



Sunshine Heart, Inc.

ABN 79 109 440 888

Half-Year report – 31 December 2010

Lodged with the ASX under Listing Rule 4.2A

This report is to be read in conjunction with the annual report for the year ended 30 June 2010 and any public announcements made by Sunshine Heart, Inc. during the interim reporting period in accordance with the continuous disclosure requirements of the *Corporations Act 2001*.

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About Sunshine Heart

Sunshine Heart Inc (ASX: SHC), a global medical device company focused on innovative technologies for the treatment of moderate heart failure, is commercializing the C-Pulse® Heart Assist System, a minimally invasive, implantable, non-blood contacting, heart assist therapy for the treatment of moderate heart failure. The C-Pulse System is designed to relieve the symptoms of heart failure through the use of counterpulsation technology which enables an increase in cardiac output, an increase in coronary blood flow and a reduction in the heart's pumping load. The Company has received approval from the US Food and Drug Administration (FDA) to conduct a 20-patient US feasibility clinical trial with the C-Pulse System and the study has achieved eighty five percent enrolment as of 31 December 2010. Sunshine Heart, Inc. is a Delaware-based Corporation headquartered in Minneapolis with a subsidiary presence in Australia.

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

Sunshine Heart, Inc.

ABN 79 109 440 888

Reporting period: Half-year ended 31 December 2010
(Previous corresponding period: Half-year ended 31 December 2009)

Results for announcement to the market

				A\$'000
Revenue from ordinary activities	Up	40%	to	281
Loss from ordinary activities after tax attributable to members	Up	51%	to	(5,037)
Loss for the half-year attributable to members	Up	51%	to	(5,037)

Dividends

It is not proposed to pay a dividend.

Other Appendix 4D information

	<u>31 December 2010</u>	<u>31 December 2009</u>
Net tangible assets per ordinary share	\$0.01	\$ 0.01

This report has been compiled using the attached 31 December 2010 half-year financial report which has been prepared in accordance with AASB 134 *Interim Financial Reporting* ('AASB 134') using Australian Equivalents to International Financial Reporting Standards (AIFRS).

Please refer to the attached Directors' Report, 'Review and Results of Operations' for further explanation of the entity's milestones achieved and financial highlights.

Sunshine Heart, Inc.

ABN 79 109 440 888

Half-Year Financial Report

for the six months ended 31 December 2010

Corporate Information

ABN 79 109 440 888

Directors

Mr Nicholas Callinan (Non-executive Chairman)
Mr David Rosa (Chief Executive Officer)
Mr John Brennan
Dr Geoff Brooke
Mr Crispin Marsh
Mr Donal O'Dwyer
Dr William Peters

Company Secretary

Mrs Rowena Hubble

Principal Place of Business and Registered Office in Australia

Unit 3, 12 Frederick Street
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Australian Solicitors

Henry Davis York
44 Martin Place
Sydney NSW 2000

Bankers

National Australia Bank Limited

Share Registry

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

Auditors

Ernst & Young
680 George Street
Sydney NSW 2000

Internet Address

www.sunshineheart.com

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Directors' Report

Your directors submit their report for the half year ended 31 December 2010.

DIRECTORS

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

Mr Nicholas Callinan	(Non-executive Chairman)
Mr David Rosa	(Chief Executive Officer)
Mr John Brennan	
Dr Geoff Brooke	
Mr Crispin Marsh	
Mr Donal O'Dwyer	
Dr William Peters	

REVIEW AND RESULTS OF OPERATIONS

The Company's business is the commercialising of its proprietary C-Pulse® device which is an implantable, non-blood contacting, heart assist therapy for the treatment of people with Class III and ambulatory class IV heart failure. In this condition, patients suffer a significant negative impact on the quality of their life due to the heart losing its ability to pump blood efficiently around the body. The American Heart Association Heart Disease and Stroke Statistics in its 2010 update forecast estimates that \$39.2 billion will be spent treating patients for heart failure patients in the US alone. The November 2010 HRI US Heart Failure Technologies Report estimates approximately 1.5 million Class III patients which represents around 25% of the total sufferers and they presently are mainly treated with medications. For Class IV, the most severe category, which is about one-seventh the size of Class III, treatment becomes critical and is either by the installation of a ventricular assist device (VAD) or a heart transplant, and, increasingly by a VAD than a transplant as the number of available hearts for transplant in the U.S. has been relatively flat for years at less than 3,000.

