholder approval, and a rights issue to raise up to \$22 million.

## **Share Options**

#### **Unissued shares**

As at the date of this report, there were 31,757,816 employee options and placement options over unissued ordinary shares in Sunshine Heart, Inc.

#### **Employee Options**

During the year ended 30 June 2010, no options over unissued ordinary shares were issued as remuneration to consultants and employees of the Company. During the year 8,783,654 options were cancelled or forfeited.

#### **Placement Options**

Refer to note 10(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.

## Shares issued as a result of the exercise of options

During the financial year employees and executives have exercised options to acquire 2,188,923 fully paid ordinary shares in Sunshine Heart, Inc for a total consideration of \$37,629 or a weighted average exercise price of \$0.02 per share.

## 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 19 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 caliber, 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 2010 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

In determining the level and make-up of executive remuneration, the remuneration and nomination committee primarily relies upon internal surveying of prevailing market conditions. However it may seek external advice as required.

## Directors' Report continued

## Remuneration Report - Audited continued

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 [14].

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.

#### **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 at the Boards discretion. The Board determines the total amount of discretionary variable compensation to be paid to the Group's employees. The amount of variable compensation payable to an individual is not dependent on the satisfaction by employees of a performance condition, or the performance of the Group, the Company's share price, or dividends paid by the Company, but at the discretion of the Board.

As neither the fixed or variable component of the Other key Management Personnel and the Other Executive remuneration is dependent on the satisfaction of a performance condition, or the performance of the Group, the Company's share price, or dividends paid by the Company, a discussion of the relationship between the Board's remuneration policy and the Group's performance is not provided.

## 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.

As neither the fixed or variable component of the Other key Management Personnel and the Other Executive remuneration is dependent on the satisfaction of a performance condition, or the performance of the Group, the Company's share price, or dividends paid by the Company, a discussion of the relationship between the Board's remuneration policy and the Group's performance is not provided. There were no performance options issued during either the financial year 2010 or 2009. There was no performance bonus issued in either financial year 2010 or 2009.

Details of options granted, including the value of options and vesting periods under the LTIP plan, is detailed in Note 14 for employees and Note 19(c) for directors.

### **Employment and Consultancy Contracts**

Remuneration arrangements for Key management Personnel are formalised in employment or consulting agreements.

Mr Don Rohrbaugh who ceased in his position as Chief Executive Officer and Director on 31 October 2009 received continued payment of his monthly fee until the six month anniversary of his termination date, as required by his contract.

There are no termination provisions in Debra Kridner's employment contract. In the event of termination of contract by Sunshine Heart for all other Key Management Personnel, the Company is required to provide one months notice of termination, or payment in lieu of actual notice.

## Directors' Report continued

## Remuneration Report - Audited continued

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

Table 1: Remuneration for the year ended 30 June 2010

Table 1: Remuneration for	·	SHORT TERM NON-MONETARY		POST EMPLOYMENT SUPERANNUATION	SHARE BASED PAYMENTS	TOTAL	PERFORMANCE RELATED <sup>a</sup>
Non and outline Discotor	SALARY & FEES	BENEFITS	CASH STI	AND OTHER	OPTIONS <sup>b</sup>		%
Non-executive Director N Callinan					4 270	104 270	
	100,000	_	_	_	4,379	104,379	_
C Marsh	50,000	_	_	_	1,036	51,036	_
D O'Dwyer Subtotal	50,000			<del>-</del>	<del>-</del>	50,000	
	200.000				E 41E	205 415	
Non-executive Directors <b>Executive Directors</b>	200,000				5,415	205,415	
	122 261			244 527	2 220	270 117	
D Rohrbaugh	123,361	_	_	244,527	2,229	370,117	_
W Peters	265,152	16.003	17.062	_	9,193	274,345	_
D Rosa <sup>d</sup>	214,963	16,083	17,063	_	_	248,109	_
Other KMP							
J Weitzner	196,527	_	_	_	6,356	202,883	_
S Miller	183,372	_	_	16,503	4,038	202,003	_
D Kridner <sup>e</sup>	132,334	3,674	_	10,303	-,030	136,008	_
Subtotal Executive KMP	1,115,709	19,757	17,063	261,030	21,816	1,435,375	
Total	1,332,772	19,757	17,063	261,030	27,231	1,640,790	
Table 2:Remuneration fo	•	nded <b>30 June</b>	2009				
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	_	_	_	_,5_5	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	
Subtotal Executive KMP	1,919,001	_	171,121	65,997	136,556	2,292,275	
Total	2,134,323	_	171,121	65,997	155,786	2,526,827	
NOTES			-	· · · · · · · · · · · · · · · · · · ·	•		

NOTES

No future maximum or minimum total value of performance related remuneration has been determined as at the date of this report.

Options issued to Director's related parties and other Key Management Personnel as described in Note 20(c).

