UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

AMENDMENT NO. 2 TO

FORM 10

GENERAL FORM FOR REGISTRATION OF SECURITIES
PURSUANT TO SECTION 12(b) or (g) OF THE SECURITIES EXCHANGE ACT OF 1934

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 Number)
7651 Anagram Drive **Eden Prairie, Minnesota** (Address of principal executive offices)	**55344** (zip code)

(952) 345-4200
(Issuer's telephone number, including area code)

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

Title of each class to be so registered	**Name of each exchange on which each class is to be registered**
Common stock, par value $0.0001 per share	The NASDAQ Stock Market LLC

Securities to be registered under Section 12(g) of the Act:

None
(Title of Class)

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. (Check one):

Large accelerated filer o	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company x

Cautionary Note Regarding Forward-Looking Statements

This registration statement contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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. Forward-looking statements are not a guarantee of future performance or results, and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. Forward-looking statements are based on information available at the time the statements are made and involve known and unknown risks, uncertainties and other factors that may cause our results, levels of activity, performance or achievements to be materially different from the information expressed or implied by the forward-looking statements in this registration statement. These factors include:

- our ability to obtain additional financing;
- the cost, timing and results of our clinical trials, regulatory submissions and approvals;
- our ability to develop sales, marketing and distribution capabilities;
- continued manufacturing services and supplies of critical components from our business partners;
- the rate of market acceptance of our C-Pulse System;

- our ability to obtain adequate reimbursement from third party payers;
- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patent or other intellectual property rights or that our product is defective;
- our ability to protect and enforce our intellectual property rights;
- our ability to effectively manage our growth;
- our estimates regarding our capital requirements and our need for additional financing; and
- other risk factors included under “Risk Factors” in this registration statement.

You should read the matters described in “Risk Factors” and the other cautionary statements made in this registration statement as being applicable to all related forward-looking statements wherever they appear in this registration statement. We cannot assure you that the forward-looking statements in this registration statement will prove to be accurate and therefore you are encouraged not to place undue reliance on forward-looking statements. You should read this registration statement completely. Other than as required by law, we undertake no obligation to update or revise these forward-looking statements, even though our situation may change in the future.

Trademarks

C-Pulse® and Sunshine Heart™ and other trademarks or service marks of Sunshine Heart appearing in this registration statement are the property of Sunshine Heart, Inc. Trade names, trademarks and service marks of other companies appearing in this registration statement are the property of the respective owners.

Market Data

We obtained industry and market data used throughout this registration statement through our research, surveys and studies conducted by third parties and industry and general publications. We have not independently verified market and industry data from third-party sources.

Reverse Stock Split

We intend to effect a reverse stock split of our common stock ranging from 250 for 1 to 100 for 1 prior to the effective date of this registration statement. Except as otherwise indicated, none of the share or per share information referenced throughout this registration statement has been adjusted to reflect this reverse stock split.

Fiscal Year

Historically, our fiscal years have consisted of 12-month periods ending June 30. In September 2011, we changed our fiscal year to coincide with the calendar year. As a result, June 30, 2011 was our last fiscal year that will end on June 30, we will have a six-month fiscal year that began on July 1, 2011 and will end on December 31, 2011, and all future fiscal years will begin on January 1 and end on December 31 of that year. Except as otherwise indicated, all references in this registration statement to “fiscal 2010” or “2010” refer to the 12-month period ended December 31, 2010 and all references to a year or fiscal year prior to 2010 refer to the 12-month period ended on December 31 of the year referenced.

Currency

Unless otherwise indicated in this registration statement, all references to AUD 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.

Other Information

In this registration statement, we, our, us and company refer to Sunshine Heart, Inc. and its subsidiary, except where the context otherwise requires.

The information in this registration statement speaks only as of the date it is filed with the U.S. Securities and Exchange Commission unless the information specifically indicates that another date applies.

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 conducting clinical trials of our C-Pulse System in the U.S., which we expect to extend into 2016 before we will have a determination if it can be marketed in the U.S. 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 test data to the United States Food and Drug Administration, or FDA.

We believe the results of the six-month follow up demonstrate the feasibility and preliminary safety and efficacy of the C-Pulse System in patients with moderate to severe heart failure and we expect to submit an investigational device exemption, or IDE, application to the FDA in early 2012 for approval of our pivotal trial.

We are seeking CE Mark for the C-Pulse and anticipate that we will obtain approval in the first half 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 $7.6 million and $5.3 million in the years ended December 31, 2010 and 2009, respectively, and $11.0 million for the nine months ended September 30, 2011. All of our revenue for the years ended December 31, 2010 and 2009 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 complete our clinical trials.

The Heart Failure Market

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 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.
- *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 recently 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 three to four 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.