C-Pulse is designed to improve the Class III patient's condition or, at worst to prevent its deterioration into Class IV. It does this through its use of extra-aortic counterpulsation technology which increases the cardiac output, increases coronary blood flow and reduces the heart's pumping workload and pulmonary capillary wedge pressure.

Clinical Trial

The Company has to date implanted 18 patients with the C-Pulse device as part of its 20 patient FDA IDE feasibility trial. Each patient's performance with the implanted C-Pulse will be closely monitored during a six-month follow-up period as required by the FDA. While we cannot disclose interim data or guarantee outcomes at this stage, the trial is progressing as anticipated.

The Company has commenced preparations to conduct a larger randomized pivotal trial. Once this is complete FDA approval will be sought to market C-Pulse in the US.

CE Mark Approval

In parallel with obtaining the FDA approvals for the US, the Company will apply for CE Mark approval in 2011. Plans are being developed for sales outside the US on a controlled basis.

Directors' Report

Reimbursement

The FDA has already approved a Category B Reimbursement for the C-Pulse device during the feasibility clinical trial. This means that the cost of the C-Pulse system as well as hospital costs were eligible for US Medicare reimbursement. Many US private pay insurance companies follow the FA Reimbursement for devices in a clinical trial, but not all do so a small number of the trial devices were not reimbursed. The Company will seek to carry this designation over to the pivotal trial.

Physician Advisory Board

The Company has secured the commitment from five well respected and recognized heart failure physician experts to assist with the development of the pivotal trial. All have a great deal of experience either participating, developing or serving as principal investigators of heart failure trial for class II – IV heart failure. They are Dr. William Abraham of the Ohio State University School of Medicine, Dr. Leslie Miller of the University of Tampa, Florida, Dr. Mark Slaughter of Jewish Hospital in Louisville, Kentucky, Dr. Leslie Saxon of the University of Southern California and Dr. Mark Acker of the University of Pennsylvania School of Medicine. Also participating is InChoir, an organization of physicians that have a great deal of experience developing heart failure trials including the first approved VAD trial in the United States.

New Technology Development

Based on physician and patient feedback from the feasibility trial, the Company is making a number of improvements or upgrades to the existing C-Pulse System. One current project involves the integration of the battery pack and driver into a single unit system that weighs less than the existing driver, features sound reduction and also incorporates ergonomic improvements designed to make device transport more convenient and comfortable for the patient. A second project is to incorporate cuff changes to reduce the time required and make it easier to perform the procedure minimally invasive. This will reduce or even eliminate the need for full open chest surgery. Patients obviously prefer minimally invasive procedures and this development should help patient enrolment rates and medical profession acceptance, not to mention reduce hospitalization stays, patient recovery and infection rates. Looking to the latter part of 2011, work continues on a second generation system which will be fully implanted and have no percutaneous line, further improving patient convenience and potentially improving device efficiency and performance. The Company is targeting feasibility in animals by the end of 2011.

Funding

To fund all this continuing development, the Company will need to raise additional capital. It intends to do this as soon after the release of the feasibility trial results.

Financial Results

Net Loss from ordinary activities for the six months ended 31 December 2010 was up by 51% over the previous comparable period to \$5,037,019 primarily due to the increased research and development and clinical trial activity. Cash on hand at 31 December 2010 was \$12,056,046 (30 June 2010: \$3,942,117).

Directors' Report

Auditor Independence

We have obtained the independence declaration from our auditors, Ernst & Young, a copy of which is included in the half year financial report.