J Brennan and G Brooke received no remuneration for the years ended 30 June 2009 and 30 June 2008.

D Rosa performed a consulting role for the Company prior to 1 November 2009. Total salary and fees includes consulting fees prior to 1 November 2009 and salary paid from 1 November 2009.

D Kridner's consulting contract commenced on 1 December 2009 and ceased on 14 March 2010. Her employment contract commenced on 15 March 2010 and is ongoing. Total salary and fees includes the consulting fees and salary paid for the respective periods.

No options were granted as part of remuneration for the year ended 30 June 2010.

Table 3: Options granted as part of remuneration for the year ended 30 June 2009

	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 <sup>d</sup>	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 d	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**

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.

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.

Options fully vested at grant date.
 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 14. There were no alterations to the terms and conditions of options granted as remuneration since their grant date.

Table 4: Value of options awarded, exercised and lapsed during the year ended 30 June 2010

	VALUE OF OPTIONS GRANTED DURING THE YEAR \$	VALUE OF OPTIONS EXERCISED DURING THE YEAR \$	VALUE OF OPTIONS LAPSED DURING THE YEAR \$	REMUNERATION CONSISTING OF OPTIONS FOR THE YEAR \$
D Rohrbaugh	_	6,575	206,983	_
Other KMP	_	_	_	_

For details of options that vested and lapsed during the year refer note 19(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

## **Auditor independence**

We have obtained the independence declaration from our auditors, Ernst & Young, a copy of which is included on page 57 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	COMMITTEES
	SINECTONS INEETINGS	AUDIT,COMPLIANCE AND GOVERNANCE	REMUNERATION AND NOMINATION
Number of meetings held:	10	4	4
Number of meetings attended:			
N Callinan	10	4	-
G Brooke	9	-	4
C Marsh	9	3	
D O'Dwyer	10	3	-
W Peters	7	-	
D Rohrbaugh	4	-	-
J Brennan	8	-	4
D Rosa	5	_	_

All directors were eligible to attend all meetings held, except for D Rohrbaugh who was eligible to attend 4 Directors' meetings and D Rosa who was eligible to attend 5 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), C Marsh and N Callinan.
- 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 2010. 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 18 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.

David Rosa

Director

17 September 2010

## 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 two 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. The Company's board of directors consider that Dr Brooke and Mr Brennan 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.

# Statement of Comprehensive Income

For the year ended 30 June 2010

	NOTES	CONSOLI	DATED
		2010	2009
		\$	\$
Revenue and other income	3	470,690	424,182
Depreciation and amortisation	3	(60,216)	(69,714)
Insurance		(177,604)	(208,925)
Office expenses	3	(199,841)	(193,365)
Professional fees		(440,036)	(425,100)
Salaries and employee benefits	3	(2,114,199)	(2,942,398)
Research and development	3	(3,468,512)	(3,121,406)
Travel		(513,896)	(492,679)
Patents		(163,728)	(147,828)
Other expenses		(650,756)	(901,822)
Loss from continuing operations before income tax		(7,318,098)	(8,079,055)
Income tax benefit	4	785,378	
Loss from continuing operations after income tax		(6,532,720)	(8,079,055)
Other comprehensive income		_	
Other comprehensive income after income tax		_	
Total comprehensive loss for the year attributable to			
members of Sunshine Heart, Inc.	10(e)	(6,532,720)	(8,079,055)
Basic loss per share (cents per share)	17	(1.4)	(2.8)
Diluted loss per share (cents per share)	17	(1.4)	(2.8)

# Statement of Financial Position

## At 30 June 2010

	NOTES	CONSOL	IDATED
		2010	2009
		\$	\$
ASSETS			
Current Assets			
Cash and cash equivalents	12(b)	3,942,117	2,013,816
Trade and other receivables	5	249,497	161,171
Tax rebate		785,378	_
Other current assets	6	154,646	93,071
Total Current Assets		5,131,638	2,268,058
Non-Current Assets			
Property, plant and equipment	7	133,858	188,962
Total Non-Current Assets		133,858	188,962
Total Assets		5,265,496	2,457,020
LIABILITIES			
Current Liabilities			
Trade and other payables	8	455,852	344,415
Provisions	9	82,501	83,755
Total Current Liabilities		538,353	428,170
Total Liabilities		538,353	428,170
Net Assets		4,727,143	2,028,850
EQUITY			
Contributed equity	10(a)	57,539,953	48,293,638
Accumulated losses	10(e)	(54,565,166)	(48,032,446)
Reserves	10(f)	1,752,356	1,767,658
Total Equity		4,727,143	2,028,850

