



Risk Management Statement

1. Board Responsibility

The Sunshine Heart Board is responsible for establishing policies on risk oversight and management. The Audit, Compliance and Corporate Governance (Audit) Committee is responsible for monitoring the development and annual review of the Company's risk profile and system of risk management. The Audit Committee is to make recommendations to the Board in relation to the Company's risk profile and system of risk management.

2. Senior Executive Responsibility

The Chief Executive Officer is responsible for profiling the Company's risks and ensuring appropriate risk management procedures are in place and operating effectively. Within this policy framework, areas of risk are monitored as a part of the regular reporting to the Board, in the context of longer term plans and objectives adopted by the Board.

3. Risk Profile and Management

3.1 Funding/Going Concern Risk:

Sunshine Heart has received approval from the US Food and Drug Administration (FDA) to conduct a clinical trial of its heart assist therapy in the USA. Clinical trials of the therapy have previously occurred in Australia and New Zealand. The significant cost of the ongoing product development efforts is greater than the revenues anticipated from the early stage commercial activities of the Company. The Company is therefore not cash flow positive at this phase of its development.

The Board seeks to ensure adequate funding of the Company at any time. More funding will be required to complete the remaining clinical and regulatory programs necessary for product marketing approval.

The Company's listing on the Australian Securities Exchange provides access to a wide range of potential shareholders. The willingness of existing and/or new shareholders to participate in future capital raisings will be dependent upon, amongst other factors:

- the perceived opportunities of the Company, its products and the markets its products address; and
- Management's track record in achieving product development milestones.

The funding/going concern risk is managed by:

- Shareholder/investor communications. The Board has developed a Continuous Disclosure and Shareholder Communication Policy with the objective of keeping the market well informed of the Company's opportunities and progress. Quarterly reports to shareholders, in addition to mandated ASX/ASIC reporting are released to the market. These general distributions are supplemented by regular meetings with investors and analysts (copies of presentation material are posted to the Company's website);
- Continually monitoring the market opportunities for the Company's products – new technologies available to the Company, advances in competitive technologies, changes in market dynamics or government funding of medical devices. Information gained from

such monitoring is used to update internal financial forecasts, shareholder presentations, funding priorities etc, all of which are reported to the Board;

- Monitoring technical progress on key targets/value points. Achieving successful outcomes from research, pre-clinical, and/or clinical trials increases the value of the Company's technology. Board reports include updates of progress on the Company's next generation product;
- Preparation of an annual budget and updated business plan for review and approval by the Board, in the context of long terms plans and objectives adopted by the Board;
- Regular updating of forecast costs to achieve milestones. Updated cash forecasts are provided to the Board on a regular basis; and
- Building a quality, experienced team. Sunshine Heart recruits people at all levels of the organisation with significant experience in their areas of responsibility.

3.2 Preclinical and Clinical Risk

Approval of a therapeutic product by a regulatory agency requires the submission of an extensive dossier of clinical, preclinical (safety), manufacturing and quality management. The results of the supporting clinical trials are expensive and may take several years to complete. In designing clinical trials and preclinical studies it is therefore important to ensure that the endpoints of the trials/studies will be acceptable to the regulatory agencies in all of the countries where registration will be sought; that the trials/studies will support the desired label claim of the product, and that the trial/study end points are achievable in an acceptable timeframe and at an acceptable cost.

Successful execution of clinical trials and preclinical studies requires negotiation of contracts with acceptable timetables, costs and risks with the various investigators, institutions and clinical research service providers necessary to conduct a clinical program; and constant monitoring of contract performance over the course of the trial/study.

The clinical/preclinical program risk is managed by:

- Sunshine Heart staff having the experience and capability to design and manage its clinical and preclinical program. Regular internal cross functional meetings review both trial/study design and ongoing performance;
- Finalising clinical and preclinical study designs in collaboration with investigators, regulators and experienced consultants; and
- Negotiating contractual arrangements with outside parties around a standard set of agreements. Payments to outside parties are, wherever possible, tied to contractual performance.

3.3 Research Risk

Risk is inherent in the research and development process. Sunshine Heart manages the risks associated with its research and product development activities by:

- Utilising the processes and methods during the product development lifecycle that are described in the international standard ISO14971 Medical Devices Risk Management; These include methods, such as, Failure Mode Effects Analysis, Fault Tree analysis, and Harms and Hazards analysis;
- Regular reports to the Board on research and development activities including any revisions to timelines or forecast expenditure;
- Periodic evaluation of proposed research projects against expected business returns; and

- Review of research projects by the Medical Advisory Board and independent consultants.

3.4 Operational Risk

Sunshine Heart's operational risk centres on its facilities and its contract manufacturing centres, and includes compliance with regulatory operating requirements and maintaining availability of sufficient product to meet demand. This risk is managed by:

- The Chief Executive Officer monitoring occupational health and safety matters as well as ensuring adequate product supply at the St Leonards office and reporting regularly to the executive staff and Board; and
- The Chief Executive Officer regularly monitors all contract manufacturers assuring compliance to the terms of each contract and regularly provides reports to the executive staff and Board.

