UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended: December 31, 2011

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Transition Period from to

Commission file number 001-35312

Sunshine Heart, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**68-0533453**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

12988 Valley View Road, MN 55344
(Address of Principal Executive Offices, Including Zip Code)

(952) 345-4200
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Common stock, par value $0.0001 per share	**The Nasdaq Stock Market LLC (Nasdaq Capital Market)**
(Title of each class)	(Name of each exchange on which registered)

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes o No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes o No x

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer o	Accelerated Filer o
Non-Accelerated Filer o (Do not check if a smaller reporting company)	Smaller Reporting Company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

As of December 31, 2011, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of shares of the registrant's common stock held by non-affiliates of the registrant (based upon the closing sale price of $0.036 per CHESS Depositary Interest on the Australian Securities Exchange on December 30, 2011 (using an exchange rate of 1 Australian Dollar to 1.0174 U.S. Dollars) was approximately $23.3 million.

The number of shares of the registrant's common stock, par value $0.0001 per share, outstanding as of March 16, 2012 was 6,276,538 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company's definitive Proxy Statement for the Annual Meeting of Stockholders to be held on May 23, 2012 (the "2012 Proxy Statement"), which is expected to be filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, are incorporated by reference in Part III of this Annual Report on Form 10-K.

ANNUAL REPORT ON FORM 10-K
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SPECIAL NOTE REGARDING FORWARD-LOOKING INFORMATION

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements relate to us, our business prospects and our results of operations and are subject to certain risks and uncertainties posed by many factors and events that could cause our actual business, prospects and results of operations to differ materially from those anticipated by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those described under the heading *"Risk Factors"* included in this Annual Report on Form 10-K. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. We undertake no obligation to revise any forward-looking statements in order to reflect events or circumstances that might subsequently arise. Readers are urged to carefully review and consider the various disclosures made by us in this report and in our other reports filed with the Securities and Exchange Commission ("SEC") that advise interested parties of the risks and factors that may affect our business.

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PART I

Item 1. Business

Overview

We are an early-stage medical device company focused on developing, manufacturing and commercializing our C-Pulse Heart Assist System for treatment of Class III and ambulatory Class IV heart failure. The C-Pulse Heart Assist System utilizes the scientific principles of intra-aortic balloon counter-pulsation applied in an extra-aortic approach to assist the left ventricle by reducing the workload required to pump blood throughout the body, while increasing blood flow to the coronary arteries.

We are in the process of obtaining regulatory approvals necessary to sell our product. We completed enrollment of the feasibility phase of our clinical trial in the first half of 2011. In November 2011, we obtained the results of the six-month follow-up period for the feasibility phase and we submitted the clinical data to the United States Food and Drug Administration, or FDA. In March 2012, the FDA notified us that it completed its review of the C-Pulse feasibility trial data, concluded we met the applicable agency requirements and indicated that we can move forward with an IDE application. We expect to submit an investigational device exemption, or IDE, application to the FDA in the first half of 2012 for approval to initiate our pivotal trial. We expect to complete our pivotal trial in 2015 and do not anticipate marketing our product in the U.S. before 2016.

We are seeking CE Mark for the C-Pulse and anticipate that we will obtain approval in the middle of 2012. We have taken initial steps to evaluate the market potential for our product in targeted countries that accept the CE Mark in anticipation of commencing commercial sales of the C-Pulse in Europe following CE Mark approval.

We incurred net losses of $16.2 million and $7.6 million in the years ended December 31, 2011 and 2010, respectively. All of our revenue for the years ended December 31, 2011 and 2010 was derived solely from sales of the C-Pulse System to hospitals and clinics under contract in conjunction with our feasibility clinical trial. We expect to continue to incur net losses as we continue to conduct clinical trials.

Our Industry

Heart failure is a progressive disease caused by impairment in the heart's ability to pump blood to the various organs of the body. Patients with heart failure commonly experience shortness of breath, fatigue, difficulty exercising and swelling of the legs. The heart becomes weak or stiff and enlarges over time making it harder to pump the blood needed for the body to function properly.

Heart failure is one of the leading causes of death in the U.S. and other developed countries. The American Heart Association estimates that 5.7 million people in the U.S. age 20 and over are affected by heart failure, with an estimated 670,000 new cases diagnosed each year. Nearly 30% of heart failure patients are below the age of 60, and congestive heart failure is the highest U.S. chronic healthcare expense category. In addition, the Journal of Cardiac Failure reported in January 2011 that a recent analysis of all Medicare fees for service readmission to hospitals showed heart failure is the number one cause of rehospitalization in the U.S.

The severity of heart failure depends on how well a person's heart is able to pump blood throughout the body. A common measure of heart failure severity is the New York Heart Association, or NYHA, Class guideline. Patients are classified as follows based on their symptoms and functional limitations:

- *Class I (Mild)* — Patients have no limits to daily activities and are able to do all normal daily activities without becoming tired, short of breath or having heart palpitations.
- *Class II (Mild)* — Patients have some limits to daily activities. Patients are comfortable at rest, but normal activities may cause them to be tired, short of breath or have heart palpitations.
- *Class III (Moderate)* — Patients' daily activities are significantly limited. Patients are comfortable at rest, but are unable to do daily activities without becoming tired, short of breath or having heart palpitations.

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- *Class IV (Severe)* — Patients are unable to do any physical activity without discomfort. Patients become tired, short of breath and possibly have heart palpitations even when they are at rest. Any physical activity makes discomfort worse.

Our C-Pulse Heart Assist System targets Class III and ambulatory Class IV patients as defined by the NYHA. It is estimated that approximately 1.5 million heart failure patients in the U.S. fall into this classification range, and we believe approximately 5 million worldwide are similarly affected. In addition to the symptoms described above, patients with Class III and ambulatory Class IV heart failure typically experience dizziness, low blood pressure and fluid retention.

Treatment alternatives currently available for Class III heart failure patients in the U.S. consist primarily of pharmacological therapies and pacing devices that are designed to stimulate the heart. Although these devices have shown to provide symptomatic relief and prolong the life of patients, these treatments do not always halt the progression of congestive heart failure. Circulatory assist devices, specifically left ventricular assist devices, or LVADs, have been used to treat Class IV patients in the U.S., and one product received FDA approval in the U.S. for Class IIIb patients. These devices are designed to take over some or all of the pumping function of the heart by mechanically pumping blood into the aorta. Although such devices are effective in increasing blood flow, these devices are implanted in the patient's body and by design are in contact with the patient's bloodstream, increasing the risk of adverse events, including thrombosis, bleeding and neurologic events.

Our Product

The C-Pulse Heart Assist System utilizes the scientific principles of intra-aortic balloon counter-pulsation applied in an extra-aortic approach to assist the left ventricle by reducing the workload required to pump blood throughout the body, while increasing blood flow to the coronary arteries. Combined, these potential benefits may help reverse the heart failure process or maintain the patient's current condition, thereby potentially preventing the need for later-stage heart failure devices, such as LVADs, artificial hearts or transplants.

We initially implanted the C-Pulse System in patients via a full sternotomy. We have developed tools to allow the C-Pulse to be implanted via a small pacemaker-like incision between the patient's ribs and sternum rather than a full sternotomy, and we completed our first implant using this less invasive procedure in 2010. Patients implanted via our minimally invasive procedure typically require a hospital stay of four to seven days in connection with implantation of the C-Pulse System, after which they return home. This less invasive procedure can reduce procedural time, hospital stays, overall cost and patient risk as compared to treatment options that require a full sternotomy.

Once implanted, the C-Pulse cuff is positioned on the outside of the patient's ascending aorta above the aortic valve. An electrocardiogram sensing lead is then attached to the heart to determine timing for cuff inflation and deflation in synchronization with the heartbeat. As the heart fills with blood, the C-Pulse cuff inflates to push blood from the aorta to the rest of the body and to the heart muscle and to the coronary arteries. Just before the heart pumps, the C-Pulse cuff deflates to open up the aorta and reduce the heart's workload, allowing the heart to pump with less effort. The C-Pulse cuff and electrical leads are connected to a single line that is run through the abdomen wall to connect to a power driver outside the body. The system's driver can be placed inside a carrying bag.

The C-Pulse System distinguishes itself from other mechanical heart failure therapies because it is not inserted into a patient's vascular system. The C-Pulse cuff is placed outside a patient's ascending aorta and assists the heart's normal pumping function, rather than being inserted into the vascular system and replacing heart function in a manner similar to other devices such as LVADs. Because the C-Pulse System remains outside the vascular system, there is potentially less risk of complications such as blood clots, stroke and thrombosis in comparison to other mechanical devices that reside or function inside the vascular system.

Another distinguishing feature of the C-Pulse System its ability to be turned on or off at any time. This feature allows patients intervals of freedom to perform certain activities such as showering. Patients are not required to visit a medical facility when turning our device on or off or using the device. However, patients are advised to turn off the C-Pulse System only to disconnect for specified activities, such as showering, to maximize the benefit from the product. Patients might experience a return of their heart failure symptoms, a loss of any improvement in their condition resulting from use of our product or an overall worsening of their heart failure symptoms compared to when they began using our product if the C-Pulse System is not turned on for the prescribed period of time.

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Clinical Development

The feasibility phase of our clinical trial was primarily designed to assess safety and provide indications of performance of the C-Pulse System in moderate to severe heart failure patients who suffer from symptoms such as shortness of breath and reduced mobility. We completed enrollment and implantation of 20 patients in the North American feasibility phase of our trial in the first half of 2011. In April 2011, the FDA approved an expansion protocol to allow us to implant up to 20 additional patients and add two additional centers to our feasibility study. We have not implanted any additional patients, and currently do not have plans to implant any additional patients, permitted by this approval. If we implant any additional patients permitted by the FDA's April 2011 approval, the patients would be part of our feasibility trial and not included in the results for our planned pivotal trial.

In November 2011, we obtained the results of the six-month follow-up period for the feasibility phase of our clinical trial. The table below summarizes results from the six-month follow up:

Measure	Responders	Non-Responders	Indeterminant(7)
NYHA Class Ranking	12(1)	0(2)	8
Minnesota Living with Heart Failure Quality of Life Score (MLHF score)	13(3)	1(4)	6
Six-Minute Hall Walk Test Distance	5(5)	1(6)	14

(1) For purposes of this measure, responders were deemed to include any patient whose NYHA class at the six-month follow-up decreased by at least one class relative to the patient's NYHA class prior to implantation of the C-Pulse.

(2) For purposes of this measure, non-responders were deemed to include any patient whose NYHA class at the six-month follow-up increased by at least one class relative to the patient's NYHA class prior to implantation of the C-Pulse.

(3) The MLHF score is derived from a questionnaire that asks each patient to indicate, using a six-point scale (zero to five), how much each of 21 facets prevents the patient from living as desired. For purposes of this measure, responders were deemed to include any patient whose aggregate MLHF score decreased by at least seven points at the six-month follow-up relative to the patient's MLHF score prior to implantation of the C-Pulse.

(4) For purposes of this measure, non-responders were deemed to include any patient whose aggregate MLHF score increased by at least seven points at the six-month follow-up relative to the patient's MLHF score prior to implantation of the C-Pulse.

(5) For purposes of this measure, responders were deemed to include any patient whose six-minute hall walk distance at the six-month follow-up increased by at least 50 meters relative to the patient's distance for this measure prior to implantation of the C-Pulse.

(6) For purposes of this measure, non-responders were deemed to include any patient whose six-minute hall walk distance at the six-month follow-up decreased by at least 50 meters relative to the patient's distance for this measure prior to implantation of the C-Pulse.

(7) For each measure, patients that were neither responders nor non-responders or did not have their six-month follow-up were classified as indeterminant.

As of the end of the six-month follow-up period, nine patients reported a major infection in connection with the implantation and use of the C-Pulse System and there was one death of a patient enrolled in the trial resulting from infection related to implantation of our device. Two other patients participating in the feasibility trial died prior to the end of the six-month follow-up period due to causes determined to be unrelated to the implantation or use of our product. These patients are classified as "indeterminant" in the table above. We believe the results of the six-month follow up demonstrate the feasibility of the C-Pulse implantation procedure and provide indications of safety and efficacy of the C-Pulse in patients with moderate to severe heart failure necessary to proceed with a

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pivotal trial. In March 2012, the FDA notified us that it completed its review of the C-Pulse feasibility trial data, concluded we met the applicable agency requirements and indicated that we can move forward with an IDE application.

We expect to submit an application for an IDE to the FDA in the first half of 2012 for approval to initiate our pivotal trial. Once the IDE application has been filed with the FDA, the FDA, following its review, will notify us that the IDE application is unconditionally approved, approved with certain conditions or that there exist deficiencies in the application that must be addressed prior to approval. If the FDA identifies deficiencies, we will be provided the opportunity to submit additional information to the FDA to respond to the filing deficiencies. It is common for the FDA to require additional information before approving an IDE, and thus final FDA approval on a submission commonly extends beyond the initial 30 days. We anticipate that we will have pivotal study IDE approval in 2012, begin enrollment promptly thereafter and complete our pivotal trial in 2015.

We are seeking CE Mark for the C-Pulse System. We have engaged a notified body and received documentation from our notified body that data from our 20-patient North American feasibility clinical trial could support approval of CE Mark for the product. We submitted data from our feasibility clinical trial and documentation relating to the design and manufacturing of our product to our notified body in January 2012. We anticipate that we will obtain CE Mark approval in the middle of 2012.

Research and Development

Our research and development expense in the years ended December 31, 2011 and 2010 totaled $11.2 million and $6.2 million, respectively. Research and development costs include activities related to research, development, design, testing and manufacturing of prototypes of our products as well as costs associated with certain clinical and regulatory activities.

In June 2011, we completed an initial animal study of a next-generation, fully implantable C-Pulse System. This next-generation system would be powered by a wireless, external battery unit, with the power driver and cuff implanted in the patient's body. A fully implantable system would eliminate the need for wires to breach the patient's skin, reducing the risk of infection and increasing the patient's comfort. The study resulted in an increase to the animal's heart function. While we continue to focus on commercializing our current C-Pulse System, we believe development of a next-generation, fully implantable C-Pulse System would benefit our business and prospects.

We expect our research and development expenses to increase as we continue to conduct clinical trials and perform research and develop on improvements to our C-Pulse Heart Assist System, such as the development of a fully implantable system.

Sales and Marketing

Our C-Pulse Heart Assist System is not approved for sale in any jurisdiction. To date, all of our sales of the C-Pulse System have been to U.S. hospitals and clinics under contract in conjunction with our clinical trials. We have solicited hospitals and clinics for our trials through our employees, selecting hospitals and clinics for participation in our trials based on our assessment of their expertise in the area of moderate and severe heart failure and their understanding of our product. Enrollment in our feasibility clinical trial was completed in the first half of 2011 and we did not generate any revenue from sales of our product during 2011.

We expect to commence the pivotal clinical trial in the second half of 2012, which is projected to extend into 2015. We do not expect to market our product in the U.S. prior to 2016.

We have retained consultants to analyze the conditions in various European countries for potential reimbursement for our product and the capabilities of existing hospitals and clinics to implant the C-Pulse System properly and understand the potential benefits of our product. We have not identified the European countries in which we initially will sell our product following CE Mark approval and we have not obtained approval for reimbursement from any European third-party payors. If we obtain CE Mark approval, we intend to market our product as soon as possible in targeted European countries, which we expect to begin in the second half of 2012. The degree and timing of any commencement or expansion of sales in Europe, however, cannot be predicted with certainty. We plan to sell the C-Pulse System in Europe through a direct sales force or through experienced distributors in countries where our product is approved for reimbursement or where we otherwise believe there might be a potentially profitable market for our product. We also intend to leverage the CE Mark approval to enter other targeted markets throughout the world, although the timing for our entry into other markets is uncertain and

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will depend on, among other factors, the success of our initial sales efforts in Europe, our ability to obtain funding and the other factors described in the "*Risk Factors*" section of this Annual Report on Form 10-K.

Manufacturers and Suppliers

Our products currently are utilized only in connection with clinical trials. We outsource the manufacture of our products to suppliers with our activities directed toward supply chain management and distribution of our products to clinics and hospitals. A number of critical components of our C-Pulse System, including the balloon, driver unit, cuff and interface lead are provided by outside suppliers and tested by us in-house. Our suppliers include large and small U.S.-based manufacturers of medical device components. The components for our product do not require significant customization for use in our product or necessitate any raw materials for which we believe our suppliers could not readily find alternative sources. We purchase from our suppliers primarily on a purchase order basis. We do not "second source" any components of our product, although we believe we could find alternative suppliers for each component of our product other than the balloon without materially interrupting production of our products at current levels. If the manufacturer of the balloon used in our product was unwilling or unable to supply this component for any reason, however, our business could be adversely affected. If we obtain regulatory approvals necessary to commercialize our C-Pulse Heart Assist System, all of our outsourced manufacturers will need to increase their production of our product or we will need to develop capabilities to manufacture the product ourselves.

Intellectual Property

We have established an intellectual property portfolio through which we seek to protect our products and technology. As of January 27, 2012, our portfolio consisted of 29 issued patents, of which 11 were issued in the U.S. and 18 were issued in other countries. We also had 29 patent applications pending, including 10 in the United States as of that date. Our patents and patent applications cover various aspects of both the methodology as well as the design of the C-Pulse Heart Assist System device and related components.

We have developed technical knowledge that, although non-patentable, we consider to be significant in enabling us to compete. It is our policy to enter into confidentiality agreements with each of our employees and consultants prohibiting the disclosure of any confidential information or trade secrets. In addition, these agreements provide that any inventions or discoveries by employees and consultants relating to our business will be assigned to us and become our sole property.

Despite our patent rights and policies with regard to confidential information, trade secrets and inventions, we may be subject to challenges to the validity of our patents, claims that our products allegedly infringe the patent rights of others and the disclosure of our confidential information or trade

secrets. These and other risks are described more fully under the heading "*Risks Relating to our Intellectual Property*" in the "*Risks Factors*" section of this Annual Report on Form 10-K.

At this time we are not a party to any material legal proceedings that relate to patents or proprietary rights.

Competition

Competition from medical device and medical device divisions of healthcare companies, pharmaceutical companies and gene- and cell-based therapies is intense and is expected to increase. The vast majority of Class III and Class IV heart failure patients still receive pharmacological treatment and a smaller percentage are treated with LVADs and other medical devices. We are not aware of any direct competitors that offer devices residing outside the vascular system for treatment of Class III and Class IV heart failure, and therefore we continue to expect new competitors both from the pharmacological and the medical device space. Among the medical device competitors are Thoratec Corporation, HeartWare International Inc., CircuLite, Inc., CardioKinetix, Inc. and, to a lesser extent, AbioMed, Inc., Jarvik Heart, Inc., MicroMed Technology, Inc., SynCardia Systems, Inc., Terumo Heart, Inc. and WorldHeart Corporation in the U.S. and Europe and Berlin Heart GmbH in Europe, and a range of other small, specialized medical device companies with devices at varying stages of development. Some of these competitors are larger than we are and have greater financial resources and name recognition than we do. Our product is not approved for sale in any jurisdiction and the efficacy and potential competitive disadvantages of the C-Pulse System are not fully known at this time.

If approved for sale, we believe that key competitive factors of the C-Pulse will be the following:

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- the C-Pulse's lower risk profile resulting from its position outside a patient's vascular system;
- the ability to disconnect the C-Pulse without harm to the patient, which is not possible with later-stage approved circulatory support heart failure treatments, and which we believe improves patients' quality of life and the convenience of using our device as compared to many other devices; and
- the minimally invasive manner in which the C-Pulse can be implanted, which involves only small incisions to the chest rather than a full sternotomy.

Third-Party Reimbursement

If approved in the U.S., the C-Pulse is expected to be purchased primarily by customers, such as hospitals, who then would bill various third-party payers for the services provided to the patients. These payers, which include Medicare, Medicaid, private health insurance companies and managed care organizations, would then reimburse our customers based on established payment formulas that take into account part or all of the cost associated with these devices and the related procedures performed.

The agency responsible for administering the Medicare program, the Centers for Medicare & Medicaid Services, and a majority of private insurers have approved reimbursement for our C-Pulse in clinical trials. The FDA has assigned the C-Pulse System to a Category B designation under IDE number G070096. By assigning the C-Pulse System a Category B designation, the FDA determined that the C-Pulse System is non-experimental/investigational. A non-experimental/investigational device refers to a device believed to be in Class I or Class II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.

With an IDE number assigned, providers are allowed to seek coverage and reimbursement for the C-Pulse System under the Medicare program from their Medicare fiscal intermediary for hospital services, carrier for physician services or Medicare Administrative Contractor for both services. We cannot be assured, however, that fiscal intermediaries will make payment.

We are analyzing the potential for third-party reimbursement in various European countries in anticipation of receiving CE Mark approval in the middle of 2012. Third-party reimbursement requirements vary from country to country in Europe and we are not approved for reimbursement by any European third-party payors at this time. Healthcare laws in the U.S. and other countries are subject to ongoing changes, including changes to the amount of reimbursement for hospital services. Legislative proposals can substantially change the way healthcare is financed by both governmental and private insurers and may negatively impact payment rates for our products. Also, from time to time there are a number of legislative, regulatory and other proposals both at the federal and state levels; it remains uncertain whether there will be any future changes that will be proposed or finalized and what effect, if any, such legislation or regulations would have on our business. However, in the U.S. and international markets, we expect that both government and third-party payors will continue to attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services.

Government Regulations

Regulation by governmental authorities in the U.S. and foreign countries is a significant factor in the manufacture and marketing of our current and future products and in our ongoing product research and development activities. All of our proposed products will require regulatory approval prior to commercialization. In particular, medical devices are subject to rigorous pre-clinical testing as a condition of approval by the FDA and by similar authorities in foreign countries.

United States

In the U.S., the FDA regulates the design, manufacture, distribution and promotion of medical devices pursuant to the Federal Food, Drug and Cosmetic Act, or FDCA, and its regulations. Our C-Pulse Heart Assist

System is regulated as a medical device. To obtain FDA approval to market the C-Pulse, the FDA requires proof of safety and efficacy in human clinical trials performed under an IDE. An IDE application must contain pre-clinical test data supporting the safety of the product for human investigational use, information on manufacturing processes and procedures, proposed clinical protocols and other information. If the IDE application is approved, human clinical trials may begin. The trials must be conducted in compliance with FDA regulations and with the approval of institutional review boards. Clinical trials are subject to central registration requirements. The results obtained from these trials are submitted to the FDA in support of a premarket approval, or PMA, application.

Products must be manufactured in registered establishments and must be manufactured in accordance with Quality System Regulations, or QSR. Furthermore, the FDA may at any time inspect our facilities or the facilities of our suppliers to determine whether we or our suppliers have adequate compliance with FDA regulations, including the QSR, which requires manufacturers to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process.

We and our suppliers are also subject to regulation by various state authorities, which may inspect our or our suppliers' facilities and manufacturing processes and enforce state regulations. Failure to comply with applicable state regulations may result in seizures, injunctions or other types of enforcement actions.

Healthcare Regulation

Our business is subject to extensive federal and state government regulation. This includes the federal Anti-Kickback Law and similar state anti-kickback laws, the federal False Claims Act and the Health Insurance Portability and Accountability Act of 1996, or HIPAA, the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, and similar state laws addressing privacy and security. Although we believe that our operations materially comply with the laws governing our industry, it is possible that non-compliance with existing laws or the adoption of new laws or interpretations of existing laws could adversely affect our financial performance.

Fraud and Abuse Laws

The healthcare industry is subject to extensive federal and state regulation. In particular, the federal Anti-Kickback Law prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. The definition of "remuneration" has been broadly interpreted to include anything of value, including, for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. In addition, there is no one generally accepted definition of intent for purposes of finding a violation of the Anti-Kickback Law. For instance, one court has stated that an arrangement will violate the Anti-Kickback Law where any party has the intent to unlawfully induce referrals. In contrast, another court has opined that a party must engage in the proscribed conduct with the specific intent to disobey the law in order to be found in violation of the Anti-Kickback Law. The lack of uniform interpretation of the Anti-Kickback Law makes compliance with the law difficult. The penalties for violating the Anti-Kickback Law can be severe. These sanctions include criminal penalties and civil sanctions, including fines, imprisonment and possible exclusion from the Medicare and Medicaid programs.