# Statement of Changes in Equity

For the year ended 30 June 2010

	ORDINARY SHARES	EMPLOYEE EQUITY BENEFITS RESERVE	RETAINED LOSSES	TOTAL
At 30 June 2008	48,293,638	1,594,655	(39,953,391)	9,934,902
Loss for the year	_	_	(8,079,055)	(8,079,055)
Other comprehensive income	_	_	_	-
Total comprehensive loss for the period	_	-	(8,079,055)	(8,079,055)
Transactions with owners in their capacity as				
owners:				
Shares issued	_	_	_	_
Share-based payment reserve	-	173,003	_	173,003
Transaction costs on share issue	-	_	-	_
At 30 June 2009	48,293,638	1,767,658	(48,032,446)	2,028,850
Loss for the year	_	_	(6,532,720)	(6,532,720)
Other comprehensive income	-	_	-	_
Total comprehensive loss for the period	_	_	(6,532,720)	(6,532,720)
Transactions with owners in their capacity as				
owners:				
Shares issued	9,844,219	_	-	9,844,219
Share-based payment reserve	_	(15,302)	_	(15,302)
Transaction costs on share issue	(597,904)	_	_	(597,904)
At 30 June 2010	57,539,953	1,752,356	(54,565,166)	4,727,143

# Statement of Cash Flows

For the year ended 30 June 2010

	NOTES	CONSOL	IDATED
		2010	2009
		\$	\$
Cash flows from operating activities			
Clinical implant reimbursement		249,539	_
Payments to suppliers and employees		(7,660,449)	(8,070,160)
Interest received		143,998	322,787
Net cash flow used in operating activities	12(a)	(7,266,912)	(7,747,373)
Cash flows from investing activities			
Purchase of property, plant and equipment		(5,112)	(8,567)
Net cash flows used in investing activities		(5,112)	(8,567)
Cash flows from financing activities			
Proceeds from issue of ordinary shares		9,844,219	_
Payment of share issue costs		(597,905)	_
Net cash flows from financing activities		9,246,314	-
Net increase in cash and cash equivalents		1,974,290	(7,755,940)
Net foreign exchange differences		(45,989)	(2,861)
Cash and cash equivalents at beginning of year		2,013,816	9,772,617
Cash and cash equivalents at end of year	12(b)	3,942,117	2,013,816

## Notes to the Financial Statements

For the year ended 30 June 2010

## 1. Corporate Information

The annual report of Sunshine Heart, Inc. ("Company" or "Sunshine Heart") for the year ended 30 June 2010 was authorised for issue in accordance with a resolution of the directors on 17 September 2010.

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.

The Group has adopted the following new and amended Australian Accounting Standards and AASB interpretations as of 1 July 2009.

- AASB 2008-1 Amendments to Australian Accounting Standard Share-based Payments
- AASB 7 Financial Instruments
- AASB 8 Operating Segments
- AASB 101 Presentation of Financial Statements
- AASB 2008-5 Amendments to Australian Accounting Standards arising from the Annual Improvements Project

Certain Australian Accounting Standards 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 2010. 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 2010 and 30 June 2009, the Group incurred an operating loss before tax and net cash outflows from operating activities as disclosed in the Statement of Comprehensive Income and Statement of Cash Flows, 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 14.

## (f) Significant accounting judgements

#### **Taxation**

The Group's accounting policy for taxation requires management's judgement as to the types of arrangements considered to be a tax on income in contrast to an operating cost. Judgement is also required in assessing whether deferred tax assets and certain deferred tax liabilities are recognised in the statement of financial position. Deferred tax assets, including those arising from unrecouped tax losses, capital losses and temporary differences, are recognised only where it is considered more likely than note that they will be recovered, which is dependent on the generation of sufficient future taxable profits.

### (g) 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.

## Notes to the Financial Statements continued

For the year ended 30 June 2010

## 2. Summary of Significant Accounting Policies continued

#### (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 Statement of Comprehensive Income on a straightline basis over the lease term. Lease incentives are recognised in the Statement of Comprehensive Income as an integral part of the total lease expense.

#### (i) Cash and cash equivalents

Cash and short term deposits in the Statement of Financial Position 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 Statement of Cash Flows, 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 Statement of Comprehensive Income. 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 Statement of Financial Position 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 Statement of Financial Position 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 Statement of Financial Position 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 Statement of Financial Position date.

Income taxes relating to items recognised directly in equity are recognised in equity and not in the Statement of Comprehensive Income.

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 Statement of Financial Position.

Cash flows are included in the Statement of Cash Flows 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 2010

## 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 2010/2009):

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 (only applicable to the parent entity)

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 loss from operating activities after income tax in note 11, Parent Entity Information.

## (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 Statement of Comprehensive Income 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 Statement of Comprehensive Income 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 2010

## 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.

Expenses for non-accumulating sick leave are recognised when the leave is taken and are measured at the rates paid or payable.