The C-Pulse System is an earlier intervention than other mechanical therapies, such as LVADs. Our product assists the heart's natural function rather than completely replacing it. The C-Pulse System device may be turned on or off at any time allowing the patient intervals of freedom to perform certain activities such as bathing. 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 keep the C-Pulse System on for at least 80% of each day to experience maximum 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.

Clinical Development

The feasibility phase of our clinical trial is 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, but we have not implanted any additional patients permitted by this approval.

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 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 two patients were classified as "responders," "non-responders" or "indeterminant" in the data above based on the results from their most recent follow up prior to death. We believe the results of the six-month follow up demonstrate the feasibility of the procedure and provide indications of safety and performance of the C-Pulse in patients with moderate to severe heart failure.

We expect to submit an IDE application to the FDA for approval of our pivotal trial in early 2012. 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 the first half of 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 expect to submit 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 first half of 2012.

Research and Development

Our research and development expense in the years ended December 31, 2010 and 2009 totaled $6.2 million and $3.4 million, respectively, and was $7.9 million and $3.9 million for the nine months ended September 30, 2011 and 2010, 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 the nine months ended September 30, 2011.

We expect to commence the pivotal clinical trial in the first 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 middle 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 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 registration statement.

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 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 and do not have any material long-term agreements with any of our suppliers. We do not "second source" any components of our product and, if any of our suppliers are unwilling or unable to supply a component of our product for any reason, production of the C-Pulse System would be interrupted and our business would be adversely affected. Although we believe we could find alternative suppliers for each component of our product with sufficient lead time, in the short term each of our suppliers is material to our operations in light of our reliance on single suppliers for each critical component of our product. If we obtain regulatory approvals necessary to commercialize our C-Pulse Heart Assist System, 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 December 9, 2011, our portfolio consisted of 28 issued patents, of which 11 were issued in the U.S. and 17 were issued in other countries including Australia, Canada, India, Japan and Mexico. We also have 30 patent applications pending, including 10 in the United States. and the remaining in the countries previously listed as well as in China, the European Union and the United Kingdom. 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 registration statement.

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., 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:

- 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 early 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 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 to determine whether we 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 are also subject to regulation by various state authorities, which may inspect our 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, 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, on May 20, 2009, President Obama signed into law the Fraud Enforcement and Recovery Act of 2009, which greatly expanded 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. Three standards have been promulgated under HIPAA with which we currently are required to comply. We must comply with the Standards for Privacy of Individually Identifiable Health Information, or Privacy Standards, which restrict our use and disclosure of certain individually identifiable health information. We have been required to comply with the Privacy Standards since April 14, 2003.

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 that we are not generally a business associate under HIPAA and we believe that we are in compliance with all of the applicable HIPAA standards, rules and regulations. However, if we fail to comply with these standards, we could be subject to criminal penalties and civil sanctions. 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.

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 in Europe. 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 early 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 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 September 30, 2011, we had 24 employees, consisting of 21 full-time and 3 part-time employees. 17 employees, including all but one of our executive officers, are located at our offices in Eden Prairie, Minnesota, or are otherwise based in the U.S. The remainder, mostly research and development personnel, are located in our Australia office or are otherwise based outside of the U.S. 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 Instruments, or CDIs, representing beneficial ownership of our common stock have been have traded on the Australian Securities Exchange, or ASX, under the symbol "SHC". Each CDI represents one share of our common stock, although we anticipate adjusting this ratio in connection with a reverse stock split we plan to effect prior to effectiveness of this registration statement.

Our principal executive offices are located at 7651 Anagram Drive, 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 registration statement.

Legal Proceedings

We are not currently involved in any material legal proceedings.

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 "Cautionary Note Regarding Forward-Looking Statements" and the other information contained in this Form 10 and the other documents that we will file from time to time with the Securities and Exchange Commission.

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 $7.6 million and $5.3 million for the years ended December 31, 2010 and 2009, respectively, and $11.0 million for the nine months ended September 30, 2011. As of September 30, 2011, our accumulated deficit was $60.0 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, if our listing application is approved, 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 contains a going concern opinion in connection with its audit of our financial statements for the fiscal year ended December 31, 2010. 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 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 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 driver, cuff and interface lead. We do not have any material long-term agreements with any of our suppliers and primarily purchase our components and products on a purchase order basis. If any of our existing suppliers were unable or unwilling to meet our demand for product components, or if the components or finished products that they supply 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.

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.

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 feasibility trials and a subsequent pivotal trial for our C-Pulse System. If we are unable to complete our feasibility trials, commence and complete our pivotal trial, or experience significant delays in either trial, or if the results of a 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.