Signed in accordance with a resolution of the directors



Nicholas Callinan
Chairman

24 January 2011

Statement of Comprehensive Income

FOR THE HALF-YEAR ENDED 31 DECEMBER 2010	Notes	CONSOLIDATED	
		31 December 2010 \$	31 December 2009 \$
Continuing Operations			
Revenues and other income	3	281,060	201,072
Depreciation and amortisation expenses	3	(23,194)	(31,510)
Insurance		(95,305)	(76,123)
Listing and registry fees		(56,323)	(58,115)
Office rent	3	(138,166)	(93,024)
Professional fees		(219,777)	(48,081)
Salaries, consultants and employee benefits	3	(1,305,186)	(918,564)
Research and development	3	(2,341,163)	(1,497,020)
Travel		(343,631)	(292,063)
Patents		(81,850)	(63,424)
Other expenses		(713,484)	(466,963)
Loss from continuing operations before income tax		(5,037,019)	(3,343,815)
Income tax expense		-	-
Loss from continuing operations after income tax		(5,037,019)	(3,343,815)
Other comprehensive income		-	-
Other comprehensive income after income tax		-	-
Total comprehensive loss for the half year attributable to members of Sunshine Heart, Inc.		(5,037,019)	(3,343,815)
Basic loss per share (cents per share) for the period, attributable to ordinary equity members of Sunshine Heart, Inc.		(0.8)	(0.6)
Diluted loss per share (cents per share) for the period, attributable to ordinary equity members of Sunshine Heart, Inc.		(0.8)	(0.6)

Statement of Financial Position

AS AT 31 DECEMBER 2010	Notes	CONSOLIDATED	
		As at 31 December 2010 \$	As at 30 June 2010 \$
ASSETS			
Current Assets			
Cash and cash equivalents		12,056,046	3,942,117
Trade and other receivables		200,561	249,497
Tax rebate		8,198	785,378
Other current assets		142,234	154,646
Total Current Assets		12,407,039	5,131,638
Non-Current Assets			
Property, plant and equipment		118,119	133,858
Total Non-Current Assets		118,119	133,858
Total Assets		12,525,158	5,265,496
LIABILITIES			
Current Liabilities			
Trade and other payables		657,942	455,852
Provisions		89,790	82,501
Total Current Liabilities		747,732	538,353
Total Liabilities		747,732	538,353
Net Assets		11,777,426	4,727,143
EQUITY			
Equity attributable to equity holders of the parent			
Contributed equity	5	69,589,184	57,539,953
Accumulated losses		(59,602,185)	(54,565,166)
Reserves		1,790,427	1,752,356
Total Equity		11,777,426	4,727,143

Statement of Changes in Equity

FOR THE HALF-YEAR ENDED 31 DECEMBER 2010

CONSOLIDATED

	<i>Contributed equity</i>	<i>Employee equity benefits reserve</i>	<i>Accumulated losses</i>	<i>Total</i>
At 1 July 2010	57,539,953	1,752,356	(54,565,166)	4,727,143
Loss from continuing operations	-	-	(5,037,019)	(5,037,019)
Other comprehensive income	-	-	-	-
Total comprehensive loss for the period	-	-	(5,037,019)	(5,037,019)
Shares and options issued	13,311,490	-	-	13,311,490
Transaction costs on placement and rights issue	(1,262,259)	-	-	(1,262,259)
Share-based payment	-	38,071	-	38,071
Balance at 31 December 2010	69,589,184	1,790,427	(59,602,185)	11,777,426
At 1 July 2009	48,293,638	1,767,658	(48,032,446)	2,028,850
Loss from continuing operations	-	-	(3,343,815)	(3,343,815)
Other comprehensive income	-	-	-	-
Total comprehensive loss for the period	-	-	(3,343,815)	(3,343,815)
Shares and options issued	9,844,219	-	-	9,844,219
Transaction costs on placement and rights issue	(580,380)	-	-	(580,380)
Share-based payment	-	(28,805)	-	(28,805)
Balance at 31 December 2009	57,557,477	1,738,853	(51,376,261)	7,920,069