The Anti-Kickback Law is broad, and it prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Law is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry, the U.S. Department of Health and Human Services issued regulations in July of 1991, which the Department has referred to as "safe harbors." These safe harbor regulations set forth certain provisions which, if met in form and substance, will assure healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Law. Additional safe harbor provisions providing similar protections have been published intermittently since 1991. Our arrangements with physicians, physician practice groups, hospitals and other persons or entities who are in a position to refer may not fully meet the stringent criteria specified in the various safe harbors. Although full compliance with these provisions ensures against prosecution under the federal Anti-Kickback Law, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Law will be pursued. Conduct and business arrangements

that do not fully satisfy one of these safe harbor provisions may result in increased scrutiny by government enforcement authorities such as the U.S. Department of Health and Human Services Office of Inspector General.

Many states have adopted laws similar to the federal Anti-Kickback Law. Some of these state prohibitions apply to referral of patients for healthcare services reimbursed by any source, not only the Medicare and Medicaid programs. Although we believe that we comply with both federal and state anti-kickback laws, any finding of a violation of these laws could subject us to criminal and civil penalties or possible exclusion from federal or state healthcare programs. Such penalties would adversely affect our financial performance and our ability to operate our business.

HIPAA created new federal statutes to prevent healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs such as the Medicare and Medicaid programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment or exclusion from government sponsored programs. Both federal and state government agencies are continuing heightened and coordinated civil and criminal enforcement efforts. As part of announced enforcement agency work plans, the federal government will continue to scrutinize, among other things, the billing practices of hospitals and other providers of healthcare services. The federal government also has increased funding to fight healthcare fraud, and it is coordinating its enforcement efforts among various agencies, such as the U.S. Department of Justice, the Office of Inspector General and state Medicaid fraud control units. We believe that the healthcare industry will continue to be subject to increased government scrutiny and investigations.

Federal False Claims Act

Another trend affecting the healthcare industry is the increased use of the federal False Claims Act and, in particular, actions under the False Claims Act's "whistleblower" provisions. Those provisions allow a private individual to bring actions on behalf of the government alleging that the defendant has defrauded the federal government. After the individual has initiated the lawsuit, the government must decide whether to intervene in the lawsuit and to become the primary prosecutor. If the government declines to join the lawsuit, then the individual may choose to pursue the case alone, in which case the individual's counsel will have primary control over the prosecution, although the government must be kept apprised of the progress of the lawsuit. Whether or not the federal government intervenes in the case, it will receive the majority of any recovery. If the litigation is successful, the individual is entitled to no less than 15%, but no more than 30%, of whatever amount the government recovers. The percentage of the individual's recovery varies, depending on whether the government intervened in the case and other factors. Recently, the number of suits brought against healthcare providers by private individuals has increased dramatically. In addition, various states are considering or have enacted laws modeled after the federal False Claims Act. Under the Deficit Reduction Act of 2005, states are being encouraged to adopt false claims acts similar to the federal False Claims Act, which establish liability for submission of fraudulent claims to the State Medicaid program and contain whistleblower provisions. Even in instances when a whistleblower action is dismissed with no judgment or settlement, we may incur substantial legal fees and other costs relating to an investigation. Future actions under the False Claims Act may result in significant fines and legal fees, which would adversely affect our financial performance and our ability to operate our business.

Further, the Fraud Enforcement and Recovery Act of 2009 expands the types of entities and conduct subject to the False Claims Act. We strive to ensure that we meet applicable billing requirements. However, the costs of defending claims under the False Claims Act, as well as sanctions imposed under the Act, could significantly affect our financial performance.

Health Insurance Portability and Accountability Act of 1996

In addition to creating the new federal statutes discussed above, HIPAA also establishes uniform standards governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of individually identifiable health information maintained or transmitted by healthcare providers, health plans and healthcare clearinghouses.

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The American Recovery and Reinvestment Act of 2009, signed into law on February 17, 2009, dramatically expanded, among other things, (1) the scope of HIPAA to also include "business associates," or independent contractors who receive or obtain protected health information in connection with providing a service to the covered entity, (2) substantive security and privacy obligations, including new federal security breach notification requirements to affected individuals and Department of Health and Human Services and potentially media outlets, (3) restrictions on marketing communications and a prohibition on covered entities or business associates from receiving remuneration in exchange for protected health information and (4) the civil and criminal penalties that may be imposed for HIPAA violations, increasing the annual cap in penalties from $25,000 to $1.5 million per year. We believe we are neither a HIPAA "covered entity" nor a business association, and therefore are not presently subject to HIPAA's privacy and security standards. It is possible that future changes in our operations or the law could subject us to HIPAA's privacy and security requirements and penalty provisions if we failed to comply. In addition to federal regulations issued under HIPAA, some states have enacted privacy and security statutes or regulations that, in some cases, are more stringent than those issued under HIPAA. In those cases it may be necessary to modify our operations and procedures to comply with the more stringent state laws, which may entail significant and costly changes for us. We believe that we are in compliance with such state laws and regulations. However, if we fail to comply with applicable state laws and regulations, we could be subject to additional sanctions.

Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act

In March 2010, Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, or together, the Affordable Care Act. In 2013, manufacturers are scheduled to begin paying an excise tax on sales of medical devices. Medicare is also implementing a competitive bidding system for durable medical equipment, enteral nutrition products and supplies.

The Affordable Care Act also includes provisions known as the Physician Payments Sunshine Act, which requires manufacturers of drugs, biologics, devices and medical supplies covered under Medicare and Medicaid starting in 2012 to record any transfers of value to physicians and teaching hospitals and to report this data beginning in 2013 to the Centers for Medicare and Medicaid Services for subsequent public disclosure. Similar reporting requirements have also been enacted on the state level domestically, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with health care professionals. Particularly, some states such as Massachusetts, Minnesota, and Vermont, impose an outright ban on certain gifts to physicians. Failure to report appropriate data may result in civil or criminal fines and/or penalties.

International Regulations

We are also subject to regulation in each of the foreign countries where we intend to distribute the C-Pulse. These regulations relate to product standards, packaging and labeling requirements, import restrictions, tariff regulations, duties and tax requirements. Many of the regulations applicable to our products in these countries are similar to those of the FDA. The national health or social security organizations of certain countries require our products to be qualified before they can be marketed in those countries.

The primary regulatory environment in Europe is that of the European Union, which consists of 27 member states. The European Union has adopted two directives that cover medical devices—Directive 93/42/EEC covering medical devices and Directive 90/385/EEC for active implantable medical devices, as well as numerous standards that govern and harmonize the national laws and standards regulating the design, manufacture, clinical trials, labeling, adverse event reporting and post-market surveillance activities for medical devices that are marketed in member states. Medical devices that comply with the requirements of the national law of the member state in which they are first marketed will be entitled to bear CE Marking, indicating that the device conforms to applicable regulatory requirements, and, accordingly, can be commercially marketed within EU states and other countries that recognize this mark for regulatory purposes. We are currently seeking CE Marking for the C-Pulse Heart Assist System which we have targeted to be complete in the middle of 2012.

Other Regulations

We are also subject to various federal, state and local laws and regulations relating to such matters as safe working conditions, laboratory and manufacturing practices and the use, handling and disposal of hazardous or

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potentially hazardous substances used in connection with our research and development and manufacturing activities. Specifically, the manufacture of our biomaterials is subject to compliance with federal environmental regulations and by various state and local agencies. Although we believe we are in compliance with these laws and regulations in all material respects, we cannot provide assurance that we will not be required to incur significant costs to comply with environmental laws or regulations in the future.

Employees

As of December 31, 2011, we had 25 employees, consisting of 22 full-time and 3 part-time employees. None of our employees are covered by a collective bargaining agreement. We consider relations with our employees to be good.

Corporate Information

Sunshine Heart, Inc. was incorporated in Delaware on August 22, 2002. We began operating our business through Sunshine Heart Company Pty Ltd, which currently is a wholly owned Australian subsidiary of Sunshine Heart, Inc., in November 1999. Since September 2004, CHESS Depositary Interests, or CDIs, representing beneficial ownership of our common stock have been have traded on the Australian Securities Exchange, or ASX, under the symbol "SHC." Historically, each CDI represented one share of our common stock. In connection with the 200-for-1 reverse stock split we effected on January 27, 2012 we changed this ratio so that each CDI represents 1/200th of a share of our common stock. Unless otherwise noted, all historical share and per share information in this Annual Report on Form 10-K has been adjusted to reflect this reverse stock split and adjusts information with respect to CDIs to account for the 200-to-1 CDI to common stock ratio. Unless otherwise noted, all references to AUD, AU$ or A$ are to Australian Dollars, the lawful currency of the Commonwealth of Australia, and all references to $ or dollars are to U.S. Dollars.

Our principal executive offices are located at 12988 Valley View Road, Eden Prairie, Minnesota 55344, and our telephone number is (952) 345-4200. Our website address is *www.sunshineheart.com*. The information on, or that may be accessed through, our website is not incorporated by reference into and should not be considered a part of this Annual Report on Form 10-K.

Executive Officers

Set forth below are the names, ages and titles of the persons serving as our executive officers.

Name	Age	Position
David Rosa	48	Chief Executive Officer and Director
Kevin Bassett	44	Senior Vice President, Technology & Operations
Debra Kridner	60	Vice President, Research & Regulatory Affairs
Jeffrey Mathiesen	51	Chief Financial Officer and Secretary
Dr. William Peters	46	Chief Technology Officer & Medical Director
Jim Yearick	49	Vice President, Marketing & Sales

David Rosa: Mr. Rosa is our Chief Executive Officer, a position he has held since November 2009. From 2008 to November 2009, Mr. Rosa served as the Chief Executive Officer of Milksmart, Inc., a medical device company that specializes in medical devices for animals. From 2004 to 2008, Mr. Rosa served as the Vice President of Global Marketing for cardiac surgery and cardiology for St. Jude Medical.

Kevin Bassett: Mr. Basset is our Senior Vice President of Technology and Operations, a position he has held since January 2012. From October 2010 until December 2011, Mr. Bassett served as our Vice President of Research, Development and Quality Assurance. Prior to joining to Sunshine Heart, Inc., Mr. Bassett served in various leadership roles at Acorn Cardiovascular, a medical device company that develops treatments for patients with heart failure, the most recent position being as Senior Vice President from 2006 to 2010.

Debra Kridner: Ms. Kridner is our Vice President of Clinical Research and Regulatory Affairs, a position she has held since November 2009 on a consultant basis and since March 2010 as an employee of our company. From 2008 to 2009, Ms. Kridner worked as a consultant for her company Kridner Consulting LLC, which performed consulting services for medical device companies. From 2004 to 2008, Ms. Kridner served as the Vice President of Clinical Research and Regulatory Affairs for St. Jude Medical's Cardiac Surgery and Interventional Cardiology for the Cardiovascular Division.

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Jeffrey Mathiesen: Mr. Mathiesen has served as our Chief Financial Officer since March 2011and as our Secretary since July 2011. From December 2005 through April 2010, Mr. Mathiesen served as Vice President and Chief Financial Officer for Zareba Systems, Inc., a manufacturer and marketer of medical products, perimeter fencing and security systems. Zareba was a publicly traded company that was purchased by Woodstream Corporation in April 2010. Previous positions held by Mr. Mathiesen include Vice President and Chief Financial Officer positions with publicly traded companies dating back to 1993.

Dr. William Peters: Since 2002, Dr. Peters has served as our Chief Technical Officer and Medical Director. In addition to his role within our company, Dr. Peters is an honorary clinical research fellow with the Green Lane Cardiothoracic Surgical Unit at Auckland City Hospital in New Zealand.

Jim Yearick: Since September 2011, Mr. Yearick has served as our Vice President of Marketing and Sales. From 2008 to September 2011, Mr. Yearick served as Vice President of Global Product Marketing for Medtronic's Cardiac Rhythm Management division. Previously, from 2005 to 2008, Mr. Yearick served as Vice President — Asia for Medtronic's Cardiac Rhythm Management division.

Item 1A. Risk Factors

Our business faces many risks. We believe the risks described below are the material risks we face. However, the risks described below may not be the only risks we face. Additional unknown risks or risks that we currently consider immaterial may also impair our business operations. If any of the events or circumstances described below actually occurs, our business, financial condition or results of operations could suffer, and the trading price of our shares of common stock could decline significantly. Investors should consider the specific risk factors discussed below, together with the "Special Note Regarding Forward-Looking Information" and the other information contained in this Annual Report on Form 10-K and the other documents that we will file from time to time with the SEC.

Risks Relating to Our Business

We have incurred operating losses since our inception and anticipate that we will continue to incur operating losses for the foreseeable future.

We are an early-stage company with a history of incurring net losses. We have incurred net losses since our inception, including net losses of $16.2 million and $7.6 million for the years ended December 31, 2011 and 2010, respectively. As of December 31, 2011, our accumulated deficit was $65.2 million. We do not have any products that have been approved for marketing, and we continue to incur research and development and general and administrative expenses related to our operations. We expect to continue to incur significant and increasing operating losses for the foreseeable future as we incur costs associated with the conduct of clinical trials, continue our product research and development programs, seek regulatory approvals, expand our sales and marketing capabilities, increase manufacturing of our products and comply with the requirements related to being a U.S. public company listed on the ASX and the Nasdaq Capital Market. To become and remain profitable, we must succeed in developing and commercializing products with significant market potential. This will require us to succeed in a range of challenging activities, including conducting clinical trials, obtaining regulatory approvals, manufacturing products and marketing and selling commercial products. We may never succeed in these activities, and we may never generate revenues sufficient to achieve profitability. If we do achieve profitability, we may not be able to sustain it.

We will need additional funding to continue operations, which may not be available to us on favorable terms or at all.

Currently, we have no products available for commercial sale, and to date we have generated only limited product revenue from our feasibility study. We believe our cash and cash equivalents on hand will not be sufficient to fund our operations beyond the first half of 2012. In addition, the report of our independent registered public accounting firm includes an explanatory paragraph with regards to our ability to continue as a going concern in connection with its audit of our financial statements for the fiscal year ended December 31, 2011. Our continued operations are dependent on our ability to obtain additional funding during 2012. However, additional funding may not be available on terms favorable to us, or at all, and concern about our ability to continue as a going concern may place additional constraints on operations and make it more difficult for us to meet our obligations or adversely affect the terms of possible funding. If we raise additional funding through the issuance of equity securities, our stockholders may suffer dilution and our ability to use our net operating losses to offset future income may be limited. If we raise additional funding through debt financing, we may be required to accept terms that restrict our ability to incur additional indebtedness, force us to maintain specified liquidity or other ratios or restrict our ability

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to pay dividends or make acquisitions. If we are unable to secure additional funding, our product development programs and our commercialization efforts would be delayed, reduced or eliminated.

We have limited sales, marketing and distribution experience.

To develop and increase internal sales, distribution and marketing capabilities, we would have to invest significant amounts of financial and management resources. In developing these sales, marketing and distribution functions ourselves, we could face a number of risks, including:

- we may not be able to attract and build a significant marketing or sales force;
- the cost of establishing, training and providing regulatory oversight for a marketing or sales force may be substantial; and
- there are significant legal and regulatory risks in medical device marketing and sales that we have never faced, and any failure to comply with all legal and regulatory requirements for sales, marketing and distribution could result in an enforcement action by the European countries, the FDA or other authorities that could jeopardize our ability to market the product or could subject us to substantial liability.

We plan to commercialize our products outside of the United States, which will expose us to risks associated with international operations.

We plan to commercialize our products outside of the United States and expect to commence clinical trials in certain European countries in addition to the U.S. and Canada. Conducting international operations subjects us to risks, including:

- costs of complying with varying regulatory requirements and potential, unexpected changes to those requirements;
- fluctuations in currency exchange rates;
- potentially adverse tax consequences, including the complexities of foreign value added tax systems and restrictions on the repatriation of earnings;
- government-imposed pricing controls on sales of our products;
- longer payment cycles and difficulties in collecting accounts receivable;
- difficulties in managing and staffing international operations;
- increased financial accounting and reporting burdens and complexities; and
- reduced or varied protection for intellectual property rights in some countries.

The occurrence of any one of these risks could negatively affect our international operations. Additionally, operating in international markets also requires significant management attention and financial resources. We cannot be certain that our operations in other countries will produce desired levels of revenues or profitability.

We depend on a limited number of manufacturers and suppliers of various critical components for our C-Pulse System. The loss of any of these manufacturer or supplier relationships could delay future clinical trials or prevent or delay commercialization of our C-Pulse System.

We rely entirely on third parties to manufacture our C-Pulse System and to supply us with all of the critical components of our C-Pulse System, including the balloon, driver, cuff and interface lead. We primarily purchase our components and products on a purchase order basis and do not "second source" any components of our product. If the supplier of the balloon used in our product was unable or unwilling to meet our demand for this component, or if the components or finished products provided by any of our suppliers do not meet quality and other specifications, clinical trials or commercialization of our product could be delayed and increase our expenses. Alternatively, if we have to switch to a replacement manufacturer or replacement supplier for any of our product components, we may face additional regulatory delays, and the manufacture and delivery of our C-Pulse System could be interrupted for an extended period of time and become significantly more expensive, which could delay completion of future clinical trials or commercialization of our C-Pulse System and adversely affect our results of operations. In addition, we may be required to use different suppliers or components to obtain regulatory approval from the FDA.

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If our manufacturers or our suppliers are unable to provide an adequate supply of our product following the start of commercialization, our growth could be limited and our business could be harmed.

In order to produce our C-Pulse System in the quantities that we anticipate will be required to meet market demand, we will need our manufacturers to increase, or scale-up, the production process by a significant factor over the current level of production. There are technical challenges to scaling-up manufacturing capacity and developing commercial-scale manufacturing facilities that may require the investment of substantial additional funds by our manufacturers and hiring and retaining additional management and technical personnel who have the necessary manufacturing experience. If our manufacturers are unable to do so, we may not be able to meet the requirements for the launch of the product or to meet future demand, if at all. We also may represent only a small portion of our supplier's or manufacturer's business and if they become capacity constrained they may choose to allocate their available resources to other customers that represent a larger portion of their business. We currently anticipate that we will continue to rely on third-party manufacturers and suppliers for the production of our C-Pulse System following commercialization. If we develop and obtain regulatory approval for our product and are unable to obtain a sufficient supply of our product, our revenue, business and financial prospects would be adversely affected.

If we are unable to manage our expected growth, we may not be able to commercialize our products.

We have expanded, and expect to continue to expand, our operations and grow our research and development, product development, regulatory, manufacturing, sales, marketing and administrative operations. This expansion has placed, and is expected to continue to place, a significant strain on our management and operational and financial resources. To manage any further growth and to commercialize our products, we will be required to improve existing and implement new operational and financial systems, procedures and controls and expand, train and manage our growing employee base. In addition, we will need to manage relationships with various manufacturers, suppliers and other organizations. Our ability to manage our operations and growth will require us to improve our operational, financial and management controls, as well as our internal reporting systems and controls. We may not be able to implement such improvements to our management information and internal control systems in an efficient and timely manner and may discover deficiencies in existing systems and controls. Our failure to accomplish any of these tasks could materially harm our business.

We compete against companies that have longer operating histories, more established products and greater resources than we do, which may prevent us from achieving further market penetration or improving operating results.

Competition in the medical device industry is intense. Our products will compete against current therapies, including pharmacological therapies, as well as products offered by public companies, such as Thoratec Corporation and HeartWare International, Inc., and several smaller specialized private companies, such as CircuLite, Inc. Some of these competitors have significantly greater financial and human resources than we do and have established reputations, as well as worldwide distribution channels and sales and marketing capabilities that are larger and more established than ours. Additional competitors may enter the market, and we are likely to compete with new companies in the future. We also face competition from other medical therapies which may focus on our target market as well as competition from manufacturers of pharmaceutical and other devices that have not yet been developed. Competition from these companies could adversely affect our business.

Our ability to compete effectively depends upon our ability to distinguish our company and our products from our competitors and their products. Factors affecting our competitive position include:

- financial resources;
- product performance and design;
- product safety;
- sales, marketing and distribution capabilities;
- manufacturing and assembly costs;
- success and timing of new product development and introductions;
- regulatory approvals; and
- intellectual property protection.

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The competition for qualified personnel is particularly intense in our industry. If we are unable to retain or hire key personnel, we may not be able to sustain or grow our business.

Our ability to operate successfully and manage our potential future growth depends significantly upon our ability to attract, retain and motivate highly skilled and qualified research, technical, clinical, regulatory, sales, marketing, managerial and financial personnel. We face intense competition for such personnel, and we may not be able to attract, retain and motivate these individuals. We compete for talent with numerous companies, as well as universities and nonprofit research organizations. Our future success also depends on the personal efforts and abilities of the principal members of our senior management and scientific staff to provide strategic direction, manage our operations and maintain a cohesive and stable environment. We do not maintain

key man life insurance on the lives of any of the members of our senior management. The loss of key personnel for any reason or our inability to hire, retain and motivate additional qualified personnel in the future could prevent us from sustaining or growing our business.

Product defects could adversely affect the results of our operations.

The design, manufacture and marketing of medical devices involve certain inherent risks. Manufacturing or design defects, unanticipated use of our products or inadequate disclosure of risks relating to the use of the product can lead to injury or other adverse events. These events could lead to recalls or safety alerts relating to our products (either voluntary or required by the FDA or similar governmental authorities in other countries), and could result, in certain cases, in the removal of a product from the market. Any recall could result in significant costs, as well as negative publicity and damage to our reputation that could reduce demand for our products. Personal injuries relating to the use of our products can also result in product liability claims being brought against us. In some circumstances, such adverse events could also cause delays in new product approvals.

We may be sued for product liability, which could adversely affect our business.

The design, manufacture and marketing of medical devices carries a significant risk of product liability claims. Our products treat Class III and ambulatory Class IV heart failure for patients who typically have serious medical issues. As a result, our exposure to product liability claims may be heightened because the people who use our products have a high risk of suffering adverse outcomes, regardless of the safety or efficacy of our products.

We may be held liable if any product we develop and commercialize causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or consumer use. The safety studies we must perform and the regulatory approvals required to commercialize our medical safety products will not protect us from any such liability. We carry product liability insurance with a $10 million aggregate limit. However, if there were to be product liability claims against us, our insurance may be insufficient to cover the expense of defending against such claims, or may be insufficient to pay or settle such claims. Furthermore, we may be unable to obtain adequate product liability insurance coverage for commercial sales of any of our approved products. If such insurance is insufficient to protect us, our results of operations will suffer. If any product liability claim is made against us, our reputation and future sales will be damaged, even if we have adequate insurance coverage. Even if a product liability claim against us is without merit or if we are not found liable for any damages, a product liability claim could result in decreased demand for our products, injury to our reputation, diversion of management's attention from operation or our business, withdrawal of clinical trial participants, significant costs of related litigation, loss of revenue or the inability to commercialize our products under development.

Risks Relating to Regulation

We have no products approved for commercial sale, and our success will depend heavily on the success of our pivotal trial for our C-Pulse System. If we are unable to complete our pivotal trial, or experience significant delays in the trial, or if the results of the trial do not meet its safety and efficacy endpoints, our ability to obtain regulatory approval to commercialize our product and to generate revenues will be harmed.

Upon completion of the six-month follow-up period for our feasibility trial, we submitted the trial's test data to the FDA on November 29, 2011. We expect to submit an IDE application to the FDA in the first half of 2012 for approval to initiate our pivotal trial. Completion of the pivotal trial could be delayed or adverse events during the trial could cause us to modify the existing design, repeat or terminate the trial. If the trial is delayed, if it must be repeated or if it is terminated, our costs associated with the trial will increase, and it will take us longer to

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obtain regulatory approvals and commercialize the product. Our pivotal trial also may be suspended or terminated at any time by regulatory authorities or by us. FDA scrutiny of IDE applications has intensified in recent years, increasing the risk of delay.