Our device, the C-Pulse System, is currently undergoing feasibility clinical trials at sites in the United States and Canada. Our United States feasibility clinical trial protocol requires us to obtain clinical data from at least 20 patients to assess device safety and potential efficacy from data collected. Upon completion of the six-month follow-up period for our feasibility trials, we submitted the test data to the FDA on November 29, 2011 and we expect to submit an IDE application to the FDA for approval of a pivotal trial in the first quarter of 2012.

Completion of either trial could be delayed or adverse events during the trial could cause us to modify the existing design, repeat or terminate the trial. If a clinical 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 obtain regulatory approvals and commercialize the product. Our clinical trials may also 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 a pivotal clinical trial, it must demonstrate the safety and efficacy of the C-Pulse System by meeting the trial's endpoints before we can commercial the C-Pulse System. The inability to achieve the safety or efficacy endpoints in a pivotal trial could delay our timeline for obtaining regulatory approval to commercialize our products.

In addition to successfully completing our clinical trials, 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 clinical trials for our products or obtaining regulatory approvals could harm our financial results and our prospects and cause us to seek additional funding.

Even if our feasibility clinical trial is successful and 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 intend to use the data from our North American feasibility trial to support an IDE application for FDA approval of a pivotal trial the C-Pulse System, but 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 that will allow us to commence a clinical trial in the United States. We intend to commence our U.S. pivotal trial in the first 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.

We may be unable to enroll and complete our planned U.S. 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 first half of 2012. The trial is designed to be a randomized trial that includes 270 patents and is expected to involve more than 20 locations. 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 our clinical trials on our anticipated schedule or consistent with the clinical trial protocol and good clinical practice requirements.

If our clinical trials are 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 clinical trials 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.

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.

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 U.S. 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.

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 U.S. reporting company and we have no experience as a U.S. reporting company.

Upon the effectiveness of this registration statement, we will become subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended, or 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. We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

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 December 9, 2011, we owned 11 issued patents in the United States and 10 patent applications in the United States, as well as 17 issued patents and 20 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 our ongoing or planned 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.

Prior to the effective date of this registration statement, our shares have not been listed on any U.S. securities exchange and we have not registered any of our shares of common stock for sale in the United States. 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 September 30, 2011, was approximately 811,000 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 of 1933, as amended, which we refer to as the Securities Act. As of December 9, 2011,

- 235,829,580 shares of our common stock in the form of CDIs were held by persons or entity other than our directors, officers and other affiliates and were eligible for sale in the public market;
- 400,947,831 shares of our common stock in the form of CDIs were held by persons or entity other than our directors, officers and other affiliates and were subject to re-sale restrictions of Rule 144 under the Securities Act; and
- 567,105,833 shares of our common stock in the form of CDIs were held by our directors, officers and other affiliates and were subject to re-sale restrictions of Rule 144 under the Securities Act.

Although we have applied to list our shares of common stock on Nasdaq Capital Market and intend to file with the SEC registration statements on Form S-8 covering approximately 205 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 CDIs 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$0.023 to A$0.063 for the 12 months ended September 30, 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 December 9, 2011, 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 December 9, 2011), approximately 53.1% of our outstanding common stock. Our executive officers, directors and affiliated entities, if acting together, would be able to influence significantly 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.

In general, beginning 90 days after the effective date of this registration statement, under Rule 144 a person who is not one of our directors, officers or other affiliates at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months, would be entitled to sell an unlimited number of shares of our common stock that currently are restricted from being sold in the public market, provided current public information about us is available. Beginning 90 days after the effective date of this registration statement, our directors, officers and other affiliates who have beneficially owned shares of our common stock for at least six months will be entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- one percent of the number of shares of our common stock then outstanding; and
- the average weekly trading volume of our common stock on all national securities exchanges and/or reported through the automated quotation system of a registered securities exchange during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale, or if no such notice is required, the date of receipt of the order to execute the sale.

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 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 U.S. process and enforce U.S. 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 2 — FINANCIAL INFORMATION

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 in conjunction with our consolidated and condensed financial statements and related notes appearing elsewhere in this registration statement. This discussion and analysis includes certain forward-looking statements that involve risks, uncertainties and assumptions. You should review the "Risk Factors" section of this registration statement for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by such forward-looking statements. See "Cautionary Note Regarding Forward-Looking Statements" at the beginning of this registration statement.

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 conducting clinical trials of our C-Pulse System in the U.S., which we expect to extend into 2016 before we will have a determination if it can be marketed in the U.S. 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 test data to the FDA. We believe the results of the six-month follow up demonstrate the feasibility and assessment of safety and indications of performance of the C-Pulse System in patients with moderate to severe heart failure and we expect to submit an IDE application to the FDA in early 2012 for approval of our pivotal trial.