## (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 14. 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 Statement of Comprehensive Income 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 2010

NOTES	CONSOL	IDATED
	2010	2009
	\$	\$
3. Revenues and Expenses		
(a) Revenue and other Income		
Finance revenue – bank interest	171,891	289,987
Clinical implant reimbursement	298,799	134,195
	470,690	424,182
(b) Depreciation and amortisation		
Depreciation – plant and equipment	45,534	54,766
Amortisation – leasehold improvements	14,682	14,948
	60,216	69,714
(c) Office expenses		
Lease payments	199,841	193,365
(d) Employee benefits expense		
Share based payments 10(f)	(15,302)	173,003
Employee benefits	19,757	46,103
Superannuation	64,937	106,957
Salaries and consultancy fees	2,044,807	2,616,335
	2,114,199	2,942,398
(e) Research and development expenses	3,468,512	3,121,406
(f) Foreign exchange differences		
Net foreign exchange (gain)/loss	99,450	393,450
Advertising	170,684	87,010
Other expenses	380,622	421,422
	650,756	901,882

CONSOLIC	DATED
2010	2009
\$	\$

## 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	(7,318,098)	(8,079,055)
At the Group statutory income tax rate of 39% (2009: 39%)	(2,854,058)	(3,150,831)
Expenditure not allowed for income tax purposes		
– share based payments	(5,967)	67,471
Difference in overseas tax rates	598,670	640,896
R&D tax offset	785,378	_
Current year tax losses not booked as a future tax benefit, as		
realisation of benefit is not probable	2,261,355	2,442,464
Income tax benefit reported in the		
Consolidated Statement of Comprehensive Income	785,378	
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	14,473,326	13,172,165

The unrecognised deferred tax assets relating to deductible temporary differences at 30 June 2010 is \$123,223 (2009: \$87,674). The unrecognised deferred tax liabilities relating to assessable temporary differences at 30 June 2010 is nil (2009: nil).

Consolidated franking account balance at 30 June 2010 nil (2009: nil).

For the year ended 30 June 2010

NOTES	CONSOLIDATED	
	2010	2009
	\$	\$
5. Trade and Other Receivables		
Clinical implant reimbursement – receivable	183,455	134,195
Finance revenue receivables – bank interest	27,895	_
Other receivables	38,147	26,976
	249,497	161,171

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

Prepayments and deposits	154,646	93,071
7 Drangety Plant and Favingsont		
7. Property, Plant and Equipment		
Leasehold improvements		
At cost	77,241	77,241
Accumulated amortisation	(54,716)	(40,034)
7(a)	22,525	37,207
Office furniture and equipment		
At cost	88,443	88,443
Accumulated depreciation	(28,812)	(22,330)
7(a)	59,631	66,113
Computer equipment		
At cost	84,675	79,561
Accumulated depreciation	(68,562)	(53,546)
7(a)	16,113	26,015
Laboratory and research equipment		
At cost	177,083	177,083
Accumulated depreciation	(141,494)	(117,456)
7(a)	35,589	59,627
Total property, plant and equipment		
At cost	427,442	422,328
Accumulated depreciation and amortisation	(293,584)	(233,366)
Total written down amount	133,858	188,962

## (a) Reconciliations

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

	2010	2009
	\$	\$
Leasehold improvements		
Carrying amount at beginning	37,207	52,155
Amortisation expense	(14,682)	(14,948)
Net Carrying Amount	22,525	37,207
Office furniture and equipment		
Carrying amount at beginning	66,113	72,594
Depreciation expense	(6,482)	(6,481)
Net Carrying Amount	59,631	66,113
Computer equipment		
Carrying amount at beginning	26,015	38,810
Additions	5,112	8,567
Depreciation expense	(15,014)	(18,761)
Disposals	_	(2,601)
Net Carrying Amount	16,113	26,015
Laboratory and research equipment		
Carrying amount at beginning	59,627	89,151
Depreciation expense	(24,038)	(29,524)
Net Carrying Amount	35,589	59,627
Total property, plant and equipment		
Carrying amount at beginning	188,962	252,710
Additions	5,112	8,567
Depreciation expense	(60,216)	(69,714)
Disposals	-	(2,601)
Net Carrying Amount	133,858	188,962

No property, plant and equipment is impaired.

For the year ended 30 June 2010

	CONSOLIDATED	
	2010	2009
	\$	\$
8. Trade and Other Payables (current)		
Sundry creditors	455,852	344,415
Sundry creditors are non-interest bearing and are normally settled on 30 day terms.		
9. Provisions (current)		
Annual leave	58,832	71,015
Long service leave	23,669	12,740
	82,501	83,755
Movement in annual leave provision		
Balance 1 July 2009	71,015	84,705
Arising during the year	50,894	89,845
Utilised	(63,077)	(103,535)
Balance at 30 June 2010	58,832	71,015
Movement in long service leave provision		
Balance 1 July 2009	12,740	6,400
Arising during the year	10,929	6,340
Balance at 30 June 2010	23,669	12,740
<ul><li>10. Contributed Equity and Reserves</li><li>(a) Issued and paid up capital</li></ul>		
Shares, fully paid	56,160,753	46,914,438
Warrants	1,379,200	1,379,200
	57,539,953	48,293,638