Even if we commence and complete our pivotal clinical trial, it must demonstrate the safety and efficacy of the C-Pulse System by meeting the trial's endpoints before we can commercialize the C-Pulse System in the U.S. The inability to achieve the safety or efficacy endpoints in the pivotal trial could delay our timeline for obtaining regulatory approval to commercialize our product.

In addition to successfully completing our pivotal trial, we will need to receive approval from regulatory agencies in each country in which we seek to sell our products. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval varies from country to country and approval in one country does not ensure regulatory approval in another. In addition, a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. We cannot assure you when, or if, we will be able to commence sales in any jurisdiction within or outside the United States.

Any failure or significant delay in successfully completing our pivotal trial or obtaining regulatory approvals could harm our financial results and our prospects and cause us to seek additional funding.

Even if we obtain foreign regulatory approvals, we will need to obtain FDA approval to commercialize our product in the United States, which will require us to receive FDA approval to conduct clinical trials in the United States and to complete those trials successfully. If we fail to obtain approval from the FDA, we will not be able to market and sell our products in the United States.

We do not have the necessary regulatory approvals to commercialize our C-Pulse System in the United States, which we believe is the largest potential market for our C-Pulse System. We can offer no assurance that our IDE application will be approved or that we will ever obtain FDA approval of the C-Pulse System or any future products.

In order to obtain FDA approval for our C-Pulse System, we will be required to receive a PMA from the FDA. A PMA must be supported by pre-clinical and clinical trials to demonstrate safety and efficacy. A clinical trial will be required to support an application for a PMA, and we will be seeking FDA approval of our IDE application that will allow us to commence a clinical trial in the United States. We intend to commence our U.S. pivotal trial in the second half of 2012, but there can be no assurance that our U.S. pivotal trial will begin or be completed on schedule or at all. Even if completed, we do not know if this trial will produce clinically meaningful results sufficient to show the safety and efficacy of our products so as to support an application for a PMA.

The process of obtaining a PMA from the FDA for our C-Pulse System, or any future products or enhancements or modifications to any products, could:

- take a significant period of time;
- require the expenditure of substantial resources;
- involve rigorous pre-clinical and clinical testing;
- require changes to our products; and
- result in limitations on the indicated uses of the products.

In addition, recent, widely publicized events concerning the safety of certain drug, food and medical device products have raised concerns among members of Congress, medical professionals and the public regarding the FDA's handling of these events and its perceived lack of oversight over regulated products. The increased attention to safety and oversight issues could result in a more cautious approach by the FDA to approvals for devices such as ours, which could delay or prevent FDA approval of our C-Pulse System.

There can be no assurance that we will receive the required approvals from the FDA or, if we do receive the required approvals, that we will receive them on a timely basis. The failure to receive product approval by the FDA could have a material adverse effect on our business, financial condition or results of operations.

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We may be unable to enroll and complete our planned United States pivotal trial for the C-Pulse System or other clinical trials, which could prevent or delay regulatory approval of the C-Pulse System and impair our financial position.

We intend to commence our U.S. pivotal trial in the second half of 2012. The trial is designed to be a randomized trial that includes approximately 300 patients and is expected to involve more than 30 sites. Conducting a clinical trial of this size is a complex and uncertain process.

The commencement of our trial could be delayed for a variety of reasons, including:

- reaching agreement on acceptable terms with prospective clinical trial sites;
- manufacturing sufficient quantities of our C-Pulse System;
- obtaining institutional review board approval to conduct the trial at a prospective site; and
- obtaining sufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the trial.

Once the trial has begun, the completion of the trial, and our other ongoing clinical trials, could be delayed, suspended or terminated for several reasons, including:

- ongoing discussions with regulatory authorities regarding the scope or design of our preclinical results or clinical trial or requests for supplemental information with respect to our preclinical results or clinical trial results;
- our failure or inability to conduct the clinical trials in accordance with regulatory requirements;
- sites currently participating in the trial may drop out of the trial, which may require us to engage new sites or petition the FDA for an expansion of the number of sites that are permitted to be involved in the trial;
- patients may not remain in or complete clinical trials at the rates we expect;
- patients may experience serious adverse events or side effects during the trial, which, whether or not related to our product, could cause the FDA or other regulatory authorities to place the clinical trial on hold; and
- clinical investigators may not perform clinical trials on our anticipated schedule or consistent with the clinical trial protocol and good clinical practice requirements.

If our pivotal trial is delayed, it will take us longer to ultimately commercialize a product or the delay could result in our being unable to do so. Moreover, our development costs will increase if we have material delays in our pivotal trial or if we need to perform more or larger clinical trials than planned. Any of the foregoing could harm our financial results and our prospects and cause us to seek additional funding.

We depend on clinical investigators and clinical sites to enroll patients in our clinical trials, and on other third parties to manage the trials and to perform related data collection and analysis, and, as a result, we may face costs and delays that are outside of our control.

We have and plan to continue to rely on clinical investigators and clinical sites to enroll patients in our clinical trials, including our planned U.S. pivotal trial, and other third parties to manage the trials and to perform related data collection and analysis. However, we may not be able to control the amount and timing of resources that clinical sites may devote to our clinical trials. If these clinical investigators and clinical sites fail to enroll a sufficient number of patients in our clinical trials, to ensure compliance by patients with clinical protocols or comply with regulatory requirements, we will be unable to complete these trials, which could prevent us from obtaining regulatory approvals for our product. Our agreements with clinical investigators and clinical trial sites for clinical testing place substantial responsibilities on these parties and, if these parties fail to perform as expected, our trials could be delayed or terminated. If these clinical investigators, clinical sites or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, or the clinical data may be rejected by the FDA, and we may be unable to obtain regulatory approval for, or successfully commercialize, our product.

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Our manufacturers and suppliers might not meet regulatory quality standards applicable to manufacturing and quality processes, which could have an adverse effect on our financial results and prospects.

Even after products have received marketing approval or clearance, product approvals and clearances by the FDA can be withdrawn due to failure to comply with regulatory standards. We rely entirely on third parties to manufacture our C-Pulse System and those manufacturers are required to demonstrate and maintain compliance with the FDA's Quality System Regulation, or QSR. The QSR is a complex regulatory scheme that covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. The FDA enforces the QSR through periodic unannounced inspections. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA. A failure by our manufacturers to comply with the QSR or to take satisfactory corrective action in response to an adverse QSR inspection could cause a significant delay in our ability to have our product manufactured and to complete our clinical trials, which would harm our financial results and our prospects. In addition, suppliers of components of, and products used to manufacture, our products must also comply with FDA and foreign regulatory requirements, which often require significant time, money and record-keeping and quality assurance efforts and subject us and our suppliers to potential regulatory inspections and stoppages.

We plan to operate in multiple regulatory environments that require costly and time consuming approvals.

Even if we obtain regulatory approvals to commercialize the C-Pulse System or any other product that we may develop, sales of our products in other jurisdictions will be subject to regulatory requirements that vary from country to country. The time and cost required to obtain approvals from these countries may be longer or shorter than that required for FDA approval, and requirements for licensing may differ from those of the FDA. Laws and regulations regarding the manufacture and sale of our products are subject to future changes, as are administrative interpretations and policies of regulatory agencies. If we fail to comply with applicable foreign, federal, state or local market laws or regulations, we could be subject to enforcement actions. Enforcement actions could include product seizures, recalls, withdrawal of clearances or approvals and civil and criminal penalties, which in each case would harm our business.

The C-Pulse System may never achieve market acceptance even if we obtain regulatory approvals.

Even if we obtain regulatory approvals to commercialize the C-Pulse System or any other product that we may develop, our products may not gain market acceptance among physicians, patients, health care payers or the medical community. The degree of market acceptance of any of the devices that we may develop will depend on a number of factors, including:

- the perceived effectiveness of the product;
- the prevalence and severity of any side effects;
- potential advantages over alternative treatments;
- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

If our C-Pulse System, or any other product that we may develop, is approved but does not achieve an adequate level of acceptance by physicians, patients, health care payers and the medical community, we may not generate product revenue and we may not become profitable or be able to sustain profitability.

If we fail to obtain an adequate level of reimbursement for our product by third-party payers, there may be no commercially viable markets for our product or the markets may be much smaller than expected.

The availability and levels of reimbursement by governmental and other third-party payers affect the market for our product. The FDA has assigned the C-Pulse System to a Category B designation under IDE number G070096. By assigning the C-Pulse System a Category B designation, the FDA determined that the C-Pulse System is non-experimental/investigational. A non-experimental/investigational device refers to a device believed to be in Class I or Class II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.

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Reimbursement and health care payment systems in international markets vary significantly by country, and include both government-sponsored health care and private insurance. To obtain reimbursement or pricing approval in some countries, we may be required to produce clinical data, which may involve one or more clinical trials, that compares the cost-effectiveness of our products to other available therapies. We may not obtain international reimbursement or pricing approvals in a timely manner, if at all. Our failure to receive international reimbursement or pricing approvals would negatively impact market acceptance of our products in the international markets in which those approvals are sought.

We believe that future reimbursement may be subject to increased restrictions both in the United States and in international markets. Future legislation, regulation or reimbursement policies of third-party payers may adversely affect the demand for our products currently under development and limit our ability to sell the C-Pulse System or any future products on a profitable basis. In addition, third-party payers continually attempt to contain or reduce the costs of health care by challenging the prices charged for health care products and services. If reimbursement for our products is unavailable in any market or limited in scope or amount or if pricing is set at unsatisfactory levels, market acceptance of our products would be impaired and our future revenues, if any, would be adversely affected.

We may be subject, directly or indirectly, to United States federal and state healthcare fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to, or have not fully complied with such laws, we could face substantial penalties.

If we are successful in achieving regulatory approval to market our C-Pulse System, our operations will be directly, or indirectly through our customers, subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. These laws may impact, among other things, our proposed sales, marketing and education programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be

made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and, despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the, federal government. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, commonly known as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing qui tam actions has increased significantly in recent years, causing greater numbers of medical device, pharmaceutical and healthcare companies to have to defend a False Claim Act action. When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Various states have also enacted laws modeled after the federal False Claims Act.

The Affordable Care Act includes provisions known as the Physician Payments Sunshine Act, which requires manufacturers of drugs, biologics, devices and medical supplies covered under Medicare and Medicaid starting in 2012 to record any transfers of value to physicians and teaching hospitals and to report this data beginning in 2013 to the Centers for Medicare and Medicaid Services for subsequent public disclosure. Similar reporting requirements have also been enacted on the state level in the U.S., and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with health care professionals. Particularly, some states such as Massachusetts, Minnesota, and Vermont, impose an outright ban on certain gifts to physicians. If we receive FDA clearance to market our product in the U.S., these laws could affect our promotional activities by limiting the kinds of interactions we could have with hospitals, physicians or

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other potential purchasers or users of our products. Both the disclosure laws and gift bans will impose administrative and compliance burdens on us.

We are unable to predict whether we could be subject to actions under any of these laws, or the impact of such actions. If we are found to be in violation of any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring of our operations.

We will incur increased costs as a result of being a United States reporting company and we have no experience as a U.S. reporting company.

In connection with the effectiveness of our registration statement on Form 10, as of February 14, 2012, we became subject to the periodic reporting requirements of the Exchange Act. Although we have been listed on the ASX for several years and have been required to file financial information and make certain other filings with the ASX, our status as a U.S. reporting company under the Exchange Act will cause us to incur additional legal, accounting and other expenses that we have not previously incurred, including costs related to compliance with the requirements of the Sarbanes-Oxley Act of 2002. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We also expect these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers.

Risks Relating to our Intellectual Property

We may not be able to protect our intellectual property rights effectively, which could have an adverse effect on our business, financial condition or results of operations.

Our success depends in part on our ability to obtain and maintain protection in the United States and other countries of the intellectual property relating to or incorporated into our technology and products. As of January 27, 2012, we owned 11 issued patents in the United States and 10 patent applications in the United States, as well as 18 issued patents and 19 patent applications in foreign jurisdictions. We estimate that the U.S. patents expire between June 9, 2020 and October 28, 2024. Our pending and future patent applications may not issue as patents or, if issued, may not issue in a form that will provide us any competitive advantage. Even if issued, existing or future patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of terms of patent protection we may have for our products. Changes in patent laws or their interpretation in the United States and other countries could also diminish the value of our intellectual property or narrow the scope of our patent protection. In addition, the legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. In order to preserve and enforce our patent and other intellectual property rights, we may need to make claims or file lawsuits against third parties. This can entail significant costs to us and divert our management's attention from developing and commercializing our products.

Intellectual property litigation could be costly and disruptive to us.

In recent years, there has been significant litigation involving medical device patents and other intellectual property rights. From time to time, third parties may assert patent, copyright, trademark and other intellectual property rights to technologies used in our business. Any claims, with or without merit, could be time-consuming, result in costly litigation, divert the efforts of our technical and management personnel or require us to pay substantial damages. If we are unsuccessful in defending ourselves against these types of claims, we may be required to do one or more of the following:

- stop clinical trials or delay or abandon commercialization of the product that is the subject of the suit;

- attempt to obtain a license to sell or use the relevant technology or substitute technology, which license may not be available on reasonable terms or at all; or
- redesign those products that use the relevant technology.

In the event a claim against us was successful and we could not obtain a license to the relevant technology on acceptable terms or license a substitute technology or redesign our products to avoid infringement, our business would be significantly harmed.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patented technology, we rely on our unpatented proprietary technology, trade secrets, processes and know-how. We generally seek to protect this information by confidentiality agreements with our employees, consultants, scientific advisors and third parties. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Risk Factors Related to Ownership of Our Common Stock

An active trading market for our shares of common stock in the United States may not develop and the trading price of our shares of common stock may fluctuate significantly.

Our common stock began trading on the Nasdaq Capital Market on February 16, 2012. Our common stock has been listed on the ASX in the form of CDIs since 2004 and has experienced limited trading volume. The reported average daily trading volume in our common stock on the ASX (in the form of CDIs) for the three-month period ended December 31, 2011, was approximately 1,261 shares. All of our shares of common stock that we have sold have been sold in reliance on exemptions from registration under the Securities Act and must be resold pursuant to exemptions from registration under the Securities Act and applicable state laws or must be registered for resale under the Securities Act and applicable state laws. We are not obligated to register any of our stockholders shares under the Securities Act or otherwise.

Although we have listed shares of common stock on Nasdaq Capital Market and intend to file with the SEC registration statements on Form S-8 covering approximately 1 million shares of our common stock issuable under our equity plans, there can be no assurance that a liquid public market for our shares will develop in the United States. If an active trading market does not develop in the United States, the market price and liquidity of our shares may be adversely affected.

The price of our common stock may fluctuate significantly.

Our common stock in the form of CDIs has been traded on the ASX in the form of CDIs since 2004. The price of our common stock has been, and is likely to continue to be, volatile, which means that it could decline substantially within a short period of time. For example, our closing per CDI price ranged from A$6.00 to A$12.60 for the 12 months ended December 31, 2011. The price of our common stock could fluctuate significantly for many reasons, including the following:

- future announcements concerning us or our competitors;
- regulatory developments, enforcement actions bearing on advertising, marketing or sales, and disclosure regarding completed, ongoing or future clinical trials;
- quarterly variations in operating results, which we have experienced in the past and expect to experience in the future;
- introduction of new products;
- acquisition or loss of significant manufacturers, distributors or suppliers;
- business acquisitions or divestitures;
- changes in third-party reimbursement practices;
- fluctuations of investor interest in the medical device sector; and

- fluctuations in the economy, world political events or general market conditions.

In addition, stock markets in general and the market for shares of health care stocks in particular, have experienced extreme price and volume fluctuations in recent years, fluctuations that frequently have been unrelated to the operating performance of the affected companies. These broad market fluctuations may adversely affect the market price of our common stock. The market price of our common stock could decline below its current price and the market price of our shares may fluctuate significantly in the future. These fluctuations may be unrelated to our performance.

Our directors and executive officers hold substantial control over us and could limit your ability to influence the outcome of key transactions, including changes of control.

As of March 19, 2012, our executive officers and directors and entities affiliated with them beneficially owned, in the aggregate (including options or warrants exercisable currently or within 60 days of March 19, 2012), approximately 51.8% of our outstanding common stock. Our executive officers, directors and affiliated entities, if acting together, would be able to control all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other significant corporate transactions. The concentration of ownership of our common stock may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders and CDI holders of an opportunity to receive a premium for their common stock and CDIs as part of a sale of our company and may affect the market price of our common stock and CDIs. This significant concentration of stock ownership may adversely affect the trading price of our common stock and CDIs due to investors' perception that conflicts of interest may exist or arise.

If there are substantial sales of shares of our common stock, our share price could decline.

If our existing stockholders sell a large number of shares of our common stock or CDIs if the public market, should one develop, perceives that existing stockholders might sell a large number of shares or CDIs the price at which our common stock or CDIs trade could decline significantly. Sales of substantial amounts of our common stock by stockholders in the public market, or even the potential for such sales, are likely to adversely affect the market price of our common stock and CDIs.

We do not intend to pay cash dividends on our common stock in the foreseeable future.

We have never declared or paid any cash dividends on our common stock, and we currently do not anticipate paying any cash dividends in the foreseeable future. We intend to retain any earnings to finance the development and expansion of our products and business. Accordingly, our stockholders and CDI holders will not realize a return on their investment unless the trading price of our common stock and CDIs appreciate.

We may be subject to arbitrage risks.

Investors may seek to profit by exploiting the difference, if any, between the price of our CDIs on the ASX and the price of our shares available for sale in the U.S., whether such sales would take place on a U.S. securities exchange or in the over-the-counter market or otherwise. Such arbitrage activities could cause our share price in the market with the higher value to decrease to the price set by the market with the lower value.

Investors could lose confidence in our financial reports, and the value of our common stock may be adversely affected, if our internal controls over financial reporting are found not to be effective by management or by an independent registered public accounting firm or if we make disclosure of existing or potential significant deficiencies or material weaknesses in those controls.

In connection with becoming a company required to file reports with the SEC, we will be required to comply with the internal control evaluation and certification requirements of Section 404 of the Sarbanes-Oxley Act of 2002. We continue to evaluate our existing internal controls over financial reporting against the standards adopted by the Public Company Accounting Oversight Board. During the course of our ongoing evaluation of the internal controls, we may identify areas requiring improvement, and may have to design enhanced processes and controls to address issues identified through this review. Remediating any deficiencies, significant deficiencies or material weaknesses that we or our independent registered public accounting firm may identify may require us to incur significant costs and expend significant time and management resources. We cannot assure you that any of the

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measures we implement to remedy any such deficiencies will effectively mitigate or remedy such deficiencies. The existence of one or more material weaknesses could affect the accuracy and timing of our financial reporting. Investors could lose confidence in our financial reports, and the value of our common stock and CDIs may be adversely affected, if our internal controls over financial reporting are found not to be effective by management or by an independent registered public accounting firm or if we make disclosure of existing or potential significant deficiencies or material weaknesses in those controls.

Our certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with the Company.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, or (iv) any other action asserting a claim governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions described above. This forum selection provision may limit our stockholders' ability to obtain a judicial forum that they find favorable for disputes with us or our directors, officers or other employees or stockholders.

Our certificate of incorporation, bylaws and the Delaware General Corporation Law may delay or deter a change of control transaction.

Certain provisions of our certificate of incorporation and bylaws may have the effect of deterring takeovers, such as those provisions authorizing our board of directors to issue, from time to time, any series of preferred stock and fix the designation, powers, preferences and rights of the shares of such series of preferred stock; prohibiting stockholders from acting by written consent in lieu of a meeting; requiring advance notice of stockholder intention to put forth director nominees or bring up other business at a stockholders' meeting; prohibiting stockholders from calling a special meeting of stockholders; requiring a 66 2/3% majority stockholder approval in order for stockholders to amend certain provisions of our certificate of incorporation or bylaws or adopt new bylaws; providing that, subject to the rights of preferred shares, the directors will be divided into three classes and the number of directors is to be fixed exclusively by our board of directors; and providing that none of our directors may be removed without cause. Section 203 of the Delaware General Corporation Law, from which we did not elect to opt out, provides that if a holder acquires 15% or more of our stock without prior approval of our board of directors, that holder will be subject to certain restrictions on its ability to acquire us within three years. These provisions may delay or deter a change of control of us, and could limit the price that investors might be willing to pay in the future for shares of our common stock.

It may be difficult to effect service of United States process and enforce United States legal process against our directors.

Five of our eight directors reside outside of the United States, principally in the Commonwealth of Australia. A substantial portion of the assets of our directors also are located outside of the United States. Therefore, it may not be possible to effect service of process within the United States upon these persons in order to enforce judgments of U.S. courts against these persons based on the civil liability provisions of the U.S. federal securities laws. In addition, there is doubt as to the enforceability in Australia, in original actions or in actions to enforce judgments of U.S. courts, of claims predicated solely upon U.S. federal securities laws.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We lease a 10,000 square foot facility in Eden Prairie, Minnesota that previously housed our corporate headquarters and substantially all of our functional areas, with the exception of a portion of our research and development activities. The lease expires September 30, 2012 and requires a monthly payment of approximately

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$11,000. On October 21, 2011 we entered into a lease for a 23,000 square foot facility also located in Eden Prairie, Minnesota. The lease period commenced December 1, 2011 and extends through March 31, 2016. This facility houses substantially all of our functional areas and replaced our corporate headquarters previously located at our other leased facility in Eden Prairie. Monthly rent and electricity for our new headquarters total approximately $21,000.

We believe that our current facilities are suitable and adequate to meet our current needs, and that suitable additional or substitute space will be available as needed to accommodate expansion of our operations.

Item 3. Legal Proceedings

We are not currently subject to any material legal proceedings. We believe that we have obtained adequate insurance coverage or rights to indemnification in connection with potential legal proceedings that may arise.

Item 4. Mine Safety Disclosures

Not applicable.

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PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information. Commencing February 16, 2012, our shares of common stock began trading on the Nasdaq Capital Market under the symbol "SSH." Our shares of common stock have also traded in the form of CDIs on the ASX under the symbol "SHC" since September 2004.

The following table sets forth, for the periods indicated, the high and low closing prices for our CDIs as reported on the ASX, in Australian dollars and as converted into U.S. Dollars. All currency conversions are based on the prevailing Australian dollar to the U.S. Dollar rate on the last day of each respective quarter.

Period	High (A$)	Low (A$)	High (US$)	Low (US$)
Year Ended December 31, 2011:				
First Quarter	9.00	6.00	9.40	6.20
Second Quarter	12.60	7.80	13.60	8.40
Third Quarter	11.00	7.00	10.80	6.80
Fourth Quarter	9.40	6.40	9.20	6.60
Year Ended December 31, 2010:				
First Quarter	8.20	6.20	8.00	6.00
Second Quarter	7.40	5.80	6.20	4.80
Third Quarter	7.20	4.60	7.00	4.40
Fourth Quarter	7.80	4.60	8.00	4.80

Stockholders of Record. As of March 16, 2012, we had 6,276,538 shares of common stock issued and outstanding, and there were 31 holders of record of our common stock. One stockholder of record, CHESS Depositary Nominees, or CDN, held shares of our common stock on behalf of approximately 1,185 CDI holders.

Dividends. We have not historically paid dividends on our common stock. We intend to retain our future earnings, if any, to finance the expansion and growth of our business, and we do not expect to pay cash dividends on our common stock in the foreseeable future. Payment of future cash dividends, if any, will be at the sole discretion of our board of directors after taking into account various factors, including our financial condition, earnings, capital requirements of our operating subsidiaries, covenants associated with any debt obligations, legal requirements, regulatory constraints and other factors deemed relevant by our board of directors. Moreover, if we determine to pay any dividend in the future, there can be no assurance that we will continue to pay such dividends.

Unregistered Sales of Equity Securities

We issued the securities indicated below, which were not registered under the Securities Act, during the period covered by this Annual Report on Form 10-K.