We are seeking CE Mark for the C-Pulse and anticipate that we will obtain approval early in 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, 2010 and 2009, and the nine months ended September 30, 2011, 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 January 2010, FASB issued Accounting Standards Update, or ASU, 2010-06, *Improving Disclosure about Fair Value Measurements*. ASU 2010-06 revises two disclosure requirements concerning fair value measurements and clarifies two others. It requires separate presentation of significant transfers into and out of Levels 1 and 2 of the fair value hierarchy and disclosure of the reasons for such transfers. It also requires the presentation of purchases, sales, issuances and settlements within Level 3 on a gross basis rather than a net basis. The amendments also clarify that disclosures should be disaggregated by class of asset or liability and that disclosures about inputs and valuation techniques should be provided for both recurring and non-recurring fair value

measurements. ASU 2010-06 is effective for interim and annual reporting periods beginning after December 15, 2009, except for certain Level 3 activity disclosure requirements that will be effective for reporting periods beginning after December 15, 2010.

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 September 30, 2011, we had an accumulated deficit of $60.0 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 Nine Months Ended September 30, 2011 to Nine Months Ended September 30, 2010

Revenue

Nine Months Ended September 30, 2011	Nine Months Ended September 30, 2010	Increase (Decrease)	% Change
$ —	$ 354,000	$ (354,000)	N/A

Our decrease in revenue for the nine months ended September 30, 2011 compared to the same period in 2010 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 nine months ended September 30, 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 trials, expected to commence in the first half of 2012.

Research and Development Expense

Nine Months Ended September 30, 2011	Nine Months Ended September 30, 2010	Increase (Decrease)	% Change
$ 7,939,000	$ 3,851,000	$ 4,088,000	106.2%

Our increase in research and development expense for the nine months ended September 30, 2011 compared to the same period in 2010 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

Nine Months Ended September 30, 2011	Nine Months Ended September 30, 2010	Increase (Decrease)	% Change
$ 3,250,000	$ 1,537,000	$ 1,713,000	111.5%

Our increase in selling, general and administrative expense for the nine months ended September 30, 2011 compared to the same period in 2010 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 prepare 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

Nine Months Ended September 30, 2011	Nine Months Ended September 30, 2010	Increase (Decrease)	% Change
$ 228,000	$ 113,000	$ 115,000	101.8%

Our increase in other income for the nine months ended September 30, 2011 compared to the same period in 2010 was primarily caused by increased interest income earned from our increased cash balances following the completion of our financing in September 2010.

Income Tax Expense/(Benefit)

Nine Months Ended September 30, 2011	Nine Months Ended September 30, 2010	Increase (Decrease)	% Change
—	$ (670,000)	$ (670,000)	N/A

Our income tax benefit for the nine months ended September 30, 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. We therefore did not recognize a tax benefit for the nine months ended September 30, 2011. 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.

Comparison of Year Ended December 31, 2010 to Year Ended December 31, 2009

Revenue

Year Ended December 31, 2010	Year Ended December 31, 2009	Increase (Decrease)	% Change
$ 407,000	$ 224,000	$ 183,000	81.7%

Our increase in revenue for the year ended December 31, 2010 compared to the prior year was primarily caused by increased enrollments in our feasibility clinical trial during 2010. All of our revenue during 2009 and 2010 was derived solely from sales of the C-Pulse System to hospitals and clinics under contract in conjunction with our feasibility trial.

Research and Development Expense

Year Ended December 31, 2010	Year Ended December 31, 2009	Increase (Decrease)	% Change
$ 6,229,000	$ 3,425,000	$ 2,804,000	81.9%

Our increase in research and development expense for the year ended December 31, 2010 compared to the prior year was primarily caused by increased development activities related to our C-Pulse device and the recruitment of research and development, regulatory and clinical personnel, including executive level positions, to support the completion of our feasibility clinical trial and to prepare for our pivotal clinical trial.

Selling, General and Administrative Expense

Year Ended December 31, 2010	Year Ended December 31, 2009	Increase (Decrease)	% Change
$ 2,598,000	$ 2,232,000	$ 366,000	16.4%

Our increase in selling, general and administrative expense for the year ended December 31, 2010 compared to the prior year was primarily caused by increased professional fees and personnel costs as we developed our infrastructure and transitioned our headquarter operations from California to Minnesota.

Interest Income

Year Ended December 31, 2010	Year Ended December 31, 2009	Increase (Decrease)	% Change
$ 150,000	$ 91,000	$ 59,000	64.8%

Our increase in other income for the year ended December 31, 2010 compared to the prior year was primarily caused by increased interest income earned from our increased cash balances following the completion of our financing in September 2010.