	20	2010		09
	NUMBER OF SHARES	\$	NUMBER OF SHARES	\$
(b) Movement in shares on issue Shares, fully paid				
Beginning of the financial year	291,724,429	46,914,438	291,724,429	46,914,438
Issued on 17 August 2009 – private placement	43,758,664	1,750,347	_	_
Issued on 26 August 2009 – option exercise	194,000	3,610	_	_
Issued on 29 September 2009 – rights issue	201,406,334	8,056,243	_	_
Transaction costs on private placement and				
rights issue	_	(597,904)	_	_
Issued on 3 December 2009 – option exercise	1,994,923	34,019	_	
End of the financial year	539,078,350	56,160,753	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 no options (2009: 10,315,277) over ordinary shares with an issue term of 10 years. During the year 2,188,923 (2009: nil) were exercised and 8,783,654 (2009: 3,480,228) options were forfeited.

At the end of the year there were 15,757,816 (2009: 26,730,393) 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. During the year 27,604,079 placement options expired.

At the end of the year there were 16,000,000 (2009: 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 29 June 2004 convertible promissory notes 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.

For the year ended 30 June 2010

## 10. Contributed Equity and Reserves continued

	CONSOLIDATED		
	2010	2009	
	\$	\$	
(e) Accumulated Losses			
Movement in accumulated losses were as follows:			
Balance 1 July	(48,032,446)	(39,953,391)	
Net loss attributable to members of Sunshine Heart, Inc.	(6,532,720)	(8,079,055)	
Balance 30 June	(54,565,166)	(48,032,446)	

#### (f) Reserves

#### Movement in reserves were as follows:

	CONSOLIDATED		
	EMPLOYEE EQUITY BENEFITS RESERVE	TOTAL	
At 30 June 2008	1,594,655	1,594,655	
Share-based payments	173,003	173,003	
At 30 June 2009	1,767,658	1,767,658	
Share-based payments	(15,302)	(15,302)	
At 30 June 2010	1,752,356	1,752,356	

#### (g) Dividends

No dividends were paid or recommended to be paid during the year (2009: Nil).

## 11. Parent Entity Information

	PARENT	
	2010	2009
	\$	\$
Current assets	3,713,053	178,903
Total assets	4,807,034	2,085,304
Current liabilities	79,903	56,454
Total liabilities	79,903	56,454
Issued capital	57,539,953	48,293,638
Reserves	1,752,356	1,767,658
Total Shareholders' equity	4,727,131	2,028,850
Loss from operating activities after income tax	6,532,720	8,079,055
Total comprehensive loss	6,532,720	8,079,055

The parent entity has not entered into any guarantees in relation to the debts of its subsdiaries. The parent entity has no contingent liabilities and has no contractual commitments for the acquisition of property, plant or equipment.

NOTES	CONSOL	IDATED
	2010	2009
	\$	\$
12. Cash and Cash Equivalents		
(a) Reconciliation of the net loss after tax to the		
net cash flows from operations		
Net loss	(6,532,720)	(8,079,055)
Non-Cash items		
Depreciation and amortisation of non-current assets 3(c)	60,216	69,714
Share based payments expense	(15,302)	173,003
Unrealised net foreign exchange differences	45,983	5,462
Changes in assets and liabilities		
(Increase)/decrease in prepayments and other		
receivables	(935,279)	(101,115)
Increase in trade and other payables	111,444	191,968
Decrease in provisions	(1,254)	(7,350)
Net cash outflow from operating activities	(7,266,912)	(7,747,373)
(b) Reconciliation of cash		
Cash balance comprises:		
– cash at bank	1,051,040	2,013,816
- term deposits	2,891,077	_
Closing cash balance	3,942,117	2,013,816
(c) Non-cash financing and investing activities		
Share based payments	(15,302)	173,003

## (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.

For the year ended 30 June 2010

	CONSOL	CONSOLIDATED	
	2010	2009	
	\$	\$	
3. Commitments			

## 13. Commitments

## (a) Lease expenditure commitments - Group as lessee

#### (i) Operating leases (non-cancellable)

Minimum lease payments

– not later than one year	108,969	141,357
<ul> <li>later than one year and not later than five years</li> </ul>	-	_
Aggregate lease expenditure contracted for		
at reporting date	108,969	141,357

Operating lease expenditure commitments relate to the St Leonards property where the lease expires on 31 March 2011. The lease is expected to be renewed on similar terms at expiration.

#### (ii) Research and development commitments

– not later than one year	1,220,322	394,725
– later than one year and not later than five years	-	_
Aggregate other expenditure contracted for at reporting date	1,220,322	394,725

Research and development commitments are purchase orders where the work has been committed but not yet completed.

## 14. 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 2010 there were 9 retained Key Management Personnel and 8 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 2010, being \$0.8567. All options issued and outstanding under the Plan do not carry dividend and/or voting rights.