Name or Class of Person to Whom Sold	Type of Securities	Amount of Securities	Date of Sale	Exercise Price per Share	Aggregate Offering Consideration

Institutional and high net worth Australian investors	Common Stock	17,858 Common Shares	1/25/11	N/A	A$	100,000
Institutional and high net worth Australian investors	Common Stock	119 Common Shares	1/25/11	N/A	A$	759

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Name or Class of Person to Whom Sold	Type of Securities	Amount of Securities	Date of Sale	Exercise Price per Share	Aggregate Offering Consideration	
Institutional and high net worth Australian investors	Common Stock	140 Common Shares	2/22/11	N/A	A$	891
Institutional and high net worth Australian investors	Common Stock	6,900 Common Shares	5/9/11	N/A	A$	44,157
Institutional and high net worth Australian investors	Common Stock	5,000 Common Shares	5/23/11	N/A	A$	32,000
Institutional and high net worth Australian investors	Common Stock	53 Common Shares	6/6/11	N/A	A$	335
Malcolm Legget	Common Stock	194 Common Shares	6/22/11	N/A	A$	586
Accredited Investors party to Securities Purchase Agreement dated 7/25/11	Common Stock and Warrants to purchase Common Stock	572,222 Common Shares 171,667 Warrants	7/27/11	A$8.00 per share purchase price for Common Stock A$11.20 per share exercise price for Warrants	A$	4,577,774
Summer Street Research Partners	Warrants to purchase Common Stock	9,091 Warrants	7/27/11	A$8.00		N/A
Institutional and high net worth Australian investors	Common Stock and Warrants to purchase Common Stock	154,030 Common Shares 46,209 Warrants	9/9/11	A$8.00 per share purchase price for Common Stock A$11.20 per share exercise price for Warrants	A$	1,232,240
Accredited Investors party to Securities Purchase Agreement dated 7/25/11	Common Stock and Warrants to purchase Common Stock	125,000 Common Shares 37,500 Warrants	9/13/11	A$8.00 per share purchase price for Common Stock A$11.20 per share exercise price for Warrants	A$	1,000,000

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Name or Class of Person to Whom Sold	Type of Securities	Amount of Securities	Date of Sale	Exercise Price per Share	Aggregate Offering Consideration	
Accredited Investors party to Securities Purchase Agreement dated 7/25/11	Common Stock and Warrants to purchase Common Stock	70,414 Common Shares	9/16/11	A$8.00 per share purchase price for Common Stock	A$	563,309

		21,125 Warrants		A$11.20 per share exercise price for Warrants		
Summer Street Research Partners	Warrants to Purchase Common Stock	1,532 Warrants	9/16/11	A$8.00		N/A
Institutional and high net worth Australian Investors	Common Stock	2,581	9/23/11	N/A	A$	16,514
Australian Investor under employee stock option agreement	Common Stock	266	9/23/11	N/A	A$	1,858
Institutional and high net worth Australian Investors	Common Stock	86 Common Shares	11/2/11	N/A	A$	549
Australian Investor under employee stock option agreement	Common Stock	591 Common Shares	11/2/11	N/A	A$	4,136

Shares of our common stock indicated in the table above were issued in the form of CDIs.

No underwriters were used in connection with the transactions described above. Summer Street Research Partners and Matthew Dormer were the placement agents for the July 27, 2011 transaction. The securities issued to the placement agents were made in reliance upon Section 4(2) of the Securities Act because no public offering of the securities was made and the placement agents are sophisticated persons with adequate information about us and the securities were not acquired with a view to any distribution thereof, and appropriate legends were affixed to the share certificates and instruments issued in such sales. All other sales other than to the placement agents were for cash.

The transactions described above that occurred on July 27, 2011, September 13, 2011 and September 16, 2011 were made in reliance upon the exemption from registration requirements of the Securities Act available under Section 4(2) of the Securities Act and Rule 506 of Regulation D. The purchasers of the securities in these transactions made in reliance upon Section 4(2) of the Securities Act and Rule 506 of Regulation D represented that they were sophisticated persons and that they intended to acquire the securities for investment only and not with a view to, or for sale in connection with, any distribution thereof, and appropriate legends were affixed to the share certificates and instruments issued in such sales. We believe that these purchasers either received adequate information about us or had adequate access, through their relationships with us, to such information.

The transactions described above that occurred on each of January 25, 2011, February 22, 2011, May 9, 2011, May 23, 2011, June 6, 2011, June 22, 2011, September 9, 2011, September 23, 2011 (to institutional and high net worth Australian investors) and November 2, 2011 (to institutional and high net worth Australian investors) were made in reliance upon the exemption from registration requirements of the Securities Act available under Rule 903 of Regulation S. The purchasers of the securities in these transactions represented that they were outside of the United States when each such person originated its buy order for the securities, no offers were made to persons in the United States, the Company implemented the offering restrictions required by Regulation S, the purchasers

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agreed to offer or sell the securities acquired only in compliance with the restrictions and conditions imposed by Regulation S during the applicable distribution compliance period and we agreed to refuse to register any transfer of the securities not made in accordance with Regulation S, pursuant to registration under the Securities Act, or pursuant to an available exemption from registration.

All other sales of common stock described above were made pursuant to the exercise of stock options granted under our 2002 Stock Plan to our officers, directors, employees and consultants in reliance upon an available exemption from the registration requirements of the Securities Act, including those contained in Rule 701 promulgated under Section 3(b) of the Securities Act. Among other things, we relied on the fact that, under Rule 701, companies that are not subject to the reporting requirements of Section 13 or Section 15(d) of the Exchange Act are exempt from registration under the Securities Act with respect to certain offers and sales of securities pursuant to “compensatory benefit plans” as defined under that rule. We believe that the 2002 Stock Plan qualifies as a “compensatory benefit plan” under Rule 701.

The following table sets forth information on the stock options issued by us to our officers, directors, employees and consultants during the period covered by this Annual Report on Form 10-K.

Date of Issuance	Number of Options Granted	Exercise Price per Share	
8/18/11	595,590	A$	7.00
8/18/11	15,000	A$	10.40
8/19/11	29,210	A$	12.80
11/2/11	88,755	A$	8.20
11/29/11	66,370	A$	8.20

No consideration was paid to us by any recipient of any of the foregoing options for the grant of such options. All of the stock options described above were granted under our 2011 Equity Incentive Plan to our officers, directors, employees and consultants in reliance upon an available exemption from the registration requirements of the Securities Act, including those contained in Rule 701 promulgated under Section 3(b) of the Securities Act. Among other things, we relied on the fact that, under Rule 701, companies that are not subject to the reporting requirements of Section 13 or Section 15(d) of the Exchange Act are exempt from registration under the Securities Act with respect to certain offers and sales of securities pursuant to “compensatory benefit plans” as defined under that rule. We believe that our 2011 Equity Incentive Plan qualify as a compensatory benefit plans.

Use of Proceeds from Sales of Registered Securities

None.

Stock Repurchases

None.

Item 6. Selected Financial Data

Not applicable.

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Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with our audited financial statements and related notes which are included elsewhere in this Annual Report on Form 10-K. Our actual results could differ materially from those anticipated in the forward-looking statements included in this discussion as a result of certain factors, including, but not limited to, those discussed in "Risk Factors" included elsewhere in this Annual Report on Form 10-K.

Overview

We are an early-stage medical device company focused on developing, manufacturing and commercializing our C-Pulse Heart Assist System for treatment of Class III and ambulatory Class IV heart failure. The C-Pulse Heart Assist System utilizes the scientific principles of intra-aortic balloon counter-pulsation applied in an extra-aortic approach to assist the left ventricle by reducing the workload required to pump blood throughout the body, while increasing blood flow to the coronary arteries.

We are in the process of obtaining regulatory approvals necessary to sell our product. We completed enrollment of the feasibility phase of our clinical trial in the first half of 2011. In November 2011, we obtained the results of the six-month follow-up period for the feasibility phase and we submitted the clinical data to the United States Food and Drug Administration, or FDA. In March 2012, the FDA notified us that it completed its review of the C-Pulse feasibility trial data, concluded we met the applicable agency requirements and indicated that we can move forward with an IDE application. We expect to submit an IDE application to the FDA in the first half of 2012 for approval to initiate our pivotal trial. We expect to complete our pivotal trial in 2015 and do not anticipate marketing our product in the U.S. before 2016.

We are seeking CE Mark for the C-Pulse and anticipate that we will obtain approval in the middle of 2012. We have taken initial steps to evaluate the potential market for our product in targeted countries in Europe in anticipation of commencing commercial sales of the C-Pulse in Europe following CE Mark approval.

Critical Accounting Policies and Estimates

Revenue Recognition: We recognize revenue when (i) persuasive evidence of a customer arrangement exists; (ii) the price is fixed or determinable and free of contingencies or uncertainties; (iii) collectability is reasonably assured; and (iv) product delivery has occurred, which is when product title transfers to the customer, or services have been rendered. Sales are not conditional based on customer acceptance provisions or installation obligations. Our C-Pulse Heart Assist System is not approved for commercial sale. Our revenue consists solely of sales of the C-Pulse to hospitals and clinics under contract in conjunction with our clinical trials. For clinical trial implant revenue, the product title generally transfers on the date the product is implanted. We do not charge hospitals and clinics for shipping. We expense shipping costs at the time we report the related revenue and record such costs in cost of sales.

Foreign Currency Translation and Transactions: Foreign denominated monetary assets and liabilities are translated at the rate of exchange prevailing at the balance sheet date. Results of operations are translated using the average rates prevailing during the reporting period. Our Australian subsidiary's functional currency is the Australian Dollar. Translation adjustments result from translating the subsidiary's financial statements into our reporting currency, the U.S. Dollar. The translation adjustment has not been included in determining our net loss, but has been reported separately and is accumulated in a separate component of equity.

Effective January 1, 2011, we concluded that the functional currency of our U.S. based parent company is the U.S. Dollar. We have concluded that the functional currency of the Australian subsidiary remains the Australian Dollar.

Comprehensive Income (Loss): The components of comprehensive income (loss) include net income (loss) and the effects of foreign currency translation adjustments.

Stock-Based Compensation: We recognize all share-based payments, including grants of stock options in the income statement as an operating expense based on their fair value over the requisite service period.

We compute the estimated fair values of stock options using the Black-Scholes option pricing model. No tax benefit has been recorded due to the full valuation allowance on deferred tax assets that we have recorded.

Stock-based compensation expense is based on awards ultimately expected to vest and is reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Equity instruments issued to non-employees, and for services and goods, are shares of our common stock, warrants or options to purchase shares of our common stock. These shares, warrants or options are either fully-vested and exercisable at the date of grant or vest over a certain period during which services are provided. We expense the fair market value of these securities over the period in which the related services are received.

Going Concern: Our financial statements have been prepared and presented on a basis assuming we continue as a going concern.

During the years ended December 31, 2011 and 2010, we incurred losses from operations and net cash outflows from operating activities as disclosed in the consolidated statements of operations and cash flows, respectively.

Our ability to continue as a going concern is dependent on our ability to raise additional capital based on the achievement of existing milestones as and when required. Our directors, after due consideration, believe that we will be able to raise new equity capital as required to fund our business plan. Should the future capital raising not be successful, we may not be able to continue as a going concern. Furthermore, our ability to continue as a going concern is subject to our ability to develop and successfully commercialize the product being developed. If we are unable to obtain such funding of an amount and timing necessary to meet our future operational plans, or to successfully commercialize our intellectual property, we 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 we not continue as a going concern.

Recent Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board, or FASB, issued additional guidance for the presentation of comprehensive income. The new guidance changes the way other comprehensive income ("OCI") appears within the financial statements. Companies will be required to show net income, OCI and total comprehensive income in one continuous statement or in two separate but consecutive statements. Components of OCI may no longer be presented solely in the statement of changes in shareholders' equity. Any reclassification between OCI and net income will be presented on the face of the financial statements. The new guidance is effective for our company beginning January 1, 2012. The adoption of the new guidance will not impact the measurement of net income or other comprehensive income.

In May 2011, FASB issued ASU 2011-04, *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS.* This accounting update generally aligns the principles for fair value measurements and the related disclosure requirements under U.S. GAAP and International Financial Reporting Standards. From a U.S. GAAP perspective, the amendments are largely clarifications, but some could have a significant effect on certain companies. A number of new disclosures also are required. Except for certain disclosures, the guidance applies to public and nonpublic companies and is to be applied prospectively. For public companies and nonpublic companies, the amendments are effective during interim and annual periods beginning after December 15, 2011. Early adoption by public companies is not permitted. Nonpublic companies may apply the amendments early, but no earlier than for interim periods beginning after December 15, 2011.

Financial Overview

We are an early-stage medical device company focused on developing, manufacturing and commercializing our C-Pulse Heart Assist System for treatment of Class III and ambulatory Class IV heart failure. Our activities since inception have consisted principally of raising capital, performing research and development and conducting preclinical and clinical trials. At December 31, 2011, we had an accumulated deficit of $65.2 million and we expect to incur losses for the foreseeable future. To date, we have been funded by private and public equity financings. Although we believe that we will be able to successfully fund our operations, there can be no assurance that we will be able to do so or that we will ever operate profitably.

Results of Operations

Comparison of Year Ended December 31, 2011 to Year Ended December 31, 2010

Revenue

Year Ended December 31, 2011	Year Ended December 31, 2010	Increase (Decrease)	% Change
$ —	$ 407,000	$ (407,000)	N/A

Our decrease in revenue for the year ended December 31, 2011 compared to the prior year was primarily caused by completion of enrollment in our feasibility clinical trial in March 2011, after which we had no reimbursable implants. Our revenue during the year ended December 31, 2010 consisted solely of sales of the C-Pulse System to hospitals and clinics under contract in conjunction with our feasibility trial. We expect our revenue will be minimal until we begin enrolling patients in our pivotal clinical trial, expected to commence in the second half of 2012.

Research and Development Expense

Year Ended December 31, 2011	Year Ended December 31, 2010	Increase (Decrease)	% Change
$ 11,199,000	$ 6,229,000	$ 4,970,000	79.8%

Our increase in research and development expense for the year ended December 31, 2011 compared to the prior year was primarily caused by increased development activities related to our C-Pulse device and the accelerated development of a fully implantable model. We also increased regulatory and clinical personnel to support the completion of our feasibility clinical trial and to prepare for our pivotal clinical trial. We expect our research and development expense will increase in future periods as we add personnel to support our pivotal clinical trial and pursue our development efforts.

Selling, General and Administrative Expense

Year Ended December 31, 2011	Year Ended December 31, 2010	Increase (Decrease)	% Change
$ 5,363,000	$ 2,598,000	$ 2,765,000	106.4%

Our increase in selling, general and administrative expense for the year ended December 31, 2011 compared to the prior year was primarily caused by increased stock-based compensation expense resulting from current year stock option grants, and increased professional fees and personnel costs as we develop our infrastructure and prepared for our pivotal clinical and Nasdaq listing. We expect our selling, general and administrative expense will increase in future periods as we further develop our infrastructure, invest in developing a sales force in Europe and incur professional fees and expenses associated with being listed on both the Nasdaq Capital Market and the ASX.

Interest Income

Year Ended December 31, 2011	Year Ended December 31, 2010	Increase (Decrease)	% Change
$ 251,000	$ 150,000	$ 101,000	67.3%

Our increase in other income for the year ended December 31, 2011 compared to the prior year was primarily caused by increased interest income earned from our increased average cash balances following the completion of our financings in late 2010 and mid-2011.

Income Tax Benefit

Year Ended December 31, 2011	Year Ended December 31, 2010	Increase (Decrease)	% Change
$ (115,000)	$ (670,000)	$ (555,000)	82.8%

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Our tax income benefit for the year ended December 31, 2011 resulted from a research and development credit in the state of Minnesota for our tax year ended June 30, 2011. Our income tax benefit for the year ended December 31, 2010 resulted from a research and development tax credit in Australia. We have not completed the tax return for our Australian subsidiary for the year ended June 30, 2011 and cannot be sure that the research and development expenditures of our subsidiary during that period will be less than the A$2 million threshold that results in a tax refund rather than a tax credit, for which we would maintain a full valuation allowance. During 2011, Australian authorities amended the applicable law relating to research and development tax credits and, assuming no further changes to the applicable law, we expect to receive tax refunds in the future in amounts that vary based on research and development expenditures in Australia.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations primarily through a series of equity issuances, including the issuance of common shares in the form of CDIs for net proceeds of $7.6 million in 2011 and $11.9 million in 2010. As of December 31, 2011 and 2010, cash and cash equivalents were $6.6 million and $12.4 million, respectively. Subsequent to December 31, 2011, we received net proceeds of $2.1 million from the issuance of additional common shares in the form of CDIs.

We believe that our cash on hand will be sufficient to fund our operations through substantially all of the first half of 2012 as we prepare for the pivotal clinical trial, but that we will require additional financing within the next 12 months to sufficiently fund our operations. We expect to obtain additional financing as needed through sales of our common stock or other securities. Although we have successfully financed our operations through the issuance of common stock to date, we cannot be assured that we will be able to continue to be successful in financing our operations in the future.

Cash Flows from Operating Activities

Net cash used in operating activities was $13.1 million and $7.2 million in 2011 and 2010, respectively. The net cash used in each of these periods primarily reflects the net loss for those periods, offset in part by depreciation, non-cash, stock-based compensation and the effects of changes in operating assets and liabilities.

Cash Flows from Investing Activities

Net cash used in investing activities was $451,000 and $7,000 in 2011 and 2010, respectively. The majority of cash used in investing activities in 2011 was for leasehold improvements, furniture and equipment associated with the relocation of our headquarters. Cash used in investing activities in 2010 related to purchases of property and equipment.

Cash Flows from Financing Activities

Net cash provided by financing activities was $7.6 million and $11.9 million in 2011 and 2010, respectively. Net cash provided by financing activities was primarily attributable to proceeds from sales of our common stock.

Capital Resource Requirements

As of December 31, 2011, we did not have any material commitments for capital expenditures.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

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Item 8. Financial Statements and Supplementary Data

Report of Independent Registered Public Accounting Firm

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Sunshine Heart, Inc.

We have audited the accompanying consolidated balance sheets of Sunshine Heart, Inc. and subsidiary as of December 31, 2011 and 2010, and the related statements of operations, stockholders' equity, and cash flows for each of the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Sunshine Heart, Inc. at December 31, 2011 and 2010, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company's recurring losses from operations and projected future capital requirements raise substantial doubt about its ability to continue as a going concern. The financial statements do not contain any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

Minneapolis, Minnesota
March 23, 2012

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SUNSHINE HEART, INC. AND SUBSIDIARY

Consolidated Balance Sheets

Dollars in thousands, except per share amounts	Dec 31, 2011	Dec 31, 2010
Current assets		
Cash and cash equivalents	$ 6,563	$ 12,350
Accounts receivable, net	—	247
Other current assets	346	182
Total current assets	**6,909**	**12,779**
Property, plant and equipment	**522**	**120**
TOTAL ASSETS	**$ 7,431**	**$ 12,899**
Current liabilities		
Accounts payable	$ 1,857	$ 696
Accrued salaries, wages, and other compensation	978	114
Total current liabilities	**2,835**	**810**
Total liabilities	**2,835**	**810**
Stockholders' equity		
Preferred stock as of December 31, 2011 and December 31, 2010, $0.0001 par value per share; authorized 40,000,000 shares	—	—
Common stock as of December 31, 2011 and December 31, 2010, par value $0.0001 per share; authorized 100,000,000 shares; issued and outstanding 6,019,663 and 5,063,968, respectively	1	1
Additional paid-in capital	68,652	60,086
Accumulated other comprehensive income:		
Foreign currency translation adjustment	1,132	995

Accumulated deficit	(65,189)	(48,993)
Total stockholders' equity	**4,596**	**12,089**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 7,431**	**$ 12,899**

See notes to the consolidated financial statements

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SUNSHINE HEART, INC. AND SUBSIDIARY

Consolidated Statements of Operations

In thousands, except per share amounts	Year ended Dec 31, 2011	Year ended Dec 31, 2010
Net sales	**$ —**	**$ 407**
Operating expenses		
Selling, general and administrative	5,363	2,598
Research and development	11,199	6,229
Total operating expenses	16,562	8,827
Loss from operations	**(16,562)**	**(8,420)**
Interest income	251	150
Loss before income taxes	**(16,311)**	**(8,270)**
Income tax benefit	**115**	**(670)**
Net loss	**$ (16,196)**	**$ (7,600)**
Basic and diluted loss per share	**$ (2.98)**	**$ (2.63)**
Weighted average shares outstanding - basic and diluted	**5,442**	**2,885**

See notes to the consolidated financial statements

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SUNSHINE HEART, INC. AND SUBSIDIARY

Consolidated Statements of Stockholders' Equity

(In thousands)	Outstanding Shares	Common Stock	Additional Paid in Capital	Accumulated Other Comprehensive Income Foreign Currency Translation Adjustment	Accumulated Deficit	Stockholders' Equity
Balance December 31, 2009	**2,696**	**$ —**	**$ 48,092**	**$ 372**	**$ (41,393)**	**$ 7,071**
Comprehensive loss:						
Net loss					(7,600)	(7,600)
Foreign currency translation adjustment				623		623
Total comprehensive loss						(6,977)
Stock based compensation			78			78
Issuance of common stock, net	2,368	1	11,916			11,917
Balance December 31, 2010	**5,064**	**1**	**60,086**	**995**	**(48,993)**	**12,089**
Comprehensive loss:						
Net loss					(16,196)	(16,196)
Foreign currency translation adjustment				137		137
Total comprehensive loss						(16,059)
Stock based compensation			939			939
Issuance of common stock, net	955		7,627			7,627
Balance December 31, 2011	**6,019**	**$ 1**	**$ 68,652**	**$ 1,132**	**$ (65,189)**	**$ 4,596**

See notes to the consolidated financial statements

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SUNSHINE HEART, INC. AND SUBSIDIARY

Consolidated Statements of Cash Flows

(In thousands)	Year ended Dec 31, 2011	Year ended Dec 31, 2010
Net loss	$ (16,196)	$ (7,600)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	50	32
Stock based compensation expense	939	78
Changes in asset and liabilities:		
Accounts receivable	258	(123)
Other current assets	(166)	(94)
Accounts payable and accrued expenses	2,026	496
Net cash used in operations	**(13,089)**	**(7,210)**
Cash flows used in investing activities:		
Purchase of property and equipment	(451)	(7)
Net cash used in investing activities	**(451)**	**(7)**
Cash flows provided by financing activities:		
Net proceeds from the sale of common stock	7,627	11,917
Net cash provided by financing activities	**7,627**	**11,917**
Effect of exchange rate changes on cash	126	623
Net increase (decrease) in cash and cash equivalents	(5,787)	5,322
Cash and cash equivalents - beginning of period	12,350	7,028
Cash and cash equivalents - end of period	**$ 6,563**	**$ 12,350**

See notes to the consolidated financial statements

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SUNSHINE HEART, INC. AND SUBSIDIARY

Notes to Consolidated Financial Statements

(in thousands, except share and per share data)

Note 1 - Nature of Business and Significant Accounting Policies

Nature of Business: Sunshine Heart ("we" or the "Company") was founded in November 1999 and incorporated in Delaware in August 2002. We are headquartered in Eden Prairie, MN and have a wholly owned subsidiary, Sunshine Heart Company Pty Ltd, located in St Leonards, New South Wales, Australia. We are a medical device company developing innovative technologies for cardiac and coronary disease. The Company's primary product, the C-Pulse® Heart Assist System, is an implantable, non-blood contacting, heart assist therapy for the treatment of moderate to severe heart failure which can be implanted using a minimally invasive procedure. C-Pulse is designed to relieve the symptoms of heart failure through the use of counter-pulsation technology by enabling 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 U.S. Food and Drug Administration to conduct a U.S. feasibility clinical trial with the C-Pulse System. Our shares of common stock in the form of CHESS Depositary Interests (CDIs) have been publicly traded in Australia on the Australian Securities Exchange (ASX) since September 2004.

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

During the years ended December 31, 2011 and 2010, the Company incurred losses from operations and net cash outflows from operating activities as disclosed in the consolidated statements of operations and cash flows, respectively. At December 31, 2011, we had an accumulated deficit of $65.2 million and we expect to incur losses for the foreseeable future. To date, we have been funded by private and public equity financings. Although we believe that we will be able to successfully fund our operations, there can be no assurance that we will be able to do so or that we will ever operate profitably.