Income Tax Benefit

Year Ended December 31, 2010	Year Ended December 31, 2009	Increase (Decrease)	% Change
$ 670,000	—	$ 670,000	N/A

Our income tax benefit increased for the year ended December 31, 2010 compared to the prior year was primarily due to a research and development tax credit in Australia that we received in 2010 that we did not receive in the prior year period.

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 $11.9 million in 2010 and $7.4 million through the first nine months of 2011. As of September 30, 2011 and December 31, 2010 and 2009, cash and cash equivalents were $10.3 million, $12.4 million and $7.0 million, respectively. 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 $7.2 million in 2010, $5.8 million in 2009, and $9.7 million and $5.1 million in the nine months ended September 30, 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 $7,000 in 2010, $3,000 in 2009, and $34,000 and $3,000 for the nine months ended September 30, 2011 and 2010, respectively. Cash used in investing activities is related to purchases of property and equipment.

Cash Flows from Financing Activities

Net cash provided by financing activities was $11.9 million in 2010, $8.0 million in 2009, and $7.6 million and $0 in the nine months ended September 30, 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 30, 2010, we did not have any material commitments for capital expenditures.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

ITEM 3 — PROPERTIES

We currently lease a 10,000 square foot facility in Eden Prairie, Minnesota that houses 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 $11,000. We also lease approximately 2,000 square feet of office space in an office complex in St Leonards, New South Wales, Australia, for certain research and development activities. The lease extends on a month-to-month basis through January 31, 2012. Monthly rent and electricity for this facility total approximately $14,000. Upon termination of the lease, we plan to transfer substantially all of the research and development activities to our corporate headquarters.

On October 21, 2011 we entered into a lease for a 23,000 square foot facility in Eden Prairie, Minnesota. The lease period commenced December 1, 2011 and extends through March 31, 2016. This facility will house substantially all of our functional areas and will replace our current corporate headquarters. We have taken possession of this facility and expect to complete the relocation of our headquarters to this space in January 2012. Monthly rent and electricity for this facility total approximately $21,000.

ITEM 4 — SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table shows the number of shares and percentage ownership of our common stock that were beneficially owned as of December 9, 2011 by each of our directors, by each of our executive officers named in the Summary Compensation Table under the heading “Item 6. Executive Compensation” below and by all of our

directors and executive officers as a group. Unless otherwise noted, the persons listed in the table have sole voting and investment power with respect to the shares owned by them.

Beneficial Ownership of Directors and Executive Officers

The following table sets forth certain information with respect to the beneficial ownership of our outstanding common stock as of December 9, 2011 by (i) each of our named executive officers listed in the Summary Compensation Table below; (ii) each of our directors; and (iii) all of our executive officers and directors as a group. Beneficial ownership is determined in accordance with the rules of the SEC. To our knowledge and subject to applicable community property laws, each of the holders of stock listed below has sole voting and investment power as to the stock owned unless otherwise noted. The address for each of our directors and named executive officers is c/o Sunshine Heart, Inc., 7651 Anagram Drive, Eden Prairie, Minnesota 55344.

Name of Beneficial Owner	Number of Shares	Percent(1)
Dr. Geoffrey Brooke	291,697,290(2)	23.2%
Paul Buckman	486,875(3)	*
Nicholas Callinan	10,219,262(4)	*
Dr. Mark Harvey	368,246,778(5)	29.0%
Debra Kridner	2,223,145(6)	*
Donal O’Dwyer	12,362,478(7)	1.0%
Dr. William Peters	16,244,565(8)	1.3%
David Rosa	14,135,417(9)	1.1%
Gregory Waller	—	—
All directors, director nominees, named executive officers and other executive officers as a group (12 persons)	719,450,684(10)	53.1%

* Less than 1%.

(1) Based on 1,203,883,244 shares outstanding as of December 9, 2011.

(2) Includes 238,951,964 shares owned by GBS Bioventures II A/C and GBS Bioventures III A/C, which we collectively refer to as GBS; 563,667 shares subject to outstanding options exercisable within 60 days of December 9, 2011; 49,781,659 shares subject to outstanding options held by GBS exercisable within 60 days of December 9, 2011; and 2,400,000 shares acquirable upon exercise of outstanding warrants held by GBS exercisable within 60 days of December 9, 2011. Dr. Brooke is the managing director of GBS Venture Partners Pty Ltd, which manages each of GBS Bioventures II A/C and GBS Bioventures III A/C. Dr. Brooke disclaims beneficial ownership of the shares held by GBS except to the extent of his pecuniary interest therein.