Statement of Cash Flows

FOR THE HALF-YEAR ENDED 31 DECEMBER 2010

CONSOLIDATED
31 December **31 December**
2010 **2009**
\$ **\$**

Cash flows from operating activities		
Payments to suppliers and employees	(5,004,312)	(3,521,941)
Clinical implant reimbursement	344,232	134,195
Interest received	75,069	62,275
Tax rebate	777,180	-
Net cash flows used in operating activities	(3,807,831)	(3,325,471)
Cash flows from investing activities		
Purchase of property, plant and equipment	(7,454)	(5,115)
Net cash flows used in investing activities	(7,454)	(5,115)
Cash flows from financing activities		
Proceeds from issues of ordinary shares	13,264,023	9,844,219
Transaction costs on rights issue and placement	(970,455)	(580,380)
Net cash flows from financing activities	12,293,568	9,263,839
Net increase in cash and cash equivalents	8,478,283	5,933,253
Net foreign exchange differences	(364,354)	(168,851)
Cash and cash equivalents at beginning of period	3,942,117	2,013,816
Cash and cash equivalents at end of the period	12,056,046	7,778,218

Notes to the Financial Statements (Cont'd)

HALF-YEAR ENDED 31 DECEMBER 2010

1. Corporate Information

The financial report of Sunshine Heart, Inc. for the half-year ended 31 December 2010 was authorised for issuance in accordance with a resolution of the directors on 21 January 2010. Sunshine Heart, Inc. is a Delaware corporation incorporated and domiciled in the United States and is limited by shares, which are publicly traded as Chess Depository Instruments on the Australian Stock Exchange. During the year Sunshine Heart, Inc. continued to progress the development of the C-Pulse heart assist device through its operations headquartered in Sydney Australia and in the US and New Zealand.

2. Summary of Significant Accounting Policies

The half-year financial report does not include all notes of the type normally included within the annual financial report and therefore cannot be expected to provide as full an understanding of the financial performance, financial position and financing and investing activities of the consolidated entity as the full financial report.

The half-year financial report should be read in conjunction with the annual Financial Report of Sunshine Heart, Inc. as at 30 June 2010.

It is also recommended that the half-year financial report be considered together with any public announcements made by Sunshine Heart, Inc. and its controlled entity during the half-year ended 31 December 2010 in accordance with the continuous disclosure obligations of the ASX listing rules.

(a) Basis of preparation

The half-year consolidated financial report is a general-purpose financial report, which has been prepared in accordance with the requirements of the *Corporations Act 2001*, IAS34 *Interim Financial Reporting*, AASB 134 *Interim Financial Reporting* and other mandatory professional reporting requirements.

The half-year financial report is presented in Australian dollars and has been prepared on an historical cost basis.

For the purpose of preparing the half-year financial report, the half-year has been treated as a discrete reporting period.

(b) Significant accounting policies

The half-year consolidated financial statements have been prepared using the same accounting policies as used in the annual financial statements for the year ended 30 June 2010, except for the adoption of amending mandatory standards for annual reporting periods beginning on or after 1 July 2010, as described in Note 2(d).

(c) Basis of consolidation

The half-year consolidated financial statements comprise the financial statements of Sunshine Heart, Inc. and its Australian subsidiary as at 31 December 2010 ('the Entity', 'the Group' or 'Sunshine Heart').

Notes to the Financial Statements (Cont'd)

HALF-YEAR ENDED 31 DECEMBER 2010

2. Summary of Significant Accounting Policies (continued)

d) Changes in accounting policies

The accounting policies adopted are consistent with those of the previous financial year except as follows:

The Group has adopted the following new and amended Australian Accounting Standards and AASB Interpretations as of 1 January 2010:

- ▶ AASB 2009-8 Amendments to Australian Accounting Standards — Group Cash-settled Share-based Payment Transactions [AASB 2] effective 1 January 2010
- ▶ AASB 2009-5 Further Amendments to Australian Accounting Standards arising from the Annual Improvements Project [AASB 5, 8, 101, 107, 117, 118, 136 & 139] effective 1 January 2010
- ▶ AASB 127 Consolidated and Separate Financial Statements (revised 2008) effective 1 July 2009
- ▶ AASB 2009-4 Amendments to Australian Accounting Standards arising from the Annual Improvements Project effective 1 July 2009
- ▶ AASB 2008-6 Further Amendments to Australian Accounting Standards arising from the Annual Improvements Project [AASB 1 & AASB 5] effective 1 July 2009
- ▶ AASB 2008-3 Amendments to Australian Accounting Standards arising from AASB 3 and AASB 127 effective 1 July 2009

The adoption of these standards had no effect on the financial position or performance of the Group.