	2010		2009	
	NUMBER OF OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE	NUMBER OF OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE
		\$		\$
Balance at beginning of year	26,730,393	0.19	19,895,344	0.24
– granted	-	_	10,315,277	0.09
– exercised	(2,188,923)	0.02	-	_
– forfeited	(8,783,654)	0.25	(3,480,228)	0.19
Balance at end of year	15,757,816	0.18	26,730,393	0.19

Options were exercised on 26 August 2010 and 3 December 2010. The weighted average share price at the date of exercise was \$0.05 and \$0.04 respectively.

#### 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 2010. 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 COMMENCEMENT DATE	EXPIRY DATE	WEIGHTED AVERAGE EXERCISE PRICE
				\$
1,695,497	31 Jan 03	31 Jan 03	30 Jan 13	0.07
38,800	29 Apr 03	31 Jan 03	28 Apr 13	0.12
601,400	19 May 04	30 Mar 04	18 May 14	0.08
3,210,000	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
40,000	21 Jun 05	10 Jan 05 to 21 Jun 05	20 June 10	0.48
300,000	21 Apr 06	31 Mar 06	20 Apr 16	0.37
58,200	2 Jun 06	1 Jun 06	1 Jun 16	0.25
698,784	1 Nov 06	1 Nov 06	31 Oct 16	0.20
428,958	31 Jan 07	31 Jan 07	30 Jan 17	0.29
706,000	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	17 Dec 17	0.30
290,063	14 Feb 08	14 Feb 08	13 Feb 18	0.18
2,097,500	10 Jul 08	10 Jul 08 to 30 Oct 08	9 Jul 18	0.11
4,347,214	21 Aug 08	21 Aug 09	20 Aug 18	0.08

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.

For the year ended 30 June 2010

### 14. Share-based Payments Plan continued

#### 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:

	2010	2009
Dividend yield (%)	No options granted	0%
Risk-free Interest rate (%)	-	5.84%
Expected volatility (%)	-	45%
Expected life of option (years)	-	5 years
Weighted average exercise price	_	\$0.09

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 Statement of Comprehensive Income with a corresponding adjustment to equity.

#### Weighted average fair value

The weighted average fair value of options granted during the year was \$nil (no options granted) (2009: \$0.016).

#### Weighted average remaining contractual life

The weighted average remaining contractual life for the share options outstanding as at 30 June 2010 is 6.07 years (2009: 7.02 years).

### 15. 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 2010 was \$4.07 million.

## 16. Subsequent Events

On 16 September 2010 the Company announced a placement, subject to Shareholder approval, and a rights issue to raise up to \$22 million. The Company has secured commitments from US institutional investors of \$3.7 million. The Company's major shareholders, GBS Venture Partners and CM Capital, have indicated their intention to take up their entitlement in the rights issue.

## 17. Earnings Per Share

	2010	2009
	\$	\$
The following reflects the income and share data used in the calculations of basic and diluted loss per share:		
Net loss	(6,532,720)	(8,079,055)
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	400 007 004	201 701 100
the net loss per share):	482,227,231	291,724,429

## 18. Auditors' Remuneration

	CONSOLIDATED		
	2010	2009	
	\$	\$	
Amounts received or due and receivable by Ernst & Young			
Australia for:			
- an audit or review of the financial report of the entity and			
any other entity in the consolidated entity	106,605	106,605	
- other services in relation to the entity and any other entity			
in the consolidated entity			
- Tax compliance services	20,000	8,496	
- Advisory services	_	4,060	
	126,605	119,161	

For the year ended 30 June 2010

#### 19. Director and Executive Disclosures

#### (a) Details of Key Management Personnel

#### **Directors**

Mr Nicholas Callinan Chairman (non-executive)
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 (resigned 31 October 2009)
Mr David Rosa Chief Executive Officer (appointed 1 November 2009)

**Executives** 

Mr John Weitzner Vice President US Operations
Mr Scott Miller Director Australian Operations

Ms Debra Kridner Vice President Research and Regulatory Affairs

## (b) Compensation of Key Management Personnel

	CONSOLIDATED		
	2010	2009	
	\$	\$	
Short-Term	1,352,529	2,305,444	
Post Employment	261,030	65,997	
Share-based Payment	27,231	155,786	
	1,640,790	2,527,227	