(3) Includes 486,875 shares subject to outstanding options exercisable within 60 days of December 9, 2011.
(4) Includes 5,919,054 shares owned by Beraleigh Pty Ltd. and 4,300,208 shares subject to outstanding options exercisable within 60 days of December 9, 2011. Mr. Callinan is a director of Beraleigh Pty Ltd.
(5) Includes 150,000 shares owned by Dr. Harvey's pension fund, for which he has the power to make investment and voting decisions; 300,142,260 shares owned by venture capital funds affiliated with CM Capital; 67,857,143 shares subject to outstanding options owned by CM Capital and its affiliated funds exercisable within 60 days of December 9, 2011; and 97,375 shares subject to outstanding options exercisable within 60 days of December 9, 2011. Dr. Harvey disclaims beneficial ownership of the shares held by CM Capital and its affiliates except to the extent of his pecuniary interest therein.
(6) Includes 1,825,417 shares subject to outstanding options exercisable within 60 days of December 9, 2011.
(7) Includes 1,629,144 shares held by a family trust, for which Mr. O'Dwyer serves as a trustee, 7,758,095 shares held by a pension fund for which Mr. O'Dwyer and his wife jointly have the power to make investment and voting decisions, and 2,393,667 subject to outstanding options exercisable within 60 days of December 9, 2011.
(8) Includes 1,450,000 shares owned by Dr. William Peters and Szigetvary Trustee Services Ltd as trustees to Peters JAM Trust; 490,000 shares owned by Szigetvary Trustee Services Ltd; 7,000 shares owned by Dr. William Peters for the benefit of Ava Peters; 7,000 shares owned by Dr. William Peters for the benefit of Michael Peters; 10,464 owned by Dr. William Peters for the benefit of James Peters; 6,686,552 owned by Dr. William Peters and Apollo Trustees No. 1 Limited as trustees to Peters Apollo Trust; 280,000 shares acquirable upon exercise of outstanding warrants exercisable within 60 days of December 9, 2011; and 7,313,549 shares subject to outstanding options exercisable within 60 days of December 9, 2011.
(9) Includes 13,935,417 shares subject to outstanding options exercisable within 60 days of December 9, 2011.

(10) Consists of (i) 567,255,833 shares beneficially owned by the current directors and executive officers; and (ii) 152,194,851 shares issuable upon exercise of outstanding options or warrants that are exercisable within 60 days of December 9, 2011.

Beneficial Owners of More than Five Percent of Our Common Stock

Based on information filed with the ASX and provided to us by certain of our directors, the following table sets forth certain information with respect to the beneficial ownership of persons known by us to be beneficial owners of more than 5% of our common stock as of December 9, 2011. Beneficial ownership is determined in accordance with the rules of the SEC.

Name of Beneficial Owner	Number of Shares	Percent(1)
GBS Venture Partners Pty Ltd	291,133,623(2)	23.2%
Funds affiliated with CM Capital	367,999,403(3)	28.9%
Funds affiliated with Straus & Partners	114,361,344(4)	9.2%
New Emerging Medical Opportunities Fund LP	81,250,000(5)	6.6%

(1) Based on 1,203,883,244 shares outstanding as of December 9, 2011.
(2) Includes 49,781,659 shares subject to outstanding options exercisable within 60 days of December 9, 2011 and 2,400,000 shares acquirable upon exercise of outstanding warrants exercisable within 60 days of December 9, 2011. Dr. Geoff Brooke and Brigitte Smith of GBS Venture Partners Pty Ltd. hold voting and investment power with respect to these shares. The address for GBS Venture Partners Pty Ltd is Harley House, Level 5, 71 Collins Street, Melbourne Vic 3000, Australia.
(3) Includes 67,857,143 shares subject to outstanding options exercisable within 60 days of December 9, 2011. Michel Begun, Andy Jane, Carrie Hillyard, Mark Gill and Dr. Mark Harvey are the partners of CM Capital Investments Pty Ltd and hold voting investment power with respect to these shares. The address for CM Capital is Level 9, 545 Queen Street, Brisbane QLD 4000, Australia.
(4) Based upon share registry provided to us by our transfer agent, Link Market Services. Includes 38,120,488 shares subject to outstanding warrants held by Straus Healthcare Partners, L.P. and 38,120,488 shares subject to outstanding warrants held by Straus Partners LLP. Ravinder Holder and Melville Straus, Partner and Managing Prinicipal, respectively, of Straus Capital Management LLC share voting and investment power over the shares due to their affiliate relationships. The address for Straus & Partners is 767 Third Avenue, 21st Floor, New York, NY 10017.
(5) Based upon share registry provided to us by our transfer agent, Link Market Services. Includes 18,750,000 shares subject to outstanding warrants. Jérôme G.P Fund, Director and CEO of Sectoral Asset Management holds investment and voting power over these shares as investment manager for New Emerging Medical Opportunities Fund LP. The address for New Emerging Medical Opportunities Fund LP is 1000 Sherbrooke St. West, #2120, Montreal, QC Canada H3A 3G4.