3.5 Sales and Marketing Risk

The Company has not yet received approval to market its C-Pulse therapy. Preparatory to approval to market the Company is undertaking the following:

- Having an appropriately experienced management team;
- Identifying potential marketing partners;
- Leveraging its good relationships with influential key cardiologists and heart surgeons throughout the world; and
- Assuring that clinical studies provide sufficient data to gain reimbursement approval in all the intended markets.

3.6 Financial Risk

Financial risk includes:

- Safeguarding of the Company's physical assets. With the Company's physical assets all located at one of two locations and given the small number of employees, management is currently able to effectively safeguard the physical assets with minimum procedures. The Company maintains an appropriate level of insurance covering physical loss of assets;
- Safeguarding against fraud. Risks in this area are managed by an appropriate expenditure approval policy delegating spending within budget and up to set limits to various levels of management supported by a robust financial control system. The Board also receives regular reporting of financial performance against a Board approved budget; cash usage; and cash investments;
- Credit risk. The Company receives grant income from the Australian government. The other material source of revenue is interest on invested cash funds. The credit risk on both the interest and the underlying funds is managed in accordance with a Board approved policy that limits the approved investment instruments to bank deposits commercial bills, limits the term of the investment period, specifies the acceptable counterparty banks and requires monthly reporting of investment details to the Board;
- Foreign exchange risk. The Company contracts with a number of international organisations and institutions to provide a range of pre-clinical support services or clinical trial management. In most cases these organisations require payment in their local currency. Sunshine Heart does not seek to hedge the long term purchasing power of its Australian dollar funds which it uses to pay for this clinical research. However the

Company does seek to limit its exposure to amounts due under contracts by paying non Australian dollar liabilities as soon as possible after receipt of an invoice; and

- The Company has a financial and management system that provides comprehensive management and oversight of the Company's financial and IT risks.

3.7 Human Resources Risk

- The growth of Sunshine Heart depends on its ability to recruit and retain employees with relevant expertise and experience throughout all levels of the Company. High calibre employees are attracted to the Company by a number of factors including working environment, career opportunities, individual contribution to growth, responsibility and remuneration; and
- The Company has a formal annual employee performance appraisal policy which is linked to employee share option incentives, and to the payment of performance linked bonuses.

3.8 Intellectual Property Risk

Sunshine Heart must appropriately protect and safeguard the intellectual property that underpins the future growth and success of the Company. The Company therefore:

- Maintains appropriate records of its research and development activities;
- Patents innovations it considers have possible commercial value;
- Engages appropriately qualified and experienced patent attorneys;
- Requires all employees to sign confidentiality and intellectual property ownership agreements as a condition of employment;
- Establishes confidentiality agreements with outside parties before discussing any matters of a confidential nature; and
- Monitors developments in competing technologies that seek to address the same or similar clinical end points through different means.

3.9 Public Liability Risk

Sunshine Heart is exposed to certain risks associated with the conduct of its clinical trials. This risk is managed by:

- Employing appropriately qualified and experienced staff. Sunshine Heart's clinical trial staff are led by its Medical Director, a qualified medical practitioner with over 15 years' clinical trial experience;
- Designing its clinical trials to comply with Good Clinical Practice, which incorporates review and approval of clinical trial protocols by the independent investigators as well as the ethics committees of each site where clinical trials are conducted;
- Obtaining an appropriate level of clinical trial insurance from an underwriter of good financial standing;
- Assuring that the trials are approved by the appropriate regulatory agencies and the appropriate ethics committees at the investigational clinical sites;
- Assuring that enrolled patients are properly informed on the benefits and risks associated with the trial and that an informed consent is achieved from the patient; and
- Seeking expert advice on clinical trial designs prior to initiating the trial.

Sunshine Heart is also exposed to certain risks associated with the manufacture of its products for both clinical trials and for commercial sale. This risk is managed by:

- Employing appropriately qualified and experienced staff. Sunshine Heart manufacturing staff experienced in the active implantable medical device industry and a Quality Assurance Manager experienced in medical devices;
- Utilizing a Quality Management System that encompass the entire design, testing, production and clinical process and that meets the appropriate international standards for active implantable medical devices;
- Obtaining an appropriate level of liability insurance from an underwriter of good financial standing; and
- Engaging external consultants to provide expert industry advice on systems and controls processes.

3.10 Other

- Continuous Disclosure. As a listed public company Sunshine Heart has externally imposed disclosure requirements by the ASX and its own internal standards of shareholder communications. The Continuous Disclosure and Shareholder Communication Policy sets out the Company's approach to management in this area; and
- Insider Trading. The Share Trading Policy sets out the Company's approach to management in this area.

4. Effectiveness of risk management

This Sunshine Heart risk management statement is annually updated by management and reviewed by the Audit Committee. The Chief Executive Officer and Chief Financial Officer must annually attest to the effective operation of the Company's system of risk management.

Adopted 20 July 2004

Last reviewed 22 December 2010