## (c) Option holdings of Key Management Personnel

June 2010	BALANCE		OPTIONS	24144165	AT 30 JU	INE 2010
	AT BEGINNING OF PERIOD 1 JULY 2009	OPTIONS EXERCISED	OPTIONS CANCELLED/ FORFEITED	BALANCE AT END OF PERIOD 30 JUNE 2010	NOT EXERCISABLE	VESTED AND EXERCISABLE
Directors						
N Callinan	2,000,000	_	_	2,000,000	592,999	1,407,001
G Brooke 1,3	15,963,667	_	(8,400,000)	7,563,667	_	7,563,667
C Marsh <sup>3</sup>	2,106,665	_	(1,000,000)	1,106,665	21,802	1,084,863
D O'Dwyer	97,000	_	_	97,000	_	97,000
W Peters	3,712,482	_	_	3,712,482	663,280	3,049,202
J Brennan <sup>2,3</sup>	18,133,333	_	(9,600,000)	8,533,333	_	8,533,333
D Rohrbaugh <sup>4</sup>	8,768,341	(1,994,923)	(4,833,418)	1,940,000	_	1,940,000
Executives						
J Weitzner	1,115,730	_	_	1,115,730	465,775	649,955
S Miller	1,115,730	_	_	1,115,730	269,851	845,879
Total	53,012,948	(1,994,923)	(23,833,418)	27,184,607	2,013,707	25,170,900

No options were granted during the year.

June 2009	BALANCE AT BEGINNING OF		OPTIONS	BALANCE	AT 30 JU	INE 2009
	PERIOD 1 JULY 2008	OPTIONS GRANTED	CANCELLED/ FORFEITED	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>4</sup>	1,880,000	192,500	(716,667)	1,355,833	_	1,355,833
B Bolton 4	1,690,000	1,052,752	(1,622,752)	1,120,000	_	1,120,000
M Kepler <sup>4</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.

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

Total	190,485,779	319,991	190,805,770	108,359,696	299,164,666
S Miller	38,800	_	38,800	_	38,000
Executives					
J Brennan <sup>2</sup>	82,112,479	_	82,112,479	57,315,496	139,427,975
W Peters	7,562,309	319,991	7,882,300	6,564	7,888,864
D O'Dwyer	625,000	_	625,000	1,000,000	1,625,000
C Marsh	7,999,282	_	7,999,282	1,296,900	9,296,182
G Brooke 1	92,147,909	_	92,147,909	47,240,736	139,388,645
N Callinan	-	_	_	1,500,000	1,500,000
Directors					
	1 JULY 2008	30 JUNE 2009	30 JUNE 2009	30 JUNE 2010	30 JUNE 2010
	BALANCE	PURCHASED 1 JULY 2008 TO	BALANCE	PURCHASED/ (SOLD) 1 JULY 2009 TO	BALANCE

<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.

<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 cancelled due to expiry.

<sup>4</sup> Options forfeited due to termination of employment.

<sup>2</sup> Shares are held by Australian Executor Trustees Ltd as custodian of CM Capital Venture 4A and 4B accounts. Mr J Brennan has an indirect interest as a member and Partner of CM Capital Investments.

For the year ended 30 June 2010

#### 19. Director and Executive Disclosures continued

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

During the year ended 30 June 2010, Sunshine Heart Company Pty Limited paid \$10,875 (2009: \$10,189) 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 2010, there were no monies outstanding with Key Management Personnel (2009: \$nil).

### 20. Related Party Disclosures

#### **Ultimate parent**

Sunshine Heart, Inc. (incorporated in Delaware, USA) is the ultimate parent entity and Sunshine Heart Company Pty Ltd (incorporated in Australia) is the wholly owned subsidiary.

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.

## 21. Segment Information

The consolidated entity has only one operating segment which is the research and development of heart assist devices.

The chief operating decision maker only obtains information regarding cash flows and does not consider segment revenues, results or assets due to the entity's stage of development in its life-cycle. The focus is ensuring the group has enough funds to reach the next stage of the FDA approval ladder.

The directors believe there is sufficient disclosure in the financial statements to allow users to evaluate the nature and financial effects of the business activities in which it engages and the economic environments in which it operates.

#### Information about geographical areas

Finance revenue (bank interest) is generated by funds held in Australia. Clinical implant reimbursement is received from hospitals where implants have occurred. In the years ended 30 June 2009 and 2010 all reimbursements received or receivable have been from hospitals in the US.

#### 22. 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.

#### (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 2010 or 30 June 2009) exposed to Australian variable interest rate not designated in cash flow hedges:

	CONSOL	CONSOLIDATED		
	2010 2009			
	\$	\$		
Financial Assets				
Cash and cash equivalents	3,942,117	2,013,816		
	3,942,117	2,013,816		

The following sensitivity analysis is based on the interest rate risk exposures in existence at the Statement of Financial Position date. At 30 June 2010, 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)	
	2010	2009	2010	2009
	\$	\$	\$	\$
Consolidated				
+1% (100 basis points)	39,421	20,138	_	-
-0.5% (50 basis points)	(19,711)	(10,069)	-	_

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.