ITEM 5 — DIRECTORS AND EXECUTIVE OFFICERS

Directors and Executive Officers

Our directors and executive officers are as follows:

Name	Age	Position
Kevin Bassett	44	Vice President Research, Development & Quality Assurance
Debra Kridner	59	Vice President Research & Regulatory Affairs
Jim Yearick	49	Vice President Marketing & Sales
Jeffrey Mathiesen	51	Chief Financial Officer and Secretary
Paul Buckman	56	Director
Dr. Geoffrey Brooke	56	Director
Nicholas Callinan	65	Chairman of the Board, Director
Dr. Mark Harvey	46	Director
Dr. William Peters	46	Director; Chief Technology Officer & Medical Director
Donal O'Dwyer	58	Director
David Rosa	47	Director; Chief Executive Officer
Gregory Waller	62	Director

The principal occupation and business experience of each officer, director and key employee of the Company is as follows:

Executive Officers

Kevin Bassett: Mr. Basset is our Vice President of Research, Development and Quality Assurance, a position he has held since October 2010. From 2006 to 2010, Mr. Bassett served as the Senior Vice President of Research and Development, Operations, and Quality Assurance at Acorn Cardiovascular, a medical device company that develops treatments for patients with heart failure.

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.

Jeffrey Mathiesen: Since March 2011, Mr. Mathiesen has served as our Chief Financial Officer and Secretary. 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 for Delphax Technologies, Inc., a print solutions provider, from July 2004 to December 2005.

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.

Directors

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. Mr. Buckman has served as Chief Executive Officer and Director of Pathway Medical Technologies, Inc., a medical device company focused on treatment of peripheral arterial disease, since September 2008. 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'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. 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.

Mr. Waller's qualifications to serve on our board of directors include his 35 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.

As described above, Mr. Waller was the Chief Financial Officer and Treasurer of Universal Building Products from 2006 to 2011. Universal Building Products filed a voluntary petition for bankruptcy on August 4, 2010. Except as described in the preceding sentence, no other event has occurred during the past ten years requiring disclosure pursuant to Item 401(f) of Regulation S-K.

Director Classification

Our board of directors is divided into three classes with staggered three-year terms. At each annual general meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time

of election and qualification until the third annual meeting following election. Our directors are divided among the three classes as follows:

- The Class II directors are Dr. Brooke and Mr. Rosa and their terms expire at the annual meeting of stockholders to be held in 2012;
- The Class III directors are Messrs. Callinan, O'Dwyer and Waller and their terms expire at the annual meeting of stockholders to be held in 2013; and
- The Class I directors are Dr. Peters, Mr. Buckman and Dr. Harvey and their terms expire at the annual meeting of stockholders to be held in 2014;

Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors.

There is no family relationship between any director, executive officer or person nominated to become a director or executive officer.

Director Compensation

The following table sets forth certain information regarding compensation of person who served as one of our non-employee directors during the year ended June 30, 2011. During the year ended June 30, 2011, we did not provide any separate compensation to our directors who were also employees.

Name	Fees Earned or Paid in Cash ($)	Total ($)
John Brennan(1)	—	—
Paul Buckman	19,542	19,542
Geoffrey Brooke, MD	—	—
Nicholas Callinan	103,234	103,234
Crispin Marsh	50,853	50,853
Donal O'Dwyer	49,941	49,941

(1) Mr. Brennan resigned from our board of director in May 2011.

All amounts in the table above were converted from Australian Dollars to U.S. Dollars using the conversion rate in effect on the date of invoices submitted by the directors.

Pursuant to our director compensation policy approved by our stockholders in 2004, our non-employee directors were collectively entitled to receive a maximum of A$250,000 (approximately $247,500 based on a conversion rate of AUD1 to $0.99) in cash compensation for their service on our board of directors during the year ended June 30, 2011. Our board of directors had the authority to allocate up to the maximum aggregate compensation among the directors in its discretion. For the year ended June 30, 2011, our board of directors paid each of our directors other than our Chairman and our directors affiliated with venture capital funds A$50,000 in equally quarterly installments. Our Chairman was paid A$100,000 annually in equal quarterly installments. We historically have not provided compensation to our directors affiliated with venture capital funds in connection with their service on our board. Our board may grant directors stock options or equity awards from time to time, but we

do not have a policy of regularly granting of equity or equity-based awards to our directors. All equity compensation awarded to our directors requires approval by our stockholders pursuant to the ASX Listing Rules.

As of June 30, 2011, each director listed in the table above held options to purchase up to the aggregate number of shares of common stock indicated below. Messrs. Brennan and Buckman did not hold any outstanding equity awards as of June 30, 2011.