The Company's ability to continue as a going concern is dependent on the Company's ability to raise additional capital based on the achievement of existing milestones as and when required. Should the future capital raising not be successful, the Company may not be able to continue as a going concern. Furthermore, the ability of the Company to continue as a going concern is subject to the ability of the Company to develop and successfully commercialize the product being developed. If the Company is unable to obtain such funding of an amount and timing necessary to meet its future operational plans, or to successfully commercialize its intellectual property, the Company 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 Company not continue as a going concern.

Basis of Presentation: The accompanying consolidated financial statements include the accounts of Sunshine Heart, Inc. and its wholly-owned subsidiary, Sunshine Heart Company Pty Ltd. (collectively, "Sunshine Heart" or the "Company"). All inter-company accounts and transactions between

consolidated entities have been eliminated.

Use of Estimates: The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts and disclosures in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

Fair Value of Financial Instruments: Our financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities. We believe that the carrying amounts of the financial instruments approximate their respective current fair values due to their relatively short maturities.

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Pursuant to the requirements of the Fair Value Measurements and Disclosures Topic of the FASB Codification, the Company's financial assets and liabilities measured at fair value on a recurring basis are classified and disclosed in one of the following three categories:

Level 1: Financial instruments with unadjusted quoted prices listed on active market exchanges.

Level 2: Financial instruments lacking unadjusted, quoted prices from active market exchanges, including over the counter traded financial instruments. The prices for the financial instruments are determined using prices for recently traded financial instruments with similar underlying terms as well as directly or indirectly observable inputs, such as interest rates and yield curves that are observable at commonly quoted intervals.

Level 3: Financial instruments that are not actively traded on a market exchange. This category includes situations where there is little, if any, market activity for the financial instrument. The prices are determined using significant unobservable inputs or valuation techniques.

All cash and cash equivalents are considered Level 1 measurements for all periods presented. We do not have any financial instruments classified as Level 2 or Level 3 and there were no movements between these categories.

Cash and Cash Equivalents: Cash and cash equivalents consist of cash, money market funds and term deposits with original maturities of three months or less. The carrying value of these instruments approximates fair value. The balances, at times, may exceed federally insured limits. We have not experienced any losses on our cash and cash equivalents.

Accounts Receivable: Accounts receivable are unsecured, are recorded at net realizable value, and do not bear interest. We make judgments as to our ability to collect outstanding receivables based upon significant patterns of uncollectiblity, historical experience, and managements' evaluation of specific accounts and will provide an allowance for credit losses when collection becomes doubtful. The Company performs credit evaluations of its customers' financial condition on an as-needed basis. Payment is generally due 30 days from the invoice date and accounts past 30 days are individually analyzed for collectability. When all collection efforts have been exhausted, the account is written off against the related allowance. No allowance for doubtful accounts was considered necessary as of December 31, 2011 or December 31, 2010.

Other Current Assets: Other current assets represent prepayments and deposits made by the Company.

Property, Plant and Equipment: Property and equipment is stated at cost less accumulated depreciation. Depreciation is computed based upon the estimated useful lives of the respective assets. Leasehold improvements are amortized using the straight-line method over the shorter of the lease term or the estimated useful life of the assets. Repairs and maintenance costs are expensed as incurred. Major betterments and improvements, which extend the useful life of the item, are capitalized and depreciated. The cost and accumulated depreciation of property, plant and equipment retired or otherwise disposed of are removed from the related accounts, and any residual values are charged or credited to expenses. Depreciation expense has been calculated using the following estimated useful lives:

Office furniture and equipment	5-15 years
Computer software and equipment	3-4 years
Laboratory and research equipment	3-15 years
Production equipment	7 years

Depreciation expense was $49 and $32 for the years ended December 31, 2011 and 2010, respectively.

Impairment of Long-lived Assets: Long-lived assets, such as property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If the impairment tests indicate that the carrying value of the asset is greater than the expected undiscounted cash flows to be generated by such asset, an impairment loss would be recognized. The impairment loss is determined as the amount by which the carrying value of such asset exceeds its fair value. We generally measure fair value by considering sale prices for similar assets or by discounting estimated future cash flows from such assets using an appropriate discount rate. Assets to be disposed of are carried at the lower of their carrying

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value or fair value less costs to sell. Considerable management judgment is necessary to estimate the fair value of assets, and accordingly, actual results could vary significantly from such estimates. There have been no impairment losses for long-lived assets, for the years ended December 31, 2011 and 2010.

Revenue Recognition: We recognize revenue when (i) persuasive evidence of a customer arrangement exists; (ii) the price is fixed or determinable and free of contingencies or uncertainties; (iii) collectability is reasonably assured; and (iv) product delivery has occurred, which is when product title transfers to the customer, or services have been rendered. Sales are not conditional based on customer acceptance provisions or installation obligations. Our C-Pulse Heart Assist System is not approved for commercial sale. Our revenue consists solely of sales of the C-Pulse to hospitals and clinics under contract in

conjunction with our clinical trials. For clinical trial implant revenue, the product title generally transfers on the date the product is implanted. We do not charge hospitals and clinics for shipping. We expense shipping costs at the time we report the related revenue and record them in cost of sales.

Foreign Currency Translation and Transactions: Foreign denominated monetary assets and liabilities are translated at the rate of exchange prevailing at the balance sheet date. Results of operations are translated using the average rates prevailing during the reporting period. The translation adjustment has not been included in determining the Company's net loss, but has been reported separately and is accumulated in a separate component of equity. Effective January 1, 2011, we concluded that the functional currency of our U.S. based parent company is the U.S. dollar. Prior to that date the functional currency of both the U.S. based parent company and the Company's Australian subsidiary was the Australian dollar. For financial reporting purposes, the reporting currency of the company is the U.S. dollar. When a transaction is denominated in a currency other than the entity's functional currency, the Company recognizes a transaction gain or loss in net earnings.

Comprehensive Income (Loss): The components of comprehensive income (loss) include net income (loss) and the effects of foreign currency translation adjustments.

Stock-Based Compensation: The Company recognizes all share-based payments, including grants of stock options, to in the income statement as an operating expense, based on their fair value over the requisite service period.

The Company computes the estimated fair values of stock options using the Black-Scholes option pricing model. No tax benefit has been recorded due to the full valuation allowance on deferred tax assets that the Company has recorded.

Stock-based compensation expense is based on awards ultimately expected to vest and is reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Equity instruments issued to non-employees, and for services and goods are shares of the Company's common stock, warrants or options to purchase shares of the Company's common stock. These shares, warrants or options are either fully-vested and exercisable at the date of grant or vest over a certain period during which services are provided. The Company expenses the fair market value of these securities over the period in which the related services are received.

See Note 3 for further information regarding the assumptions used to calculate the fair value of share-based compensation.

Income Taxes: Deferred income taxes are provided on a liability method whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carry forwards. Deferred tax liabilities are recognized for taxable temporary differences, which are the differences between the reported amounts of assets and liabilities and their tax basis. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment.

Net Loss per Share: Basic net loss attributable to common stockholders, on a per share basis, is computed by dividing income available to common stockholders (the numerator) by the weighted-average number of common

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shares outstanding (the denominator) during the period. Shares issued during the period and shares reacquired during the period are weighted for the portion of the period that they were outstanding. The computation of diluted earnings per share, or EPS, is similar to the computation of basic EPS except that the denominator is increased to include the number of additional common shares that would have been outstanding if the dilutive potential common shares had been issued and computed in accordance with the treasury stock method. In addition, in computing the dilutive effect of convertible securities, the numerator is adjusted to add back the after-tax amount of interest recognized in the period associated with any convertible debt. Shares reserved for outstanding stock warrants and options totaling 2,216,615 and 1,310,987 for the years ended December 31, 2011 and 2010, respectively, were excluded from the computation of loss per share as their effect was antidilutive due to the Company's net loss in each of those years.

Research and Development: Research and development expenses consist primarily of development personnel and non-employee contractor costs related to the development of new products and services, enhancement of existing products and services, quality assurance and testing. The Company incurred research and development expenses of $11,199 and $6,229 for the years ended December 31, 2011 and 2010, respectively.

Reverse Stock Split: On January 24, 2012, the board of directors declared a 1-for-200 reverse stock split and a corresponding inverse change in the transmutation ratio of CHESS Depositary Instruments ("CDIs") trading on the ASX in Australia such that one CDI will represent 1/200th of a share. The reverse split and change in transmutation ratio became effective for trading on the ASX on January 30, 2012. All share and per share data included in the consolidated financial statements and accompanying notes have been adjusted to reflect this reverse stock split.

Subsequent Events: The Company evaluates events through the date the financial statements are filed for events requiring adjustment to or disclosure in the financial statements. See Note 7, *Subsequent Events* for additional information.

New Accounting Pronouncements: In June 2011, the FASB issued additional guidance for the presentation of comprehensive income. The new guidance changes the way other comprehensive income ("OCI") appears within the financial statements. Companies will be required to show net income, OCI and total comprehensive income in one continuous statement or in two separate but consecutive statements. Components of OCI may no longer be presented solely in the statement of changes in shareholders' equity. Any reclassification between OCI and net income will be presented on the face of the financial statements. The new guidance is effective for the Company beginning January 1, 2012. The adoption of the new guidance will not impact the measurement of net income or other comprehensive income.

In May 2011, FASB issued ASU 2011-04, *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS.* This accounting update generally aligns the principles for fair value measurements and the related disclosure requirements under U.S. GAAP and International Financial Reporting Standards. From a U.S. GAAP perspective, the amendments are largely clarifications, but some could have a significant effect on certain companies. A number of new disclosures also are required. Except for certain disclosures, the guidance applies to public and nonpublic companies and is to be applied prospectively. For public companies and nonpublic companies, the amendments are effective during interim and annual

periods beginning after December 15, 2011. Early adoption by public companies is not permitted. Nonpublic companies may apply the amendments early, but no earlier than for interim periods beginning after December 15, 2011.

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Note 2 - Balance Sheet Information

Property, Plant and Equipment

Property, plant and equipment were as follows:

	December 31, 2011	December 31, 2010
Library	$ 1	$ 1
Office Furniture & Fixtures	177	90
Leasehold Improvements	251	78
Software	37	28
Production Equipment	293	179
Computer Equipment	134	65
Total	893	441
Accumulated Depreciation	(371)	(321)
	$ 522	$ 120

Note 3 - Equity

Private Placement

In November and December, 2010, the Company placed 2,368,576 shares of common stock (in the form of CDIs) for proceeds, net of transaction costs, of $11,917.

In January 2011, the Company placed 17,858 shares of common stock (in the form of CDIs) for proceeds, net of transaction costs, of $99.

In July 2011, the Company placed 572,222 shares of common stock (in the form of CDIs) for proceeds, net of transaction costs, of $4,597.

In September 2011, the Company placed 349,444 shares of common stock (in the form of CDIs) for proceeds, net of transaction costs, of $2,838.

Stock Options

The Company recognized share-based compensation expense related to stock options and grants of common stock to employees, directors and consultants of $939 and $78 during the years ended December 31, 2011 and 2010, respectively. The following table summarizes the stock-based compensation expense which was recognized in the Consolidated Statements of Operations for the years ended December 31, 2011 and 2010:

	December 31, 2011	December 31, 2010
Selling, general and administrative	$ 621	$ 55
Research and development	318	23
Total	$ 939	$ 78

As of December 31, 2011 and December 31, 2010 the total compensation cost related to all nonvested awards not yet recognized was $4,582 and $94, respectively. This amount is expected to be recognized over the remaining weighted-average period of 9.21 years as of December 31, 2011 and 1.19 years as of December 31, 2010.

The Company has granted stock options to certain employees and directors under the Amended and Restated 2002 Stock Plan and its 2011 Equity Incentive Plan (collectively the “Plans”). The Plans are designed to assist in the motivation and retention of employees and to recognize the importance of employees to the long-term performance and success of the Company. The Company has also granted stock options to certain consultants outside of the Plans. The majority of the options to purchase common stock vest on the anniversary of the date of

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grant, which ranges from one to four years. Additionally, certain stock options vest upon the closing price of the Company’s common stock reaching certain minimum levels, as defined in the agreements. Finally, certain other stock options vest upon the meeting of certain Company milestones such as the signing of specific agreements and the completion of the Company’s anticipated listing on a U.S. stock exchange. As of December 31, 2011, the Company expects that all such market and performance conditions will be met. Share-based compensation expense related to these awards is recognized on a straight-line basis over the related vesting term. It is the Company’s policy to issue new shares upon the exercise of options.

The following is a summary of the Plan and non-Plan stock option activity during the year ended December 31, 2011 and 2010.

	Options Outstanding	Weighted Average	Remaining Average Contractual	Aggregate Intrinsic Value

		Exercise price	Term (Years)	
Outstanding, December 31, 2009	78,789	$ 37.94		
2010 Grants	50,000	10.72		
2010 Exercises	—	—		
2010 Forfeitures/expiration	2,091	36.70		
Outstanding, December 31, 2010	126,698	28.00	7.26	$ 819
Exercisable at December 31, 2010	90,427	6.94	6.54	819
2011 Grants	794,926	7.64		
2011 Exercises	1,560	6.58		
2011 Forfeitures/expiration	33,231	13.02		
Outstanding, December 31, 2011	886,833	$ 10.05	9.21	$ 62,674
Exercisable at December 31, 2011	184,296	$ 18.74	10.06	$ 24,013

The aggregate intrinsic value is defined as the difference between the market value of the Company's common stock (based on the trading price of the Company's CDIs on ASX) as of the end of the period and the exercise price of the in-the-money stock options. The total intrinsic value of stock options exercised during the years ended December 31, 2011 and 2010 was $3 and $0, respectively. Of the 702,537 non vested options, 40 are held by consultants, the majority of which vest in 2012. Total cash proceeds from exercised options were $10 and $0 for the years ended December 31, 2011 and 2010, respectively.

The weighted-average fair value of stock options granted during the years ended December 31, 2011 and 2010 was $6.62 and $10.72, respectively.

The fair value of each stock option is estimated at the grant date using the Black-Scholes option pricing model. The Company has not historically paid dividends to its shareholders, and, as a result assumed a dividend yield of 0%. The 2011 risk free interest rate is based upon the rates of US Treasury bins with a term equal to the expected term of the option. The 2010 risk free interest rate is based upon the rates of Australian bonds with a term equal to the expected term of the option. The expected volatility is based upon the historical price of the Company's CDIs. The expected term of the stock options to purchase common stock is based upon the outstanding contractual expected life of the stock option on the date of grant. The Company used the following weighted-average assumptions in calculating the fair value of options granted during the years ended December 31, 2011 and 2010.

	Year ended December 31	
	2011	2010
Expected dividend yield	0%	0%
Risk-free interest rate	1.43%	4.97%
Expected volatility	100%	65%
Expected life (in years)	6.5	5

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Warrants

Warrants to purchase 1,496,032 and 1,223,787 shares of common stock were outstanding at December 31, 2011 and 2010, respectively.

On November 10, 2010, the Company issued 357,050 warrants at an exercise price of AU$6.40 and a term of 4 years as part of the private placements previously described.

Also, as part of the private placements completed during 2010, the Company issued 850,737 warrants to purchase common stock at an exercise price of AU$6.40 per share. The warrants have a stated life of four years.

As part of the private placement completed during 2011, the Company issued 10,623 warrants to purchase common stock at an exercise price of AU$8.20 per share and 276,501 warrants to purchase common stock at an exercise price of AU$11.20 per share. The warrants have a stated life of four years.

Additional warrants to purchase common stock were issued in connection with the issuance of $800 convertible promissory notes in June 2004, which were issued as a bridging loan prior to the initial public offering of the Company's CDIs on the ASX. These warrants were issued to related party entities affiliated with certain directors of the Company and to one unrelated party. The warrants entitle the holders to receive 16,000 shares at an exercise price of AU$5.00. The warrants have an exercise period of ten years and expire in June 2014.

During the year ended December 31, 2011, 14,879 warrants were exercised at a price of AU$6.40 for total proceeds of $99.

Note 4 - Income Taxes

Domestic and foreign loss before provision for income taxes consists of the following:

	December 31, 2011	December 31, 2010
Domestic	(11,252)	(2,207)
Foreign	(4,944)	(5,563)
Total	(16,196)	(8,270)

The components of income tax expense for the years ended December 31, 2011 and 2010 consist of the following:

	December 31, 2011	December 31, 2010

Income tax provision:		
Current:		
U.S. and state	(115)	—
Foreign	—	(670)
Deferred:		
U.S. and state	—	—
Foreign	—	—
Total income tax (benefit) expense	(115)	(670)

Actual income tax expense differs from statutory federal income tax benefit for the years ended December 31, 2011 and 2010 as follows:

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	December 31, 2011	December 31, 2010
Statutory federal income tax benefit	(5,555)	(2,812)
State tax benefit, net of federal taxes	(727)	(417)
Foreign tax	199	225
R&D tax credit rebate	(265)	(670)
Valuation allowance increase	6,121	3,033
Other	112	(29)
Total income tax (benefit) expense	(115)	(670)

Deferred taxes as of December 31, 2011 and 2010 consist of the following:

	December 31, 2011	December 31, 2010
Deferred tax assets (liabilities):		
Accrued expenses	115	120
Stock based compensation	658	385
Capitalized patent costs	126	140
Deferred rent	78	—
Fixed assets	(76)	—
R&D credits	150	—
Other	7	7
Net operating losses	22,357	16,210
	23,415	16,862
Less: valuation allowance	(23,415)	(16,862)
	—	—

As of December 31, 2011, we had U.S. net operating loss (NOL) carryforwards of approximately $14.6 million for U.S. income tax purposes, which expire in 2023 through 2031, and NOLs in the Commonwealth of Australia of approximately $54.1 million which we can carry forward indefinitely. U.S. net operating loss carryforwards cannot be used to offset taxable income in foreign jurisdictions. In addition, future utilization of net operating loss carryforwards in the U.S. may be subject to certain limitations under Section 382 of the Internal Revenue Code. This section generally relates to a 50 percent change in ownership of a company over a three-year period. No formal study has been prepared as of the balance sheet date to determine any applicable limitations on the utilization of the U.S. net operating losses.

We received a $670 fully refundable research and development tax credit in 2010, determined as a combined average of 44% of qualified research and development expenditures of our Australian subsidiary for its tax period ended June 30, 2010. The Australian research and development tax credit is paid as a refundable credit to small and medium enterprises for tax years ending on or before June 30, 2011, when total research and development expenses of the Australian subsidiary are less than A$2 million for the tax period. If total eligible research and development expenses exceed A$2 million, the tax credit is instead applied as a carryforward reduction against future income taxes. We have not completed the Australian tax return for the period ended June 30, 2011, and cannot be assured that our total eligible research and development expenses will be less than A$2 million. Therefore, we have reflected $0 net benefit related to the research and development credit for 2011. We also computed a $115 fully refundable research and development tax credit for the state of Minnesota for the fiscal year ended June 30, 2011. This credit is computed as a percentage of qualified research expenditures that were incurred in the state of Minnesota during the fiscal year. We have not yet completed a study to determine whether a similar credit will be generated for the six months ended December 31, 2011; therefore, we have reflected $0 net benefit related to the Minnesota research and development credit for the six months ended December 31, 2011.

We provide for a valuation allowance when it is more likely than not that we will not realize a portion of the deferred tax assets. We have established a valuation allowance for U.S. and foreign deferred tax assets due to

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the uncertainty that enough taxable income will be generated in those taxing jurisdictions to utilize the assets. Therefore, we have not reflected any benefit of such deferred tax assets in the accompanying financial statements. For the years ended December 31, 2011 and 2010, the valuation allowance increased by

$6.6 million and $4.5 million, respectively. Changes in the valuation allowance do not equal the amounts reflected in the statutory rate reconciliation due to fluctuating currency exchange rates.

The Company has adopted accounting guidance related to uncertain tax positions. This accounting guidance prescribes a recognition threshold and measurement attribute for recognition and measurement of a tax position taken or expected to be taken in a tax return. It also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The adoption of uncertain tax position guidance did not have a material impact on the Company's consolidated financial statements. Additionally, the adoption of the guidance had no impact on retained earnings. The Company had no material uncertain tax positions as of December 31, 2011 or December 31, 2010.

We recognize interest and penalties on unrecognized tax benefits as well as interest received from favorable tax settlements within income tax expense. Upon adoption of this guidance, we recognized no interest or penalties related to uncertain tax positions. During the years ended December 31, 2011 and 2010 we recorded no accrued interest or penalties related to uncertain tax positions.

The fiscal tax years ended June 30, 2008 through December 31, 2011 remain open to examination by the Internal Revenue Service. For the states of California and Minnesota, all years subsequent to the fiscal tax year ended June 30, 2006 are also open to examination. Additionally, the returns of the Company's Australian subsidiary are subject to examination by Australian tax authorities for the fiscal tax years ended June 30, 2007 through June 30, 2011.

Note 5 — Commitments and Contingencies

Leases

We lease office space under non-cancelable operating leases that expire at various times through March 2016. Rent expense related to operating leases was approximately $274 and $186 for the years ended December 31, 2011 and 2010, respectively. Future minimum lease payments under non-cancelable operating leases as of December 31, 2011 were approximately $260, $194, $262, $267 and $67 for each the years ended December 31, 2012, through 2016, respectively.

Employee 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 Company of up to 9% of employees' wages and salaries are legally enforceable in Australia. For the years ended December 31, 2011 and 2010, the Company incurred expense of $82 and $64, respectively.

Note 6 — Related Party Transaction

During the year ended December 31, 2011 and 2010, we paid $9 and $4 to SCP Technology and Growth Pty Limited, a company controlled by a director of our Australian subsidiary, for the provision of intellectual property and patent services. There were no amounts outstanding to this entity at December 31, 2011 or December 31, 2010. In September 2011, we sold 14,375 shares of our common stock to Jeffrey Mathiesen, our Chief Financial Officer, at the price of A$8.00 per share as part of a private placement.

Note 7 — Subsequent Events

On February 9, 2012, we placed 259,000 shares of common stock for proceeds, net of transaction costs, of $2.1 million.

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On February 14, 2012, the SEC certified our common shares for listing on The Nasdaq Stock Exchange, effective that same day. Our common shares began trading on The Nasdaq Capital Market on February 16, 2012 under the symbol "SSH."

Note 8 — Segment and Geographic Information

The Company has one reportable segment, cardiac and coronary disease products. The Company's geographic regions include the United States and Australia.

Revenue earned relating to reimbursement of clinical trials is earned primarily in the United States. Interest income is primarily earned in Australia.

Long-lived assets are located primarily in the United States at December 31, 2011.

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Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2011, the end of the period covered by this Annual Report on Form 10-K. This evaluation was done under the supervision and with the participation of management, including our Chief

Executive Officer ("CEO") and Chief Financial Officer ("CFO"). Disclosure controls and procedures means controls and other procedures that are designed to provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act, such as this Annual Report on Form 10-K, is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed such that information is accumulated and communicated to our management, including our CEO and CFO, as appropriate to allow timely decisions regarding required disclosure. Based on this evaluation, our CEO and CFO have concluded that as of December 31, 2011, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the most recent fiscal quarter ended December 31, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item with respect to executive officers is contained in Item 1 of this Annual Report on Form 10-K under the heading "Executive Officers" and with respect to other information relating to our directors and executive officers will be set forth in our 2012 Proxy Statement under the caption "Proposal 1 — Election of Directors," which will be filed no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and is incorporated herein by reference.

The information required by this item under Item 405 of Regulation S-K is incorporated herein by reference to the section titled "Section 16(a) Beneficial Ownership Reporting Compliance" of our 2012 Proxy Statement, which will be filed no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K. The information required by this item under Item 407(d)(4) and (d)(5) of Regulation S-K is incorporated herein by reference to the section titled "Information Regarding the Board of Directors and Corporate Governance—Board Committees—Audit Committee" of our 2012 Proxy Statement, which will be filed no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

We have adopted a code of business conduct applicable to our directors, officers (including our principal executive officer and principal financial officer) and employees. The Code of Business Conduct is available on our website at *www.sunshineheart.com* under the Investor Relations section. We plan to post on our website at the address described above any future amendments or waivers of our Code of Conduct.