For the year ended 30 June 2010

#### 22. Financial Instruments continued

#### (b) Risk exposures and responses continued

At 30 June 2010, the group had the following exposure to US\$ foreign currency that is not designated in cash flow hedges:

	CONSOLIDATED	
	2010	2009
	\$	\$
Financial Assets		
Cash and cash equivalents	385,851	909,595
Clinical implant reimbursement receivable	183,454	134,195
Financial Liabilities		
Sundry creditors	296,303	238,782

#### Net exposure

The following sensitivity is based on the foreign currency risk exposures in existence at the Statement of Financial Position date. At 30 June 2010, 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)	
	2010	2009	2010	2009
	\$	\$	\$	\$
Consolidated				
AUS/USD +10%	27,300	80,501	-	_
AUS/USD -5%	(13,650)	(40,250)	-	_

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 consolidated entity are in accordance with the *Corporations Act* 2001, including:
  - (i) giving a true and fair view of the consolidated entity's financial position as at 30 June 2010 and of its 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; and
- (b) the financial statements and notes also comply with International Financial Reporting Standards as disclosed in note 2.
- (c) there are reasonable grounds to believe that the consolidated entity will be able to pay its debts as and when they become due and payable.
- (d) 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 2010.

On behalf of the Board

David Rosa Director

17 September 2010

# **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 2010 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
Ernst & Young

Canini Matinus

Gamini Martinus Partner 17 September 2010

## 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 statement of financial position as at 30 June 2010, and the statement of comprehensive income, statement of changes in equity and statement of cash flows 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. 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.

Liability limited by a scheme approved under Professional Standards Legislation.

## Independent Audit Report continued



#### 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 consolidated entity's financial position at 30 June 2010 and of its 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.

## Material Uncertainty Regarding Continuation as a Going Concern

Without qualifying our opinion, we draw attention to Note 2(c) "Going Concern" in the financial report which indicates there is significant uncertainty whether the consolidated entity will continue as a going concern, and therefore whether it will be able to pay its debts as and when they fall due and realise its 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 consolidated entity not continue as a going concern.

#### Report on the Remuneration Report

We have audited the Remuneration Report included in the directors' report for the year ended 30 June 2010. 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

Ernst - Young

In our opinion the Remuneration Report of Sunshine Heart, Inc. for the year ended 30 June 2010, complies with section 300A of the *Corporations Act 2001*.

Ernst & Young

Canin Matinus

Gamini Martinus Partner Sydney 17 September 2010

## **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 31 August 2010.

#### (a) Distribution of equity securities

#### (i) Ordinary share capital

539,078,350 fully paid ordinary shares are held by 1083 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

 31,757,816 unquoted options over ordinary shares are held by 36 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	20	-	_
1,001 - 5,000	99	-	1
5,001 - 10,000	133	-	_
10,001 – 100,000	563	-	16
100,001 and over	268	4	15
	1083	4	32
Holding less than a marketable parcel of shares	;		
are:	367	_	_

# ASX Additional Information continued

## (b) Substantial shareholders

	FULLY PAID	
	NUMBER	PERCENTAGE
GBS Venture Partners Limited (GBS Bioventures III A/C)	95,102,505	17.64
Australian Executor Trustees Ltd (CM Capital Venture 4A A/C)	69,713,988	12.93
Australian Executor Trustees Ltd (CM Capital Venture 4B A/C)	69,713,987	12.93
GBS Venture Partners Limited (GBS Bioventures II A/C)	44,286,140	8.22
	278,816,620	51.72

## (c) Twenty largest holders of quoted equity securities

	FULLY PAID		
	NUMBER	PERCENTAGE	
Ordinary shareholders			
GBS Venture Partners Limited (GBS Bioventures III A/C)	95,102,505	17.64	
Australian Executor Trustees Ltd (CM Capital Venture 4A A/C)	69,713,988	12.93	
Australian Executor Trustees Ltd (CM Capital Venture 4B A/C)	69,713,987	12.93	
GBS Venture Partners Limited (GBS Bioventures II A/C)	44,286,140	8.22	
J P Morgan Nominees Australia Limited	22,094,354	4.10	
Three Arch Partners III LP	15,062,652	2.79	
Phillip Asset Management Ltd (IB Aus Bioscience Fund I A/C)	12,725,400	2.36	
Asia Union Investments Pty Ltd	9,800,000	1.82	
PCLM Investments Pty Ltd	9,301,090	1.73	
David Frederick Oakley	8,000,000	1.48	
Weresyd Proprietary Limited	7,250,000	1.34	
Riverdwell Pty Ltd	7,099,349	1.32	
Apollo Trustees No.1 Limited	5,886,552	1.09	
Diamond Building Products Pty Ltd	4,830,000	0.90	
Bruce Rodney Pettit	4,415,732	0.82	
Robert William Honeywill	4,350,000	0.81	
Asia Union Investments Pty Ltd	3,200,000	0.59	
UBS Nominees Pty Ltd	3,000,000	0.56	
Hayward Australasia Pty Ltd	2,950,000	0.55	
Jason Wesley Armstrong	2,627,547	0.49	
	401,439,296	74.47	

# **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 Dave Rosa (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