Certain Australian Accounting Standards have recently been issued or amended but not yet effective and have not been adopted by the group for the interim reporting period. The directors have not yet assessed the impact of these new or amended standards (to the extent relevant to the group) and interpretations.

(e) Going Concern

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

During the half-year ended 31 December 2010 and 31 December 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 cashflows, respectively.

Notes to the Financial Statements (Cont'd)

HALF-YEAR ENDED 31 DECEMBER 2010

2. Summary of Significant Accounting Policies (continued)

(e) Going Concern (continued)

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. The Directors, after due consideration, believe that the Group will be able to raise new equity capital to fund its business plan. Should future capital raisings 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.

	Notes	CONSOLIDATED	
		31 December 2010	31 December 2009
		\$	\$
3. Revenues and Expenses			
(a) Revenue and other income			
Finance revenue – bank interest		63,566	71,576
Clinical implant reimbursement		217,494	129,496
		281,060	201,072
(b) Depreciation and amortisation			
Depreciation – plant and equipment		16,287	23,975
Amortisation – leasehold improvements		6,907	7,535
		23,194	31,510
(c) Office rent			
Minimum sub-lease payments		138,166	93,024
(d) Salaries, consultants and employee benefits			
Share based payments		37,160	(28,805)
Employee provision		7,288	(7,255)
Salaries and consultants		1,260,738	954,624
		1,305,186	918,564
(e) Research and development expenses			
		2,341,163	1,497,020
(f) Foreign exchange differences			
Net foreign currency loss		363,491	168,851

Notes to the Financial Statements (Cont'd)

HALF-YEAR ENDED 31 DECEMBER 2010

4. Share-based Payment Plans

During the half-year ended 31 December 2010 the following options were granted:

To Employees:

No. options:	10,000,000
Grant Date:	29 November 2010
Vesting commencement date:	29 November 2010
Expiry date:	31 October 2019
Exercise price:	\$0.05

Fair values 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 for the half-year ended 31 December 2010:

Risk-free interest rate	4.97%
Dividend Yield	0%
Expected Volatility	65%
Expected life of options	5 years

To the Placement Agent:

No. options:	4,699,418
Grant Date:	15 November 2010
Expiry date:	15 November 2015
Exercise price:	\$0.028

Fair values 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 for the half-year ended 31 December 2010:

Risk-free interest rate	5.15%
Dividend Yield	0%
Expected Volatility	65%
Expected life of options	2 years

Attached to these options is a requirement to lodge a Form 10-12G registering the share of the Company's common stock with the SEC and file an application to list on a US Stock exchange by 30 September 2011. In the event the Company does not satisfy these requirements, the number of options issued in this placement will increase by 10%.

Notes to the Financial Statements (Cont'd)

HALF-YEAR ENDED 31 DECEMBER 2010

	Notes	CONSOLIDATED	
		31 December 2010 \$	30 June 2010 \$
5. Contributed Equity			
(a) Issued and paid up capital			
Shares, fully paid		68,209,984	56,160,753
Warrants		1,379,200	1,379,200
		<u>69,589,184</u>	<u>57,539,953</u>
(b) Movements in shares on issue			
		Number of shares	\$
Ordinary Shares, fully paid			
Beginning of the half-year		539,078,350	56,160,753
Issued on 15 November, 2010 – placement		133,420,518	3,735,774
Issued on 8 December, 2010 – rights issue		340,294,600	9,528,249
Transaction costs on rights issue and placement		-	(1,214,792)
		<u>1,012,793,468</u>	<u>68,209,984</u>
Warrants			
Beginning of the half-year		800	1,379,200
End of the half-year		<u>800</u>	<u>1,379,200</u>

Placement options

Sunshine Heart, Inc issued 66,710,259 options over ordinary shares with an issue term of 4 years as part of the placement. These options were issued on 13 November 2010 and had an exercise price of \$0.032.