Item 11. Executive Compensation

Information related to security ownership required by this item is incorporated herein by reference to the sections titled "Executive Compensation," and "Certain Relationships and Related Transactions—Compensation Committee Interlocks and Insider Participation" of our 2012 Proxy Statement, which will be filed no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Information related to security ownership required by this item is incorporated herein by reference to the section titled "Security Ownership" of our 2012 Proxy Statement, which will be filed no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K. Information related to our equity compensation plans required by this item is incorporated herein by reference to the section titled "Proposal 3—Approval of Amendments to Amended and Restated 2011 Equity Incentive Plan—Equity Compensation Plan Information" of our 2012 Proxy Statement, which will be filed no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Information required by this item is incorporated herein by reference to the sections titled "Certain Relationships and Related Transactions—Related Party Transactions," and "Information Regarding the Board of Directors and Corporate Governance—Director Independence" of our 2012 Proxy Statement, which will be filed no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 14. Principal Accounting Fees and Services

Information required by this item is incorporated herein by reference to the section titled "Proposal 4—Ratification of Selection of Independent Auditor" of our 2012 Proxy Statement, which will be filed no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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Australian Disclosure Requirements

In addition to our primary listing on Nasdaq, we are also listed for quotation in the form of CDIs on ASX and trade under the symbol "SHC". As part of our ASX listing, we are required to comply with various disclosure requirements as set out in the ASX Listing Rules. The following information is intended to comply with the ASX Listing Rules and is not intended to fulfill information required by Part III of this Annual Report on Form 10-K.

Substantial Shareholders

The number of CDIs held by our substantial shareholders (being shareholders who, together with their associates, have a relevant interest in at least 5% of our voting shares) should their stockholdings be converted from common stock into CDIs as of March 19, 2012 are set out below:

	Number of CDIs	Percentage %
Australian Executor Trustees Ltd (CM Capital Vent. 4A & 4B)	300,142,400	23.9
GBS Venture Partners Pty Ltd (GBS Bioventures II & III A/C)	238,952,200	19.0
Straus (HSBC Custody Nominees)	88,741,000	7.1
Sectoral Asset Mgmt (New Emerging Medical)	62,500,000	5.0

Distribution of equity security holders as of March 19, 2012

As of March 19, 2012, there were 6,276,538 shares of our common stock outstanding, a portion of which were held as CDIs. The table below presents the number of shares of common stock and the number of CDIs held, as well as the number of shares underlying outstanding stock options and warrants.

	Common Stock		CDIs*		Options (unlisted)		Warrants (unlisted)	
	Number of holders	Number of Shares	Number of holders	Number of CDIs	Number of holders	Number of options	Number of holders	Number of warrants
1 — 1,000	4	2,504	41	12,787	29	16,780	214	79,436
1,001 — 5,000	11	29,152	92	324,200	22	124,448	43	113,579
5,001 — 10,000	6	47,889	113	961,181	—	—	15	109,256
10,001 — 100,000	5	203,100	575	23,105,028	23	623,030	18	590,291
100,001 — and over	4	1,063,251	363	961,725,204	1	154,450	5	699,716
	30	1,345,896	1,184	986,128,400	75	918,708	295	1,592,278

* Holders of CDIs may receive 1 share of common stock for every 200 CDIs held by them. The common stock equivalent of the number of CDIs outstanding at March 19, 2012 was 4,930,642 shares.

Unmarketable parcels

As of February 29, 2012, the number of shareholders holding less than a marketable parcel (for the purposes of the ASX Listing Rules) was 293.

Top 20 equity security holders

The table below shows the top 20 holders of our CDIs as of March 19, 2012:

No	Holder	Number of CDI's held	% of CDIs Outstanding
1	Australian Executor Trustees Ltd (CM Capital Vent. 4A & 4B)	300,142,400	30.4
2	GBS Venture Partners Pty Ltd (GBS Bioventures II & III A/C)	238,952,200	24.2
3	Mr. Bruce Rodney Petit	27,080,000	2.7
4	HSBC Custody Nominees	24,074,538	2.4
5	JP Morgan Nominees Australia	23,114,600	2.3
6	Asia Union Investments	18,050,600	1.8
7	Merrill Lynch Australia	17,592,600	1.8
8	Citicorp Nominees Pty Limited	16,102,600	1.6
9	Mr. David Frederick Oakley	14,750,000	1.5
10	PCLM Investments Pty Limited	12,872,600	1.3
11	Mr. Donal & Mrs. Judith O'Dwyer/Dundrum Investments (6 A/Cs)	9,969,400	1.0
12	Dr. William Peters / Apollo / Szigetvary (6 A/Cs)	8,655,200	0.9
13	Iguana Healthcare Master Fund	8,000,000	0.8
14	Dr. Jason Wesley Armstrong	7,489,492	0.8
15	Maryfair Pty Ltd	7,300,155	0.7
16	Dr. Robert William Honeywill	6,129,000	0.6
17	Mrs. Adrienne Renton	6,000,000	0.6
18	Berne No 132 Nominees Pty Ltd	6,000,000	0.6
19	Beraleigh Pty Ltd	5,929,400	0.6
20	Samuel Hershkowitz	5,875,000	0.6
Total CDIs held by top 20 shareholders		764,080,385	77.5
Total CDIs held by all other shareholders		222,048,015	22.5

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Voting Rights

Our Fourth Amended and Restated Certificate of Incorporation, as amended, provides that each share of common stock entitles the holder to one vote, subject to certain limited exceptions set out in the amended and restated certificate of incorporation.

Holders of CDIs have one vote for every 200 CDIs held by such stockholder.

If holders of CDIs wish to attend our general meetings, they will be able to do so. Under the ASX Listing Rules, Sunshine Heart, Inc. ("Sunshine Heart" or the "Company"), as an issuer of CDIs, must allow CDI holders to attend any meeting of the holders of the underlying securities unless relevant U.S. law at the time of the meeting prevents CDI holders from attending those meetings.

In order to vote at such meetings, CDI holders have the following options:

(a) instructing CDN, as the legal owner, to vote the Sunshine Heart shares of common stock underlying their CDIs in a particular manner. The instruction form must be completed and returned to Sunshine Heart's share registry prior to the meeting;

(b) informing Sunshine Heart that they wish to nominate themselves or another person to be appointed as CDN's proxy for the purposes of attending and voting at the general meeting; or

(c) converting their CDIs into a holding of Sunshine Heart's shares of common stock and voting these at the meeting (however, if thereafter the former CDI holder wishes to sell their investment on ASX, it would be necessary to convert Sunshine Heart shares of common stock back to CDIs). This must be done prior to the record date for the meeting.

As holders of CDIs will not appear on Sunshine Heart's share register as the legal holders of Sunshine Heart shares of common stock, they will not be entitled to vote at Sunshine Heart shareholder meetings unless one of the above steps is undertaken.

Proxy forms and details of these alternatives will be included in each notice of meeting and proxy statement sent to CDI holders by Sunshine Heart.

Holders of options and warrants are not entitled to vote.

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Required Statements

Sunshine Heart makes the following disclosures:

(a) There is no current on-market buy-back of Sunshine Heart's securities.

(b) Sunshine Heart was incorporated in the state of Delaware in the United States of America.

(c) Sunshine Heart is not subject to Chapters 6, 6A, 6B or 6C of the Corporations Act 2001 (Cth) dealing with the acquisitions of shares (i.e. substantial shareholdings and takeovers).

(d) Under the Delaware General Corporation Law, shares are generally freely transferable subject to restrictions imposed by U.S. federal or state securities laws, by the certificate of incorporation or by-laws of Sunshine Heart or by an agreement signed with the holders of the shares at issue. Sunshine Heart's certificate of incorporation and by-laws do not impose any specific restrictions on transfer.

General Information

The name of the Company Secretary is Mr. Jeffrey Mathiesen.

The address of the principal registered office in Australia is 385 Pacific Highway, Suite 3, Crows Nest, NSW, Australia 2065 (+1952 3224200).

Registers of securities are held at Link Market Services Limited, Level 12, 680 George Street, Sydney, NSW, Australia 2000 (+61 2 82807111). A list of registered holders of the common stock of Sunshine Heart entitled to vote at the general meeting of stockholders is available at our corporate headquarters at 12988 Valley View Road, Eden Prairie, MN, U.S. 55344.

Quotation has been granted for Sunshine Heart's CDIs on ASX Limited. In addition, Sunshine Heart's common stock became listed on Nasdaq on February 16, 2012.

Australian Corporate Governance Statement

The board of directors and employees of Sunshine Heart are committed to developing, promoting and maintaining a strong culture of good corporate governance and ethical conduct.

The board of directors is pleased to confirm that the Company's corporate governance framework is generally consistent with the ASX's Corporate Governance Council's "Corporate Governance Principles and Recommendations with 2010 amendments (2nd Edition)" ("ASX Governance Recommendations"), other than as set out below. To this end, the Company provides below a review of its corporate governance framework using the same numbering as adopted for the Principles as set out in the ASX Governance Recommendations.

Copies of the Company's codes and policies may be downloaded from the corporate governance section of the Sunshine Heart website (*www.sunshineheart.com*).

Additionally, to meet Nasdaq listing requirements, the policies and practices adopted by Sunshine Heart have been adopted to be consistent with U.S. listing standards.

Principle 1—Lay solid foundations for management and oversight

Recommendation 1.1 — Establish the functions reserved to the board of directors and those delegated to senior executives and disclose those functions

The board reviews, monitors and approves fundamental business and financial strategies and major corporate actions, and reviews and discusses reports by management on the performance of the Company and its prospects, as well as issues and risks facing the Company.

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Our senior executives are responsible for the day-to-day management of operation of the Company.

The board's responsibilities are documented in the Corporate Governance Guidelines. A copy of the Guidelines is available on the corporate governance section of the Company's website under the "Investors" tab.

Recommendation 1.2 — Disclose the process for evaluating the performance 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/or Governance and Nominating Committee and provide independent advice to enhance and improve the process. During the year the performance of the senior executives was assessed in accordance with the Company's usual process. Areas for improvement were identified and strategies adopted to implement improvements.

Recommendation 1.3— Disclosure of information indicated in the guide to reporting on Principle I of the ASX Governance Recommendations

Reporting Requirement

The Company fully complied with Recommendation 1.1 to 1.3 during the year ended December 31, 2011.

Further information regarding executive compensation for the year ended December 31, 2011, as required by Item 11, is incorporated by reference to the section titled "Executive Compensation" of our 2012 Proxy Statement, which will be filed no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Principle 2—Structure the board to add value

Recommendation 2.1 — A majority of the board of directors should be independent

Recommendation 2.2 — The Chair should be an independent director

Recommendation 2.3 — The roles of Chairman and Chief Executive Officer should not be exercised by the same individual

At March 22, 2012, the board presently comprises eight (8) directors. The eight (8) directors include six (6) independent non-executive directors (including the Chairman of the board), two (2) executive directors (being our Chief Executive Officer and our Medical Director and Chief Technical Officer).

The current composition of the board and length of tenure of each member of the board is as follows:

Name	Position	Date Appointed	Tenure*	Independent
Mr. Nicholas Callinan	Chairman, Non-executive Director	October 30, 2008	3.4 years	Yes
Mr. David Rosa	Chief Executive Officer, Executive Director	July 15, 2010	1.7 years	No
Dr. William Peters	Medical Director, Chief Technical Officer, Executive Director	August 22, 2002	9.6 years	No
Dr. Geoffrey Brooke	Non-executive Director	September 25, 2003	8.5 years	Yes
Mr. Paul Buckman	Non-executive Director	February 1, 2011	1.2 years	Yes
Dr. Mark Harvey	Non-executive Director	September 29, 2011	0.5 years	Yes
Mr. Donal O'Dwyer	Non-executive Director	July 20, 2004	7.7 years	Yes
Mr. Gregory Waller	Non-executive Director	August 3, 2011	0.7 years	Yes

* Calculated as of March 22, 2012.

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Director biographies, skills, experience and expertise

Dr. Geoff Brooke: Director since September 2003. Dr. Brooke is a managing director of GBS Venture Partners Pty Ltd., an Australian venture capital firm that seeks out investments in life sciences companies. Dr. Brooke co-founded the venture capital firm in October 1996.

Dr. Brooke's qualifications to serve on our board of directors include his experience in financial matters and fund raising as a fund manager and his experience with clinical medicine.

Paul Buckman: Director since February 2011. Since February 2012, Mr. Buckman has served as the President and Chief Executive Officer of Sentreheart, Inc., a medical technology company focused on closure of various anatomic structures. Buckman served as Chief Executive Officer and Director of Pathway Medical Technologies, Inc., a medical device company focused on treatment of peripheral arterial disease from September 2008 to February, 2012. From December 2006 until September 2008, Mr. Buckman served as Chief Executive Officer of Devax, Inc., a developer and manufacturer of drug eluting stents, while also serving as Chairman of the Board of Directors for Pathway Medical Technologies, Inc. From August 2004 to December 2006, Mr. Buckman served as President of the Cardiology Division of St. Jude Medical, Inc., a diversified medical products company. Prior to joining St. Jude Medical, Mr. Buckman served as Chairman of the Board of Directors and Chief Executive Officer of ev3, LLC, a Minnesota-based medical device company focused on endovascular therapies that Mr. Buckman founded and developed into an $80 million business, from January 2001 to January 2004. Mr. Buckman has worked in the medical device industry for over 30 years, including 10 years at Scimed Life Systems, Inc. and Boston Scientific Corporation, where he held several executive positions before becoming President of the Cardiology Division of Boston Scientific in January 2000. In addition to Pathway Medical Technologies, Inc., Mr. Buckman also currently serves as a Director for SentreHeart, Inc., Conventus, and also as a Business Advisory Board member for Bio Star Ventures. In the past, Mr. Buckman has served on the boards of Velocimed, Inc., where he was a co-founder, EndiCor, Inc., Microvena, Inc., and Micro Therapeutics, Inc.

Mr. Buckman's qualifications to serve on our board of directors include his extensive experience in the management of medical device companies, including his collective eleven years of experience as a Chief Executive Officer for Pathway Medical and Devax, Inc.

Nicholas Callinan: Director since October 2008. Mr. Callinan is the chairman of our board of directors. Since 2004, he has served as Principal at Collins Hill Pty Ltd., a private equity advisory and consulting firm. From 2001 to 2003, Mr. Callinan served as the Senior Vice President and Chief Executive of SIV for Shell Internet Ventures, a company that invested in information technology companies worldwide. Previously, Mr. Callinan served as the Managing Director and Chief Executive of Central and Eastern European funds for Advent International Corporation, a company focused on private equity and venture capital fund management and investment. Mr. Callinan founded the venture capital and private equity funds management company, Advent Management Group Pty. Ltd. and was chief executive of that company and a number of funds it managed, some of which were listed on the ASX. Earlier in his career, Mr. Callinan was a civil engineer in Australia and France and worked with Cummins Engine Company, Inc. in the United States and Australia.

Mr. Callinan's qualifications to serve on our board of directors include his experience as a Chief Executive Officer, a fund manager, and a board member for private companies throughout the world. In these roles, Mr. Callinan has aided numerous companies in developing their governance structure.

Dr. Mark Harvey: Director since September 2011. Since 2006, Dr. Harvey has served as a partner of CM Capital, an Australian venture capital firm that focuses on life sciences, telecommunications, information technology, and renewable energy ventures. In this role, Dr. Harvey has gained extensive experience in the formation, fund raising, and management of numerous life science companies.

Dr. Harvey's qualifications to serve on our board of directors include his extensive experience in the life sciences industry and general business experience due to his board service for other medical technology companies such as Osprey Medical Inc. since June 2007, and Pathway Therapeutics Ltd. since July 2010.

Donal O'Dwyer: Director since July 2004. Mr. O'Dwyer retired as worldwide President of Cordis Cardiology, the cardiology division of the Johnson & Johnson subsidiary, in 2003. Cordis is a developer and

manufacturer of breakthrough stents, catheters and guidewires for interventional medicine, minimally invasive computer-based imaging, and electrophysiology. Prior to joining Cordis, Mr. O'Dwyer served as President of the Cardiovascular Group, Europe of Baxter International Inc., a global healthcare company that uses its expertise in medical devices, pharmaceuticals and biotechnology to create products that advance patient care worldwide.

Mr. O'Dwyer's qualifications to serve on our board of directors include his extensive experience in the medical technology industry and general business experience due to his board service for other medical technology companies such as Angioblast Systems Inc. from November 2004 to January 2011, Atcor Medical Holdings Ltd since July 2004, Cochlear Limited since August 2005, and Mesoblast Ltd. since November 2004.

Dr. William Peters: Director since August 2002. Since 2002, Dr. Peters has served as our Chief Technical Officer and Medical Director. In addition to his role within our company, Dr. Peters is an honorary clinical research fellow with the Green Lane Cardiothoracic Surgical Unit at Auckland City Hospital in New Zealand.

Dr. Peters' qualifications to serve on our board of directors include his extensive experience with and expertise in cardiac medical technology, including his invention and development of devices and methods to achieve minimally cardiac surgery and his recognition in our industry gained from his authorship of numerous published articles regarding cardiac surgery and heart failure.

David Rosa: Director since July 2010. Mr. Rosa is our Chief Executive Officer, a position he has held since November 2009. From 2008 to November 2009, Mr. Rosa served as the Chief Executive Officer of Milksmart, Inc., a medical device company that specializes in medical devices for animals. From 2004 to 2008, Mr. Rosa served as the Vice President of Global Marketing for cardiac surgery and cardiology for St. Jude Medical.

Mr. Rosa's qualifications to serve on our board of directors include his experience in the medical device industry and his previous leadership experiences within medical device companies.

Gregory Waller: Director since August 2011. Mr. Waller has been employed as the Chief Financial Officer of Ulthera since October of 2011. Ulthera is a medical device company specializing in non-invasive facelifts using an ultrasound medical device. From 2006 to 2011, Mr. Waller was the Chief Financial Officer and Treasurer of Universal Building Products, Inc., which was a manufacturer of concrete forms and accessories for the residential and commercial projects in North America. Mr. Waller previously served as the Vice President of Finance, Chief Financial Officer, and Treasurer for Sybron Dental Specialties, Inc., a manufacturer of high technology dental, dental implant, and infection prevention products, from 1980 to 2005. Mr. Waller has served on the board of directors of Endologix Inc. since 2003. Mr. Waller also served on the board of directors of Clarient, Inc. and SenoRx, Inc. from 2006 until 2010. From 2006 to 2009, Mr. Waller served as a member of the board of directors of Alsius, Inc., and from 2009 to 2010, he served as a member of the board of directors of Biolase, Inc. and in addition, Mr. Waller served on the board of Cardiogenesis from 2007 until 2011.

Mr. Waller's qualifications to serve on our board of directors include his 37 years of financial and management experience, including his experiences as a Chief Financial Officer for Universal Building Products, Inc. and Sybron Dental Specialties, Inc., and his familiarity with public company board functions from his services on the boards of other public companies.

Director Independence

As required under The Nasdaq Stock Market rules and regulations, a majority of the members of board must qualify as "independent," as affirmatively determined by the board. The Company defines an "independent" director in the same manner as set forth in Rule 5605 of The Nasdaq Stock Market Listing Rules and the recommendations of the ASX Corporate Governance Principles and Recommendations, as they may be amended from time to time. Among other things, this rule requires the board to determine that an individual is free of any relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Consistent with these considerations, the board of directors has affirmatively determined that all of our directors are independent directors within the meaning of the applicable listing standards of The Nasdaq Stock Market, except for Mr. Rosa, our current Chief Executive Officer, and Dr. Peters, our current Chief Technical Officer and Medical Director.

Under the ASX Governance Recommendations (Box 2.1), two non-executive directors, Dr. Brooke and Dr. Harvey would be classified as independent directors due to their association with stockholders holding a voting interest of more than 5% in Sunshine Heart. Notwithstanding these associations, the board considers that each of Dr. Brooke and Dr. Harvey have operated at all times as independent directors and in the best interests of stockholders.

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Independent advice

At the Company's expense, the board and its committees may retain independent outside financial, legal, compensation or other advisors as they deem necessary or advisable.

Identification and Evaluation of Nominees for Directors

As required by our Corporate Governance Guidelines, when evaluating the appropriate characteristics of candidates for service as a director, the Governance and Nominating Committee takes into account many factors. The board selects and recommends to stockholders qualified individuals who, if added to the board, would provide the mix of director characteristics and diverse experiences, perspectives and skills appropriate for us. Board candidates are considered based on various criteria, including breadth and depth of relevant business and board skills and experiences, judgment and integrity, reputation in their profession, diversity of background, education, leadership ability, concern for the interests of stockholders and relevant regulatory guidelines. The Company does not have a formal policy with respect to diversity. Our board recommends individuals for election as directors in the context of an assessment of the perceived needs of the board at the particular point in time. Directors must be willing and able to devote sufficient time to carrying out their duties and responsibilities effectively, and should be committed to serving on the board for an extended period of time.

Recommendation 2.4 — The board should establish a Nomination Committee

The Company has a Governance and Nominating Committee comprising three non-executive directors being Mr. Waller (Chair), Mr. Buckman and Mr. Callinan. The board formed the Governance and Nominating Committee in preparation for the Company's listing on The Nasdaq Stock Market. The functions currently performed by the Governance and Nominating Committee previously were performed by the Remuneration and Nomination Committee of the board. The Company believes the combined role of the committee is appropriate for a company of its size. There were three meetings of the Remuneration and Nomination Committee and the Governance and Nominating Committee during the financial year, with all committee members attending on all occasions.

A copy of the Nominating and Governance Committee Charter is available on the corporate governance section of the Company's website under the "Investors" tab. The Company fully complied with Recommendation 2.1 to 2.4 during the year ended December 31, 2011.

Recommendation 2.5 — Disclose the process for evaluating the performance of the board, its committees and individual directors

The Company has not undertaken a formal review of the performance of the Board, its committees and individual directors. The Company has not therefore complied with Recommendation 2.5 during the year ended December 31, 2011.

Recommendation 2.6 — Disclosure of information indicated in the guide to reporting on Principle 2 of the ASX Governance Recommendations

Reporting Requirement

Further information regarding the Directors, as required by Item 10, is incorporated herein by reference to the section entitled "Proposal 1 — Election of Directors" of our 2012 Proxy Statement, which will be filed no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

The Company has fully complied with Recommendation 2.6 during the year ended December 31, 2011.

Principle 3—Promote ethical and responsible decision-making

Recommendation 3.1 — Establish a Code of Conduct and disclose it, or a summary of it as to: the practices necessary to maintain confidence in the company's integrity; the practices necessary to take into account their legal obligations and the reasonable expectations of their stakeholders; and the responsibility and accountability of individuals for reporting and investigating reports of unethical practices.

The Company has adopted a Code of Business Conduct and Ethics, a copy of which is available on the corporate governance section of the Company's website under the "Investors" tab.

The Company fully complied with Recommendation 3.1 during the year ended December 31, 2011.

Recommendation 3.2 — Establish a policy concerning diversity and disclose it, or a summary of it. The policy should include requirements for the board to establish measurable objectives for achieving gender diversity and for the board to assess annually both the objectives and progress in achieving them.

Recommendation 3.3 — Disclosure of measurable objectives for achieving gender diversity set by the board in accordance with the Diversity Policy and progress towards achieving them.

Although the Company is committed to driving diversity across all levels of the Company, it has not yet established a policy concerning diversity, and therefore has not complied with Recommendations 3.2 and 3.3 during the year ended December 31, 2011.

Recommendation 3.4 — Disclosure of the proportion of women employees in the whole organization, women in senior executive positions and women on the board

At December 31, 2011, women represented approximately 36% (9 of 25) of the total employee base, 17% (1 of 6) of executive management and 0% (0 of 8) of the board of directors.

Recommendation 3.5 — Disclosure of information indicated in the guide to reporting on Principle 3 of the ASX Governance Recommendations

The Company fully complied with Recommendations 3.1 and 3.4 during the year ended December 31, 2011.

The Company has not complied with Recommendations 3.2 and 3.3 during the year ended December 31, 2011.