Fair values 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 for the half-year ended 31 December 2010:

Risk-free interest rate	5.15%
Dividend Yield	0%
Expected Volatility	65%
Expected life of options	2 years

Notes to the Financial Statements (Cont'd)

HALF-YEAR ENDED 31 DECEMBER 2010

5. Contributed equity (continued)

Attached to these options is a requirement to lodge a Form 10-12G registering the share of the Company's common stock with the SEC and file an application to list on a US Stock exchange by 30 September 2011. In the event the Company does not satisfy these requirements, the number of options issued in this placement will increase by 10%.

Rights Issue options

As part of the rights issue Sunshine Heart, Inc issued 170,147,300 options over ordinary shares with an issue term of 4 years. These options were issued on 8 December 2010 and had an exercise price of \$0.032.

Fair values 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 for the half-year ended 31 December 2010:

Risk-free interest rate	5.15%
Dividend Yield	0%
Expected Volatility	65%
Expected life of options	2 years

6. Contingent Liabilities

Commercial Ready Grants

On 21 September 2006, the Group received approval of a second Commercial Ready Grant from the Australian Government through AusIndustry. This grant contributed fifty cents for each dollar spent on eligible project expenditure, to a maximum funding of \$2.157m.

Under the terms of the agreement, the Government may require the Group to repay all or some of the amount, including interest, in any of the following circumstances:

- (a) The entity 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.

The entity continues the development and commercialisation of all projects funded by the Commercial Ready program. The total amount received under the Commercial Ready Program as at 31 December 2010 was \$2.157m (30 June 2010: \$2.157m).

7. Events after the Balance Sheet Date

The Directors are unaware of any event or transaction that has occurred between 31 December 2010 and the date of this report that may have a significant effect on the Group.

Notes to the Financial Statements (Cont'd)

HALF-YEAR ENDED 31 DECEMBER 2010

8. Segment Information

The consolidated entity operates in one segment which is the research and development of heart assist devices.

The focus of the chief operating decision maker is cash-flow 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.

The accounting policies used by the Group in reporting segment information are the same as those contained in note two to the accounts and in the prior period.

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) give a true and fair view of the financial position as at 31 December 2010 and of the performance for the half-year ended on that date of the consolidated entity; and
 - (ii) complying with Accounting Standard AASB 134 *Interim Financial Reporting* and Corporations Regulations 2001; and
- (b) there are reasonable grounds to believe that the entity will be able to pay its debts as and when they become due and payable.

On behalf of the Board

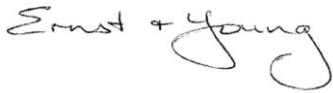


Nicholas Callinan
Chairman

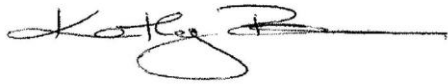
24 January 2011

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

In relation to our review of the financial report of Sunshine Heart, Inc. for the half-year ended 31 December 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.

A handwritten signature in cursive script that reads 'Ernst + Young'.

Ernst & Young

A handwritten signature in cursive script that reads 'Kathy Parsons'.

Kathy Parsons
Partner
24 January 2010

Independent Auditor's Review to members of Sunshine Heart, Inc.

Report on the Half-Year Financial Report

We have reviewed the accompanying half-year financial report of Sunshine Heart, Inc., which comprises the statement of financial position as at 31 December 2010, the statement of comprehensive income, statement of changes in equity and statement of cash flows for the half-year ended on that date, notes comprising a summary of significant accounting policies and other explanatory information, and the directors' declaration of the consolidated entity comprising the company and the entities it controlled at the half-year end or from time to time during the half-year.

Directors' Responsibility for the Half-Year Financial Report

The directors of the company are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal controls as the directors determine are necessary to enable the preparation of the half-year financial report that is free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express a conclusion on the half-year financial report based on our review. We conducted our review in accordance with Auditing Standard on Review Engagements ASRE 2410 *Review of Interim and Other Financial Reports Performed by the Independent Auditor of the Entity*, in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the financial report is not in accordance with the *Corporations Act 2001* including: giving a true and fair view of the consolidated entity's financial position as at 31 December 2010 and its performance for the half-year ended on that date; and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*. As the auditor of Sunshine Heart, Inc. and the entities it controlled during the half year, ASRE 2410 requires that we comply with the ethical requirements relevant to the audit of the annual financial report.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Independence

In conducting our review, we have complied with the independence requirements of the *Corporations Act 2001*. We have given to the directors of the company a written Auditor's Independence Declaration.

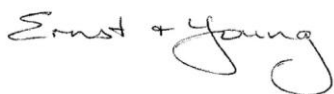
Conclusion

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the half-year financial report of Sunshine Heart, Inc. is not in accordance with the *Corporations Act 2001*, including:


- a) giving a true and fair view of the consolidated entity's financial position as at 31 December 2010 and of its performance for the half-year ended on that date; and
- b) complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

Inherent Uncertainty Regarding Continuation as a Going Concern

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

A handwritten signature in cursive script that reads 'Ernst & Young'.

Ernst & Young

A handwritten signature in cursive script that reads 'Kathy Parsons'.

Kathy Parsons
Partner
Sydney
24 January 2011

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 December 2010.

(a) Distribution of equity securities

(i) Ordinary share capital

- 1,012,793,468 fully paid ordinary shares are held by 1,122 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

- 266,896,966 unquoted options over ordinary shares are held by 267 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	27	-	2
1,001 – 5,000	95	-	42
5,001 – 10,000	117	-	24
10,001 – 100,000	560	-	104
100,001 and over	323	4	95
	1,122	4	267
Holding less than a marketable parcel of shares are:	288	-	-

Additional information

(b) Substantial shareholders

Ordinary shareholders	Fully paid	
	Number	Percentage
GBS Venture Partners Limited (GBS Bioventures III A/C)	163,032,866	16.10
Australian Executor Trustees Ltd (CM Capital Venture 4A A/C)	137,571,131	13.58
Australian Executor Trustees Ltd (CM Capital Venture 4B A/C)	137,571,129	13.58
GBS Venture Partners Ltd ATF of the GBS Bioventures II	75,919,098	7.50
Straus Healthcare Partners LP	38,120,448	3.76
Straus Partners LP	38,120,448	3.76

(c) Twenty largest holders of quoted equity securities

Ordinary shareholders	Fully paid	
	Number	Percentage
GBS Venture Partners Limited (GBS Bioventures III A/C)	163,032,866	16.10
Australian Executor Trustees Ltd (CM Capital Venture 4A A/C)	137,571,131	13.58
Australian Executor Trustees Ltd (CM Capital Venture 4B A/C)	137,571,129	13.58
GBS Venture Partners Ltd ATF of the GBS Bioventures II	75,919,098	7.50
Straus Healthcare Partners LP	38,120,448	3.76
Straus Partners LP	38,120,448	3.76
JP Morgan Nominees Australia Limited	31,636,488	3.12
RRC Bio Fund LP	26,684,314	2.63
Asia Union Investments Pty Ltd	18,800,000	1.86
Dafna Lifescience Select Ltd	16,581,786	1.64
Merrill Lynch (Australia) Nominees Pty Ltd	16,172,468	1.60
Mr David Frederick Oakley	13,100,000	1.29
PCLM Investments Pty Ltd	12,872,518	1.27
Phillip Asset Management Ltd (IB Aus Bioscience Fund I)	11,143,503	1.10
Mr Bruce Rodney Pettit	8,228,572	0.81
Riverdwell Pty Ltd	8,054,062	0.80
Dafna Lifescience Ltd	7,147,321	0.71
Maryfair Pty Ltd	6,810,586	0.67
Dr William Peters & Apollo Trustees No 1 Limited	6,686,552	0.66
Asia Union Investments Pty Ltd	6,200,000	0.61
	780,453,290	77.05