Principle 4—Safeguard integrity in financial reporting

Recommendation 4.1 — The board should establish an Audit Committee

Recommendation 4.2 — The Audit Committee should: (a) consist of non-executive directors only; (b) consist of a majority of independent directors; (c) be chaired by an independent chair who is not chair of the board; and (d) have at least three members

Recommendation 4.3 — The Audit Committee should have a formal charter

Current members of the Audit Committee are Mr. Waller (Chair), Mr. Callinan and Mr. O'Dwyer all of whom are independent non-executive directors. Prior to September 29, 2011, the members were Mr. O'Dwyer (chair), Mr. Callinan and Mr. Marsh. The Audit Committee met three times during the year with each of Mr. Waller, Mr. Callinan, Mr. Marsh and Mr. O'Dwyer attending on all occasions, as appropriate. The qualifications of the directors appointed to the Audit Committee are set out in the section titled "Director biographies, skills, experience and expertise" of this corporate governance statement.

A copy of the Audit Committee Charter is available on the corporate governance section of the Company's website.

Reporting Requirement

The Company fully complied with Recommendation 4.1 to 4.3 during the year ended December 31, 2011.

Recommendation 4.4 — Disclosure of information indicated in the guide to reporting on Principle 4 of the ASX Governance Recommendations

Reporting Requirement

The Company has not disclosed its policy for selection and appointment of the Company's external auditor or for the rotation of external audit engagement partners.

In all other respects, the Company fully complied with Recommendation 4.4 during the year ended December 31, 2011.

Principle 5 — Make timely and balanced disclosure

Recommendation 5.1 — Establish written policies designed to ensure compliance with ASX Listing Rule disclosure requirements and to ensure accountability at a senior executive level for that compliance and disclose those policies

Recommendation 5.2 — Disclosure of information indicated in the guide to reporting on Principle 5 of the ASX Governance Recommendations

The Company is committed to providing timely and balanced disclosure to the market and, in consequence, to meeting its continuous disclosure requirements. In accordance with its commitment to fully comply with its continuous disclosure requirements, the Company has adopted a Continuous Disclosure and Shareholder Communication Policy, together with other internal mechanisms and reporting requirements.

A copy of the Continuous Disclosure and Shareholder Communication Policy is available on the corporate governance section of the Company's website under the "Investors" tab. In addition, a copy of all of the Company's ASX announcements, financial reports and related public information are also available on the Company's website.

Reporting Requirement

The Company fully complied with Recommendation 5.1 and 5.2 during the year ended December 31, 2011.

Principle 6 — Respect the rights of shareholders

Recommendation 6.1 — Design a communications policy for promoting effective communication with shareholders and encourage their participation at general meetings and disclose those policies

Recommendation 6.2 — Disclosure of information indicated in the guide to reporting on Principle 6 of the ASX Governance Recommendations

The Company provides shareholders with quarterly updates of the Company's progress across all areas of the business (in addition to continuous disclosure requirements), and utilizes its website to disclose useful and relevant information about the Company. All material information released to ASX is posted on the Company's website as soon as practicable following confirmation of receipt by ASX.

All stockholders and holders of CDIs are invited to attend the Company's annual meeting of stockholders. The board regards the annual meeting of stockholders as an excellent forum in which to discuss issues relevant to the Company and thereby encourages full participation by stockholders. Stockholders and holders of CDIs may also submit questions to the Company Secretary or his delegate at any time.

The Company's Continuous Disclosure and Shareholder Communication Policy is available on the corporate governance section of the Company's website.

Reporting requirement

The Company fully complied with Recommendation 6.1 and 6.2 for the year ended December 31, 2011.

Principle 7 — Recognize and manage risk

Recommendation 7.1 — Establish policies for the oversight and management of material business risks and disclose it

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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 the corporate governance section of the Company's website under the "Investors" tab.

Recommendation 7.2 — 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 whether those risks are being managed effectively. The board should disclose that management has reported to the board as to the effectiveness of the Company's management of its material business risks

The Company's Risk Management Statement which provides an overview of the Company's risk profile and management strategies is available on the corporate governance section of the Company's website under the "Investors" tab. The board requires a statement in writing annually from the Chief Executive Officer and Chief Financial Officer (or equivalent) attesting to the risk management and internal control system. The board received and accepted Exhibits 31 and 32 of this filing as such a statement from the Chief Executive Officer and Chief Financial Officer. The Company fully complied with Recommendation 7.2 for the year ended December 31, 2011.

Reporting requirement

The Company fully complied with Recommendations 7.1 and 7.2 for the year ended December 31, 2011.

Recommendation 7.3 - Disclose whether the board has received assurance from the Chief Executive Officer and the Chief Financial Officer that the declaration under Section 295A of the Corporations Act is founded on a sound system of risk management and internal control and is operating effectively in all material respects in relation to financial reporting risks

Reporting requirement

As the Company prepares and files its financial statements under U.S. accounting practices and laws, management is required to provide representations to the board on a wide range of issues, including the effectiveness of the Company's disclosure controls and procedures. Management will be required to provide a report as to management's assessment of the Company's design or operation of internal control over financial reporting after a transition period. However, as the Company is incorporated in the United States and is not bound by the financial reporting provisions under the Australian Corporations Act 2001 (Cth), no declaration is required under section 295A of the Corporations Act. To this end, stockholders' attention is drawn to Item 9A of this Annual Report on Form 10-K and the certifications provided by the Chief Executive Officer and the Chief Financial Officer at the end of the Form 10-K. Item 9A of this Annual Report on Form 10-K discloses information regarding the Company's controls and procedures. This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

For the reasons stated above, the Company has not complied with Recommendation 7.3 for the year ended December 31, 2011.

Recommendation 7.4 — Disclosure of information indicated in the guide to reporting on Principle 7 of the ASX Governance Recommendations

Reporting requirement

Except as disclosed above, the Company has fully complied with Recommendations 7.1 to 7.4 for the year ended December 31, 2011.

A copy of the Company's Risk Management Statement is available on the corporate governance section of the Company's website under the "Investors" tab.

Principle 8—Remunerate fairly and responsibly

Recommendation 8.1 — Establish a Remuneration Committee

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Recommendation 8.2 — The Remuneration Committee should be structured so that it: (a) consist of a majority of independent directors; (b) is chaired by an independent chair; and (c) has at least three members

The members of the Compensation Committee are Mr. Buckman (Chair), Dr. Brooke, Mr. Calllinan and Dr. Harvey all of whom are independent non-executive directors. A copy of the Compensation Committee Charter is available on the corporate governance section of the Company's website under the "Investors" tab. The board formed the Compensation Committee in preparation for the Company's listing on The Nasdaq Stock Market. The functions currently performed by the Compensation Committee previously were performed by the Remuneration and Nomination Committee of the board. The Remuneration and Nomination Committee and the Compensation Committee met 4 times during 2011 with all committee members attending on all occasions.

Recommendation 8.3 — Clearly distinguish the structure of non-executive directors' remuneration from that of executive directors and senior 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 stockholder value. Non-executive directors receive no incentive cash payments other than their fixed fee. Non-executive directors have received stockholder-approved stock options which are normally issued at or above the current share price. Accordingly, any benefit to directors will only accrue from an increase in the share price. None of the Company's non-executive directors are entitled to any retirement benefits.

Further information regarding director and executive compensation, as required by Items 10 and 11, will be contained in our 2012 Proxy Statement. Such information is incorporated herein by reference.

Recommendation 8.4 — Disclosure of information indicated in the guide to reporting on Principle 8 of the ASX Governance Recommendations

The Company does not have a specific policy on prohibiting transactions in associated products which limit the economic risk of participating in unvested entitlements under any equity-based remuneration schemes.

Reporting requirement

With the exception noted above, the Company complied with Recommendations 8.1 to 8.4 during the year ended December 31, 2011.

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PART IV

Item 15. Exhibits and Financial Statement Schedules

The following documents are filed as a part of this Annual Report on Form 10-K:

(a) Financial Statements: The financial statements filed as a part of this report are listed in Part II, Item 8.

(b) Financial Statement Schedules: The schedules are either not applicable or the required information is presented in the consolidated financial statements or notes hereto.

(c) Exhibits: The exhibits incorporated by reference or filed as a part of this Annual Report on Form 10-K are listed in the Exhibit Index immediately following the signatures to this report.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: March 23, 2012

SUNSHINE HEART, INC.

By: /s/ David Rosa

David Rosa
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ David Rosa David Rosa	President, Chief Executive Officer and Director (principal executive officer)	March 23, 2012
/s/ Jeffrey Mathiesen Jeffrey Mathiesen	Chief Financial Officer (principal financial and accounting officer)	March 23, 2012
* Paul Buckman	Director	March 23, 2012
* Dr. Geoffrey Brooke	Director	March 23, 2012
* Nicholas Callinan	Director	March 23, 2012
* Mark Harvey, M.D.	Director	March 23, 2012
* William Peters, M.D.	Director	March 23, 2012
* Donal O'Dwyer	Director	March 23, 2012
* Gregory Waller	Director	March 23, 2012
*/s/ Jeffrey Mathiesen By: Jeffrey Mathiesen *Agent and attorney-in-fact*		

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EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
3.1	Certificate of Incorporation, as amended.	10	001-35312	February 1, 2012	3.1	
3.2	Amended and Restated Bylaws.	10	001-35312	September 30, 2011	3.2	
10.1	Form of Indemnity Agreement between the registrant and each of its officers and directors.*	10	001-35312	September 30, 2011	10.1	
10.2	Sunshine Heart, Inc. Amended and Restated 2002 Stock Plan.*	10	001-35312	December 16, 2011	10.2	
10.3	Form of Notice of Stock Option Grant and Option Agreement for Amended and Restated 2002 Stock Plan.*	10	001-35312	September 30, 2011	10.3	
10.4	Amended and Restated Sunshine Heart, Inc. 2011 Equity Incentive Plan.*	10	001-35312	December 16, 2011	10.4	
10.5	Form of Stock Option Grant Notice and Option Agreement for 2011 Equity Incentive Plan.*	10	001-35312	September 30, 2011	10.5	
10.6	Form of Senior Management Stock Option Grant Notice and Option Agreement for 2011 Equity Incentive Plan.*	10	001-35312	September 30, 2011	10.6	
10.7	Form of Change in Control Agreement for the registrant's executive officers.*	10	001-35312	December 16, 2011	10.7	
10.8	Form of Warrant to Purchase Common Stock issued to investors pursuant to Securities Purchase Agreement dated September 15, 2010.	10	001-35312	September 30, 2011	10.8	
10.9	Form of Warrant to Purchase Common Stock issued to Summer Street Research Partners.	10	001-35312	September 30, 2011	10.9	
10.10	Form of Securities Purchase Agreement, dated July 21, 2011, between the registrant and the purchasers party thereto.	10	001-35312	September 30, 2011	10.10	
10.11	First Amendment to Securities Purchase	10	001-35312	September 30, 2011	10.11	

	Agreement dated July 21, 2011.					
10.12	Form of Warrant to Purchase Common Stock issued to investors pursuant to Securities Purchase Agreement dated July 21, 2011.	10	001-35312	September 30, 2011	10.12	
10.13	Form of Warrant to Purchase Common Stock issued to Matthew Dormer and Summer Street Research Partners.	10	001-35312	September 30, 2011	10.13	
10.14	Employment Agreement, dated November 1, 2009, by and between the registrant and David A. Rosa.*	10	001-35312	September 30, 2011	10.14	

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Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
10.15	Letter Agreement, dated August 3, 2004, between the registrant and WSP Trading Limited.*	10	001-35312	September 30, 2011	10.15	
10.16	Lease Agreement, dated September 15, 2010, by and between the registrant and CSM Properties, Inc.	10	001-35312	September 30, 2011	10.16	
10.17	License, Supply & Manufacturing Agreement, dated April 26, 2010, by and between the registrant and DSM PTG, Inc.#	10	001-35312	February 14, 2012	10.17	
10.18	Lease Agreement, dated October 21, 2011, by and between the registrant and Silver Prairie Crossroads, LLC.	10	001-35312	December 16, 2011	10.18	
10.19	Form of Securities Purchase Agreement, dated February 6, 2012.	10	001-35312	February 8, 2012	10.19	
10.20	Form of Warrant to Purchase Common Stock issued to investors pursuant to Securities Purchase Agreement dated February 6, 2012.	10	001-35312	February 8, 2012	10.20	
10.21	Form of Warrant to Purchase Common Stock issued to Summer Street Research Partners and registered representatives on February 8, 2012.					X
21	Subsidiaries of the registrant.	10	001-35312	September 30, 2011	21	
24	Power of Attorney					X
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) under the Securities Exchange Act of 1934, as amended					X
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) under the Securities Exchange Act of 1934, as amended					X
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Sec. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X

*Indicates management contract or compensatory plan or arrangement.
#Confidential treatment granted with respect to certain portions of this exhibit. The omitted portions have been filed separately with the Securities and Exchange Commission.

NEITHER THIS SECURITY NOR THE SECURITIES ISSUABLE UPON EXERCISE OF THIS SECURITY HAVE BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE ***"SECURITIES ACT"***), OR APPLICABLE STATE SECURITIES LAWS. THE SECURITIES MAY NOT BE OFFERED FOR SALE, SOLD, TRANSFERRED OR ASSIGNED (I) IN THE ABSENCE OF (A) AN EFFECTIVE REGISTRATION STATEMENT FOR THE SECURITIES UNDER THE SECURITIES ACT OR (B) AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS OR BLUE SKY LAWS AS EVIDENCED BY A LEGAL OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE COMPANY AND ITS TRANSFER AGENT OR (II) UNLESS SOLD PURSUANT TO RULE 144 OR RULE 144A UNDER SAID ACT. NOTWITHSTANDING THE FOREGOING, THE SECURITIES MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT OR OTHER LOAN OR FINANCING ARRANGEMENT SECURED BY THE SECURITIES.

SUNSHINE HEART, INC.

WARRANT TO PURCHASE COMMON STOCK

Warrant No. CSW-** Original Issue Date: **February 8, 2012**

SUNSHINE HEART, INC., a Delaware corporation (the ***"Company"***), hereby certifies that, for value received, ******* or its/his permitted registered assigns (the ***"Holder"***), is entitled to purchase from the Company up to a total of ******* shares (subject to adjustment as provided herein) of common stock, US$0.0001 par value per share (the ***"Common Stock"***), of the Company (each such share, a ***"Warrant Share"*** and all such shares, including any additional shares, if any, to be issued pursuant to the immediately following paragraph, the ***"Warrant Shares"***) at an exercise price equal to A$8.00 per share (as adjusted from time to time as provided in Section 9 herein, the ***"Exercise Price"***), at any time and from time to time on or after the date hereof (the ***"Trigger Date"***) and through and including 5:30 P.M., New York City time, on **February 8, 2017** (the ***"Expiration Date"***), and subject to the following terms and conditions:

This Warrant (this ***"Warrant"***) is one of a series of similar warrants issued pursuant to that certain Securities Purchase Agreement, dated February 6, 2012 by and among the Company and the Purchasers identified therein (the ***"Purchase Agreement"***). All such warrants are referred to herein, collectively, as the ***"Warrants."***

1. DEFINITIONS. In addition to the terms defined elsewhere in this Warrant, capitalized terms that are not otherwise defined herein have the meanings given to such terms in the Purchase Agreement. All dollar amounts set forth herein shall refer to Australian currency.

2. REGISTRATION OF WARRANTS. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the ***"Warrant Register"***), in the name of the record Holder (which shall include the initial Holder or, as the case may be, any registered assignee to which this Warrant is permissibly assigned hereunder) from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof

for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

3. REGISTRATION OF TRANSFERS. Subject to compliance with all applicable securities laws, the Company shall register the transfer of all or any portion of this Warrant in the Warrant Register, upon surrender of this Warrant, with the Form of Assignment attached as Schedule 2 hereto duly completed and signed, to the Company's transfer agent or to the Company at its address specified in the Purchase Agreement and (x) delivery, at the request of the Company, of an opinion of counsel reasonably satisfactory to the Company to the effect that the transfer of such portion of this Warrant may be made pursuant to an available exemption from the registration requirements of the Securities Act and all applicable state securities or blue sky laws and (y) delivery by the transferee of a written statement to the Company certifying that the transferee is an "accredited investor" as defined in Rule 501(a) under the Securities Act, to the Company at its address specified in the Purchase Agreement. Upon any such registration or transfer, a new warrant to purchase Common Stock in substantially the form of this Warrant (any such new warrant, a ***"New Warrant"***) evidencing the portion of this Warrant so transferred shall be issued to the transferee, and a New Warrant evidencing the remaining portion of this Warrant not so transferred, if any, shall be issued to the transferring Holder. Any New Warrant issued pursuant to a partial exercise of this Warrant or as a result of a transfer of this Warrant shall be deemed to have the Original Issue Date of *******, 2012**, which is the date that this Warrant was initially issued to such Holder or its predecessor. The acceptance of the New Warrant by the transferee thereof shall be deemed the acceptance by such transferee of all of the rights and obligations in respect of the New Warrant that the Holder has in respect of this Warrant. The Company shall prepare, issue and deliver at its own expense any New Warrant under this Section 3.

4. EXERCISE AND DURATION OF WARRANTS.

(a) All or any part of this Warrant shall be exercisable by the registered Holder in any manner permitted by Section 10 of this Warrant at any time and from time to time on or after the Trigger Date and through and including 5:30 P.M. New York City time, on the Expiration Date. At 5:30 P.M., New York City time, on the Expiration Date, the portion of this Warrant not exercised prior thereto shall be and become void and of no value and this Warrant shall be terminated and no longer outstanding.

(b) The Holder may exercise this Warrant by delivering to the Company (i) an exercise notice (whether via facsimile or otherwise), in the form attached as Schedule 1 hereto (the ***"Exercise Notice"***), completed and duly signed, and (ii) payment of the Exercise Price for the number of Warrant Shares as to which this Warrant is being exercised (which may take the form of a "cashless exercise" if so indicated in the Exercise Notice and if a "cashless exercise" may occur at such time pursuant to Section 10 below), and the date on which the last of such items is delivered to the Company (as determined in accordance with the notice provisions hereof) is an ***"Exercise Date."*** The Holder shall not be required to deliver the original Warrant in order to effect an exercise hereunder. Execution and delivery of the Exercise Notice shall have the same effect as cancellation of the original Warrant and issuance of a New Warrant evidencing the right to purchase the remaining number of Warrant Shares.

5. DELIVERY OF WARRANT SHARES.

(a) Upon exercise of this Warrant, the Company shall promptly (but in no event later than three Trading Days after the Exercise Date) issue or cause to be issued and cause to be delivered to or upon the written order of the Holder and in such name or names as the Holder may designate (provided that, if a Registration Statement covering the resale of the Warrant Shares is not effective and the Holder directs the Company to deliver a certificate for the Warrant Shares in a name other than that of the Holder or an Affiliate of the Holder, it shall deliver to the Company on the Exercise Date an opinion of counsel reasonably satisfactory to the Company to the effect that the issuance of such Warrant Shares in such other name may be made pursuant to an available exemption from the registration requirements of the Securities Act and all applicable state securities or blue sky laws), (i) a certificate for the Warrant Shares issuable upon such exercise, free of restrictive legends, or (ii) an electronic delivery of the Warrant Shares to the Holder's account at either CHESS Depositary Nominees Pty Ltd. which will hold legal title to the Warrant Shares on behalf of the Holder for its benefit through the issue of CHESS Depositary Interests that will be quoted on the stock market of the Australian Securities Exchange or the Depository Trust Company (***"DTC"***) or a similar organization, unless in the case of clause (i) and (ii) a registration statement covering the resale of the Warrant Shares and naming the Holder as a selling stockholder thereunder is not then effective or the Warrant Shares are not freely transferable without volume and manner of sale restrictions pursuant to Rule 144 under the Securities Act, in which case such Holder shall receive a certificate for the Warrant Shares issuable upon such exercise with appropriate restrictive legends. The Holder, or any Person permissibly so designated by the Holder to receive Warrant Shares, shall be deemed to have become the holder of record of such Warrant Shares as of the Exercise Date. If the Warrant Shares are to be issued free of all restrictive legends, the Company shall, upon the written request of the Holder, use its reasonable best efforts to deliver, or cause to be delivered, Warrant Shares hereunder electronically through DTC or another established clearing corporation performing similar functions, if available; provided, that, the Company may, but will not be required to, change its transfer agent if its current transfer agent cannot deliver Warrant Shares electronically through such a clearing corporation. For purposes of this Warrant, ***"Trading Day"*** shall mean any day on which the Warrant Shares are traded on a U.S. stock exchange or, if inapplicable, the principal securities exchange or securities market on which the Warrant Shares are then traded.

(b) In addition to any other rights available to the Holder, if by the close of the third Trading Day after delivery of an Exercise Notice and the payment of the aggregate exercise price in any manner permitted by Section 10 of this Warrant, the Company fails to deliver to the Holder a certificate (or make an electronic delivery) representing the required number of Warrant Shares in the manner required pursuant to Section 5(a), and if after such third Trading Day and prior to the receipt of such Warrant Shares, the Holder or the Holder's brokerage firm purchases (in an open market transaction or otherwise) shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a ***"Buy-In"***), then the Company shall, within three (3) Trading Days after the Holder's request and in the Holder's sole discretion, either (1) pay in cash to the Holder an amount equal to the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased (the ***"Buy-In Price"***), at which point the Company's obligation to deliver such certificate (or make an electronic delivery) (and to issue such Warrant Shares) shall terminate or (2) promptly honor its obligation to deliver to the Holder a certificate or certificates

(or make an electronic delivery) representing such Warrant Shares and pay cash to the Holder in an amount equal to the excess (if any) of the Buy-In Price over the product of (A) the number of shares of Common Stock purchased in the Buy-In, times (B) the closing bid price of a share of Common Stock on the Exercise Date.

6. CHARGES, TAXES AND EXPENSES. Issuance and delivery of certificates for shares of Common Stock upon exercise of this Warrant shall be made without charge to the Holder for any issue or transfer tax, transfer agent fee or other incidental tax or expense in respect of the issuance of such certificates, all of which taxes and expenses shall be paid by the Company; *provided*, *however*, that the Company shall not be required to pay any tax that may be payable in respect of any transfer involved in the registration of any certificates for Warrant Shares or the Warrants in a name other than that of the Holder or an Affiliate thereof. The Holder shall be responsible for all other tax liability that may arise as a result of holding or transferring this Warrant or receiving Warrant Shares upon exercise hereof.

7. REPLACEMENT OF WARRANT. If this Warrant is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation hereof, or in lieu of and substitution for this Warrant, a New Warrant, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction (in such case) and, in each case, a customary and reasonable indemnity or surety bond, if requested by the Company. Applicants for a New Warrant under such circumstances shall also comply with such other reasonable regulations and procedures and pay such other reasonable third-party costs as the Company may prescribe. If a New Warrant is requested as a result of a mutilation of this Warrant, then the Holder shall deliver such mutilated Warrant to the Company as a condition precedent to the Company's obligation to issue the New Warrant.

8. RESERVATION OF WARRANT SHARES. The Company represents, warrants, covenants and agrees that it will at all times reserve and keep available out of the aggregate of its authorized but unissued and otherwise unreserved Common Stock, solely for the purpose of enabling it to issue Warrant Shares upon exercise of this Warrant as herein provided, the number of Warrant Shares that are issuable and deliverable upon the exercise of this entire Warrant, free from preemptive rights or any other contingent purchase rights of persons other than the Holder (taking into account the adjustments of Section 9). The Company covenants that all Warrant Shares so issuable and deliverable shall, upon issuance and the payment of the applicable Exercise Price (including by "cashless exercise" if permitted hereunder) in accordance with the terms hereof, be duly and validly authorized, issued and fully paid and nonassessable. The Company, without requiring any action to be taken or expense to be incurred by Holder, will take all such action as may be reasonably necessary to assure that such shares of Common Stock may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of any securities exchange or automated quotation system upon which the Common Stock may be listed.

9. CERTAIN ADJUSTMENTS. The Exercise Price and number of Warrant Shares issuable upon exercise of this Warrant are subject to adjustment from time to time as set forth in this Section 9.

(a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding, (i) pays a stock dividend on its Common Stock or otherwise makes a distribution on any class of capital stock that is payable in shares of Common Stock, (ii) subdivides its outstanding shares of Common Stock into a larger number of shares, (iii) combines its outstanding shares of Common Stock into a smaller number of shares or (iv) issues

by reclassification of shares of Common Stock any shares of capital stock of the Company, then in each such case the Exercise Price shall be multiplied by a fraction, the numerator of which shall be the number of shares of Common Stock outstanding immediately before such event and the denominator of which shall be the number of shares of Common Stock outstanding immediately after such event. Any adjustment made pursuant to clause (i) of this paragraph shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution, and any adjustment pursuant to clause (ii), (iii) or (iv) of this paragraph shall become effective immediately after the effective date of such subdivision or combination or reclassification.

(b) Pro Rata Distributions. If the Company, at any time while this Warrant is outstanding, distributes to all holders of Common Stock for no consideration (i) evidences of its indebtedness, (ii) any security (other than a distribution of Common Stock covered by the preceding paragraph) or (iii) rights, options or warrants to subscribe for or purchase any security, or (iv) any other asset (including cash or cash dividends) (in each case, ***"Distributed Property"***), then, upon any exercise of this Warrant that occurs after the record date fixed for determination of stockholders entitled to receive such distribution, the Holder shall be entitled to receive, in addition to the Warrant Shares otherwise issuable upon such exercise (if applicable), the Distributed Property that such Holder would have been entitled to receive in respect of such number of Warrant Shares had the Holder been the record holder of such Warrant Shares immediately prior to such record date without regard to any limitation on exercise contained therein.

(c) Change in Control. For the purpose of this Warrant, "***Change in Control***" means a merger or consolidation of the Company with or into any other corporation or corporations in which the stockholders of the Company immediately prior to the merger or consolidation do not own more than fifty percent (50%) of the outstanding voting power (assuming conversion of all convertible securities and the exercise of all outstanding options) of the surviving corporation or the sale, lease, licensing, transfer or other disposition of all or substantially all the assets of the Company, unless the requisite stockholders of the Company elect, pursuant to the Certificate of Incorporation (as defined below), for such transaction or transactions not to be a Change in Control of the Company.

(i) Upon the written request of the Company, the Holder agrees that, in the event of a Change in Control that is not an asset sale and in which the sole consideration is cash, either (a) the Holder shall exercise its conversion or purchase right under this Warrant and such exercise will be deemed effective immediately prior to the consummation of such Change in Control or (b) if the Holder elects not to exercise the Warrant, this Warrant will expire upon the consummation of such Change in Control. The Company shall provide the Holder with written notice of its request relating to the foregoing (together with such reasonable information as such Holder may request in connection with such contemplated Change in Control giving rise

to such notice), which is to be delivered to the Holder not less than ten (10) days prior to the closing of the proposed Change in Control.

(ii) Upon the written request of the Company, the Holder agrees that, in the event of a Change in Control that is an "arms length" sale of all or substantially all of the Company's assets (and only its assets) to a third party that is not an Affiliate (as defined below) of the Company (a "***True Asset Sale***"), either (a) the Holder shall exercise its conversion or purchase right under this Warrant and such exercise will be deemed effective immediately prior to the consummation of such Change in Control or (b) if the Holder elects not to exercise the Warrant, this Warrant will continue until the Expiration Date if the Company continues as a going concern following the closing of any such True Asset Sale. The Company shall provide the Holder with written notice of its request relating to the foregoing (together with such reasonable information as such Holder may request in connection with such contemplated Change in Control giving rise to such notice), which is to be delivered to the Holder not less than ten (10) days prior to the closing of the proposed Change in Control. As used herein "***Affiliate***" shall mean any person or entity that owns or controls directly or indirectly ten (10) percent or more of the stock of the Company, and any person or entity that controls or is controlled by or is under common control with such persons or entities.

(iii) Upon the written request of the Company, the Holder agrees that, in the event of a stock for stock Change in Control of the Company by a publicly traded acquirer if, on the record date for the Change in Control, the fair market value of the Warrant Shares (or other securities issuable upon exercise of this Warrant) is equal to or greater than two (2) times the Exercise Price, the Company may require the Warrant to be deemed automatically exercised and the Holder shall participate in the Change in Control as a holder of the Warrant Shares (or other securities issuable upon exercise of the Warrant) on the same terms as other holders of the same class of securities of the Company.

(iv) Upon the closing of any Change in Control other than those particularly described in subsections (i), (ii) and (iii) above, the successor entity, if any, and if applicable, shall assume the obligations of this Warrant, and this Warrant shall be exercisable for the same securities, cash, and property as would be payable for the Warrant Shares issuable upon exercise of the unexercised portion of this Warrant as if such Warrant Shares were outstanding on the record date for the Change in Control and subsequent closing. The Exercise Price and/or number of Warrant Shares shall be adjusted accordingly.

(d) Number of Warrant Shares. Simultaneously with any adjustment to the Exercise Price pursuant to paragraph (a) of this Section 9, the number of Warrant Shares that may be purchased upon exercise of this Warrant shall be increased or decreased proportionately, so that after such adjustment the aggregate Exercise Price payable hereunder for the increased or decreased number of Warrant Shares shall be the same as the aggregate Exercise Price in effect immediately prior to such adjustment.

(e) Calculations. All calculations under this Section 9 shall be rounded to the nearest cent or up to the next share, as applicable.

(f) Notice of Adjustments. Upon the occurrence of each adjustment pursuant to this Section 9, the Company at its expense will promptly notify the Holders of the applicable adjustment, compute such adjustment, in good faith, in accordance with the terms of this Warrant and prepare a certificate setting forth such adjustment, including a statement of the adjusted Exercise Price and adjusted number or type of Warrant Shares or other securities issuable upon exercise of this Warrant (as applicable), describing the transactions giving rise to such adjustments and showing in detail the facts upon which such adjustment is based. Upon written request, the Company will promptly deliver a copy of each such certificate to the Holder and to the Company's transfer agent.

(g) Notice of Corporate Events. If, while this Warrant is outstanding, the Company (i) declares a dividend or any other distribution of cash, securities or other property in respect of its Common Stock, including, without limitation, any granting of rights or warrants to subscribe for or

purchase any capital stock of the Company or any subsidiary, (ii) authorizes or approves, enters into any agreement contemplating or solicits stockholder approval for any Change in Control or (iii) authorizes the voluntary dissolution, liquidation or winding up of the affairs of the Company, then, except if such notice and the contents thereof shall be deemed to constitute material non-public information, the Company shall deliver to the Holder a notice of such transaction at least ten (10) business days prior to the applicable record or effective date on which a Person would need to hold Common Stock in order to participate in or vote with respect to such transaction and the Company will take all reasonable steps to give Holder the practical opportunity to exercise this Warrant prior to such time; provided, however, that the failure to deliver such notice or any defect therein shall not affect the validity of the corporate action required to be described in such notice.

(h) Special ASX Provision. For so long as shares of the Company's capital stock (or CHESS Depositary Interests representing such shares) are listed or otherwise quoted on the stock market of the Australian Securities Exchange (the ***"ASX"***), the following provisions of this Section 9(h) shall apply.

(i) The Company will, in accordance with the listing rules of the ASX (the ***"ASX Listing Rules"***), make an application to have the Warrant Shares that are issued pursuant to an exercise of this Warrant, listed for official quotation on the market conducted by ASX. In the case of any pro-rata issue (other than a bonus issue), the Exercise Price will be reduced according to the formula set out for making such an adjustment in the ASX Listing Rules. In the case of a bonus issue, the number of Warrant Shares over which this Warrant is exercisable will, in accordance with the ASX Listing Rules, be increased by the number of Warrant Shares which the Holder would have received if this Warrant had been exercised before the record date for the bonus issue. The Company will notify the ASX of the adjustments in accordance with the ASX Listing Rules.

(ii) In the event of any reorganisation (including consolidation, subdivisions, reduction or return) of the authorised or issued capital of the Company, the rights of the Holder will be changed to the extent necessary to comply with the ASX Listing Rules applying to a reorganisation of capital at the time of the reorganisation.

(iii) Upon reorganisation of the Company's capital, the rights of the Holder will, as required, be changed to comply with the ASX Listing Rules.

Other than as permitted under the ASX Listing Rules, the Warrant does not give the Holder any right to vote, receive dividends, participate in new share issues or grant any other rights to the Holder as a shareholder until Warrant Shares are allotted pursuant to the exercise of the Warrant. In the event the terms and conditions of this Section 9(h) conflict with the terms and conditions set forth in Sections 9(a)-(d) of this Warrant, the terms and conditions of this Section 9(h) shall control.

10. PAYMENT OF EXERCISE PRICE. The Holder shall pay the Exercise Price in immediately available funds; provided, however, that if, on any Exercise Date there is not an effective registration statement registering, or no current prospectus available for, the resale of the Warrant Shares by the Holder or if on any Exercise Date, the Warrant Shares (or CHESS Depository Interests representing the Warrant Shares) are not listed or quoted on the ASX, then the Holder may, in its sole discretion, satisfy its obligation to pay the Exercise Price through a "cashless exercise", in which event the Company shall issue to the Holder the number of Warrant Shares determined as follows:

$$X = Y [(A-B)/A]$$

where:

X = the number of Warrant Shares to be issued to the Holder.

Y = the total number of Warrant Shares with respect to which this Warrant is being exercised.

A = the average of the Closing Sale Prices of the shares of Common Stock (as reported by Bloomberg Financial Markets) for the five (5) consecutive Trading Days ending on the date immediately preceding the Exercise Date.

B = the Exercise Price then in effect for the applicable Warrant Shares at the time of such exercise.

For purposes of this Warrant, ***"Closing Sale Price"*** means, for any security as of any date, the last trade price for such security on the principal securities exchange or trading market for such security, as reported by Bloomberg Financial Markets, or, if such exchange or trading market begins to operate on an extended hours basis and does not designate the last trade price, then the last trade price of such security prior to 4:00 P.M., New York City time, as reported by Bloomberg Financial Markets, or if the foregoing do not apply, the last trade price of such security in the over-the-counter market on the electronic bulletin board for such security as reported by Bloomberg Financial Markets, or, if no last trade price is reported for such security by Bloomberg Financial Markets, the average of the bid prices, or the ask prices, respectively, of any market makers for such security as reported in the "pink sheets" by Pink Sheets LLC. If the Closing Sale Price cannot be calculated for a security on a particular date on any of the foregoing

bases, the Closing Sale Price of such security on such date shall be the fair market value as mutually determined by the Company and the Holder. If the Company and the Holder are unable to agree upon the fair market value of such security, then the Board of Directors of the Company shall use its good faith judgment to determine the fair market value. The Board of Directors' determination shall be binding upon all parties absent demonstrable error. All such determinations shall be appropriately adjusted for any stock dividend, stock split, stock combination or other similar transaction during the applicable calculation period.

Notwithstanding anything herein to the contrary, on the Expiration Date, this Warrant shall be automatically exercised via cashless exercise pursuant to this Section 10.

11. LIMITATIONS ON EXERCISE.

(a) Notwithstanding anything to the contrary contained in this Warrant (other than the provisions of Section 11(b) below), the Company shall not effect any exercise of this Warrant, and the Holder shall not have the right to exercise any portion of this Warrant to the extent (but only to the extent) that, after giving effect to such issuance after exercise, the Holder (together with any person acting as a group with the Holder or the Holder's Affiliates) would beneficially own in excess of 9.99% (the ***"Maximum Percentage"***) of the outstanding shares of Common Stock. To the extent the above limitation applies, the determination of whether this Warrant shall be exercisable (vis-à-vis other convertible, exercisable or exchangeable securities owned by the Holder) and of which warrants shall be exercisable (as among all warrants owned by the Holder) shall, subject to such Maximum Percentage limitation, be determined on the basis of the first submission to the Company for conversion, exercise or exchange (as the case may be). No prior inability to exercise this Warrant pursuant to this paragraph shall have any effect on the applicability of the provisions of this paragraph with respect to any subsequent determination of exercisability. For the purposes of this paragraph, beneficial ownership and all determinations and calculations (including, without limitation, with respect to calculations of percentage ownership and as to the determination of any group) shall be determined by the Holder in accordance with Section 13(d) of the Securities Exchange Act of 1934 (the ***"Exchange Act"***) and the rules and regulations promulgated thereunder. The provisions of this paragraph shall be implemented in a manner otherwise than in strict conformity with the terms of this paragraph to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Maximum Percentage beneficial ownership limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such Maximum Percentage limitation. For any reason at any time, upon the written or oral request of the Holder, the Company shall within one (1) Business Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding, including by virtue of any prior conversion or exercise of convertible or exercisable securities into Common Stock, including, without limitation, pursuant to this Warrant or securities issued pursuant to the Securities Purchase Agreement. Each delivery of an Exercise Notice by the Holder will constitute a representation by the Holder that it has evaluated the limitation set forth in this paragraph and determined that issuance of the full number of Warrant Shares requested by the Holder in such Exercise Notice is permitted under this paragraph.

(b) The provisions of Section 11(a) above shall not apply to any exercise by any Holder whose beneficial ownership of Common Stock immediately prior to the issuance of

this Warrant (together with any person acting as a group with such Holder and such Holder's Affiliates) exceeds the Maximum Percentage (an ***"Existing MP Holder"***), provided, however, if at any time after the date hereof an Existing MP Holder and its Affiliates and any other persons or entities whose beneficial ownership of Common Stock would be aggregated with such Holders for purposes of Section 13(d) of the Exchange Act (including shares held by any "group" of which the Holder is a member, but excluding shares beneficially owned by virtue of the ownership of securities or rights to acquire securities that have limitations on the right to convert, exercise or purchase similar to the limitation set forth herein) shall collectively beneficially own the Maximum Percentage or less, then such Holder may deliver a written notice to the Company (an ***"MP Notice"***) providing that such Holder irrevocably elects to be subject to the provisions of Section 11(a).

(c) Notwithstanding anything to the contrary contained in this Warrant, the Company shall not effect any exercise of this Warrant (including if held by an Existing MP Holder that has not delivered an MP Notice), and the Holder shall not have the right to exercise any portion of this Warrant to the extent (but only to the extent) that, after giving effect to such issuance after exercise, the Holder (together with any person acting as a group with the Holder or the Holder's Affiliates) would beneficially own in excess of 19.99% (the ***"Applicable Percentage***") of the outstanding shares of Common Stock. To the extent the above limitation applies, the determination of whether this Warrant shall be exercisable (vis-à-vis other convertible, exercisable or exchangeable securities owned by the Holder) and of which warrants shall be exercisable (as among all warrants owned by the Holder) shall, subject to such Applicable Percentage limitation, be determined on the basis of the first submission to the Company for conversion, exercise or exchange (as the case may be). No prior inability to exercise this Warrant pursuant to this paragraph shall have any effect on the applicability of the provisions of this paragraph with respect to any subsequent determination of exercisability. For the purposes of this paragraph, beneficial ownership and all determinations and calculations (including, without limitation, with respect to calculations of percentage ownership and as to the determination of any group) shall be determined by the Holder in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. The provisions of this paragraph shall be implemented in a manner otherwise than in strict conformity with the terms of this paragraph to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Applicable Percentage beneficial ownership limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such Applicable Percentage limitation. For any reason at any time, upon the written or oral request of the Holder, the Company shall within one (1) Business Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding, including by virtue of any prior conversion or exercise of convertible or exercisable securities into Common Stock, including, without limitation, pursuant to this Warrant or securities issued pursuant to the Securities Purchase Agreement. Each delivery of an Exercise Notice by a Holder will constitute a representation by such Holder that it has evaluated the limitation set forth in this paragraph and determined that issuance of the full number of Warrant Shares requested by the Holder in such Exercise Notice is permitted under this paragraph.

12. NO FRACTIONAL SHARES. No fractional Warrant Shares will be issued in connection with any exercise of this Warrant. In lieu of any fractional shares that would, otherwise be issuable, the number of Warrant Shares to be issued shall be rounded down to the

next whole number and the Company shall pay the Holder in cash the fair market value (based on the Closing Sale Price) for any such fractional shares.

13. NOTICES. Any and all notices or other communications or deliveries hereunder (including, without limitation, any Exercise Notice) shall be in writing and shall be deemed given and effective on the earliest of (i) the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number specified in the Purchase Agreement prior to 5:30 P.M., New York City time, on a Trading Day, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number specified in the Purchase Agreement on a day that is not a Trading Day or later than 5:30 P.M., New York City time, on any Trading Day, (iii) the Trading Day following the date of mailing, if sent by nationally recognized overnight courier service specifying next business day delivery, or (iv) upon actual receipt by the party to whom such notice is required to be given, if by hand delivery. The address and facsimile number of a party for such notices or communications shall be as set forth in the Purchase Agreement unless changed by such party by two (2) Trading Days' prior notice to the other party in accordance with this Section 13.

14. WARRANT AGENT. The Company shall serve as warrant agent under this Warrant. Upon thirty (30) days' notice to the Holder, the Company may appoint a new warrant agent. Any corporation into which the Company or any new warrant agent may be merged or any corporation resulting

from any consolidation to which the Company or any new warrant agent shall be a party or any corporation to which the Company or any new warrant agent transfers substantially all of its corporate trust or shareholders services business shall be a successor warrant agent under this Warrant without any further act. Any such successor warrant agent shall promptly cause notice of its succession as warrant agent to be mailed (by first class mail, postage prepaid) to the Holder at the Holder's last address as shown on the Warrant Register.

15. MISCELLANEOUS.

(a) No Rights as a Stockholder. Unless otherwise permitted in this Warrant, the Holder, solely in such Person's capacity as a holder of this Warrant, shall not be entitled to vote or receive dividends or be deemed the holder of share capital of the Company for any purpose, nor shall anything contained in this Warrant be construed to confer upon the Holder, solely in such Person's capacity as the Holder of this Warrant, any of the rights of a stockholder of the Company or any right to vote, give or withhold consent to any corporate action (whether any reorganization, issue of stock, reclassification of stock, consolidation, merger, amalgamation, conveyance or otherwise), receive notice of meetings, receive dividends or subscription rights, or otherwise, prior to the issuance to the Holder of the Warrant Shares which such Person is then entitled to receive upon the due exercise of this Warrant. In addition, nothing contained in this Warrant shall be construed as imposing any liabilities on the Holder to purchase any securities (upon exercise of this Warrant or otherwise) or as a stockholder of the Company, whether such liabilities are asserted by the Company or by creditors of the Company.

(b) Authorized Shares.

(i) The Company covenants that during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number

of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of executing stock certificates to execute and issue the necessary certificates for the Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the trading market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

(ii) Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (a) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (b) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant, and (c) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof as may be necessary to enable the Company to perform its obligations under this Warrant.

(iii) Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

(c) Successors and Assigns. Subject to compliance with applicable securities laws, this Warrant may be assigned by the Holder. This Warrant may not be assigned by the Company without the written consent of the Holder except to a successor in the event of a Change in Control. This Warrant shall be binding on and inure to the benefit of the parties hereto and their respective successors and assigns. Subject to the preceding sentence, nothing in this Warrant shall be construed to give to any Person other than the Company and the Holder any legal or equitable right, remedy or cause of action under this Warrant. This Warrant may be amended only in writing signed by the Company and the Holder, or their successors and assigns.

(d) Amendment and Waiver. Except as otherwise provided herein, the provisions of the Warrant may be amended and the Company may take any action herein

prohibited, or omit to perform any act herein required to be performed by it, only if the Company has obtained the written consent of the Holder.

(e) Acceptance. Receipt of this Warrant by the Holder shall constitute acceptance of and agreement to all of the terms and conditions contained herein.

(f) Governing Law; Jurisdiction. ALL QUESTIONS CONCERNING THE CONSTRUCTION, VALIDITY, ENFORCEMENT AND INTERPRETATION OF THIS WARRANT SHALL BE GOVERNED BY AND CONSTRUED AND ENFORCED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK WITHOUT REGARD TO THE PRINCIPLES OF CONFLICTS OF LAW THEREOF. EACH PARTY HEREBY IRREVOCABLY SUBMITS TO THE EXCLUSIVE JURISDICTION OF THE STATE AND FEDERAL COURTS SITTING IN THE CITY OF NEW YORK, BOROUGH OF MANHATTAN, FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION HEREWITH OR WITH ANY TRANSACTION CONTEMPLATED HEREBY OR DISCUSSED HEREIN (INCLUDING WITH RESPECT TO THE ENFORCEMENT OF ANY OF THE TRANSACTION DOCUMENTS), AND HEREBY IRREVOCABLY WAIVES, AND AGREES NOT TO ASSERT IN ANY SUIT, ACTION OR PROCEEDING, ANY CLAIM THAT IT IS NOT PERSONALLY SUBJECT TO THE JURISDICTION OF ANY SUCH COURT.

(g) Headings. The headings herein are for convenience only, do not constitute a part of this Warrant and shall not be deemed to limit or affect any of the provisions hereof.

(h) Severability. In case any one or more of the provisions of this Warrant shall be invalid or unenforceable in any respect, the validity and enforceability of the remaining terms and provisions of this Warrant shall not in any way be affected or impaired thereby, and the parties will attempt in good faith to agree upon a valid and enforceable provision which shall be a commercially reasonable substitute therefor, and upon so agreeing, shall incorporate such substitute provision in this Warrant.

(i) Remedies. The Company stipulates that the remedies at law of the Holder of this Warrant in the event of any default or threatened default by the Company in the performance of or compliance with any of the terms of this Warrant are not and will not be adequate and that, to the fullest extent permitted by law, such terms may be specifically enforced by a decree for the specific performance of any agreement contained herein or by an injunction against a violation of any of the terms hereof or otherwise.

IN WITNESS WHEREOF, the Company has caused this Warrant to be duly executed by its authorized officer as of the date first indicated above.

SUNSHINE HEART, INC.

By: _____
Name: _____
Title: _____

EXHIBIT 24

SUNSHINE HEART, INC.

Powers of Attorney

The undersigned directors of Sunshine Heart, Inc., a Delaware corporation, do hereby make, constitute and appoint David Rosa and Jeffrey Mathiesen, and either of them, the undersigned's true and lawful attorneys-in-fact, with power of substitution, for the undersigned and in the undersigned's name, place and stead, to sign and affix the undersigned's name as such director of said Corporation to an Annual Report on Form 10-K or other applicable form, and all amendments thereto, to be filed by said Corporation with the Securities and Exchange Commission, Washington, D.C., under the Securities Act of 1934, as amended, with all exhibits thereto and other supporting documents, with said Commission, granting unto said attorneys-in-fact, and either of them, full power and authority to do and perform any and all acts necessary or incidental to the performance and execution of the powers herein expressly granted.

IN WITNESS WHEREOF, each of the undersigned have hereunto set their hands as of the dates indicated below.

/s/ Geoffrey Brooke
Dr. Geoffrey Brooke
Date: 19 March, 2012

/s/ Donal O'Dwyer
Donal O'Dwyer
Date: March 23, 2012

/s/ Paul Buckman
Paul Buckman
Date: March 22, 2012

/s/ William Peters
Dr. William Peters
Date: 22 March, 2012

/s/ Nicholas Callinan
Nicholas Callinan
Date: 17 March, 2012

David Rosa
Date:

/s/ Mark Harvey
Dr. Mark Harvey
Date: 22 March, 2012

/s/ Gregory Waller
Gregory Waller
Date: March 19, 2012

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULES 13A-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, David Rosa, certify that:

1. I have reviewed this Annual Report on Form 10-K of Sunshine Heart, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2012

/s/ David Rosa
David Rosa
Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULES 13A-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Jeffrey Mathiesen, certify that:

1. I have reviewed this Annual Report on Form 10-K of Sunshine Heart, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2012

/s/ Jeffrey Mathiesen
Jeffrey Mathiesen
Chief Financial Officer and Secretary

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SEC. 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned certifies that this periodic report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in this periodic report fairly presents, in all material respects, the financial condition and results of operations of Sunshine Heart, Inc.

Date: March 23, 2012

/s/ David Rosa
David Rosa
Chief Executive Officer

Date: March 23, 2012

/s/ Jeffrey Mathiesen
Jeffrey Mathiesen
Chief Financial Officer and Secretary