- Dr. Brooke — 97,000 shares, all of which were vested;
- Mr. Callinan — 2,000,000 shares, 148,556 shares of which were unvested;
- Mr. Marsh — 1,106,665 shares, all of which were vested; and
- Mr. O'Dwyer — 97,000 shares, all of which were vested.

In August 2011, in accordance with the ASX Listing Rules, our stockholders approved an increase to the maximum aggregate cash amount payable to our directors to $500,000 per fiscal year. We do not plan to change the method by which we compensate our directors described above.

ITEM 6 — EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth certain information regarding compensation for the year ended June 30, 2011, provided to our Chief Executive Officer and the two other most highly compensated executive officers who received remuneration exceeding $100,000 during the year ended June 30, 2011, who we refer to as our named executive officers.

Name and Principal Position	Year	Salary ($)	Option Awards ($)(3)	Non-Equity Incentive Plan Compensation ($)	Total ($)
David Rosa *Chief Executive Officer*	2011	280,000	47,146	70,000	397,146
William Peters, MD (1) *Medical Director and Chief Technical Officer*	2011	275,433(2)	—	—	275,433(2)
Debra Kridner *Vice President, Clinical Research and Regulatory Affairs*	2011	211,575	—	22,500	234,075

(1) All amounts were paid to WSP Trading Limited, an entity that Dr. Peters owns.
(2) Amounts paid have been converted from Australian Dollars to U.S. Dollars using a conversion rate of AUD1.00 to $0.99, using the average daily bid rates during the period.
(3) Represents the grant date fair value of the awards granted during the period computed in accordance with FASB ASC Topic 718. For a discussion of the relevant assumptions used to determine the valuation of our option awards for accounting purposes please refer to Note 3 to the Notes to Consolidated Financial Statements filed with this registration statement.

We have an employment agreement with David Rosa, our Chief Executive Officer, which provides that his annual salary initially will be $250,000 and is subject to annual review by our board of directors. Effective January 1, 2011, our board of directors set Mr. Rosa's annual base salary to be $310,000. The board established Mr. Rosa's initial annual base salary of $250,000 in late 2009 in connection with negotiating his employment agreement. The board believed Mr. Rosa's initial base salary was less than the salaries paid to other chief executive officers of small public companies and was appropriate because Mr. Rosa previously had not served as a chief executive officer of a public company. The board increased Mr. Rosa's salary for 2011 in recognition of our company's progress towards its goals during 2010, which included the expansion of our management team, development of a less invasive procedure to implant our product and progress on our feasibility clinical trial, as well as to closer align Mr. Rosa's base salary with those of chief executive officers of other small public companies as determined by the board based on its collective experiences and industry knowledge.

Our employment agreement with Mr. Rosa also provides

that he will be eligible to participate in our short-term incentive bonus scheme with a maximum of up to 25% of his annual salary. The amount of the bonus is determined by our board of directors based on goals agreed upon by Mr. Rosa and our board. Mr. Rosa's goals for the year ended June 30, 2011 related to development projects, relocation of our headquarters to Eden Prairie, Minnesota, development of a minimally invasive procedure to implant our product, and staff development. Our board determined that Mr. Rosa achieved all of these goals and awarded him the maximum cash incentive payment provided in his employment agreement for the year. Mr. Rosa also is entitled to participate in the benefit plans available to our employees generally. The agreement is terminable (i) by either party for any reason with one month's notice, by mutual agreement of the Company and Mr. Rosa; (ii) by mutual agreement between us and Mr. Rosa; (iii) immediately by us for "cause" (as defined in the agreement) if Mr. Rosa has not cured the conduct giving rise to a termination for "cause"; (iv) by us for Mr. Rosa's disability (as defined in the agreement); or (v) immediately by Mr. Rosa for "good reason" (as defined in the agreement) if we have not cured the conduct giving rise to a termination for "good reason." The agreement also provides that, for one year following his termination, Mr. Rosa will not compete with us during the term of his employment with us and he will not solicit any person who was one of our employees during the term of his employment.

For the year ended June 30, 2011, our board determined the salaries for Dr. Peters and Ms. Kridner primarily based on the salary recommendation provided by our Chief Executive Officer. At the beginning of each year, our Chief Executive Officer evaluates three primary factors when recommending salaries for the other named executive officers for the year. Those factors are an evaluation of:

- salaries of persons occupying similar positions at other small medical device companies;
- the overall performance of our company for the prior year; and
- the individual's contributions to our results for the prior year.

Our Chief Executive Officer's evaluation of salaries for persons occupying similar positions at other small medical device companies is based on his general industry knowledge and consultation of proxy statements filed by U.S. publicly traded companies with the SEC. Our Chief Executive Officer uses this market information to confirm that the salaries he recommends for our other named executive officers is not, in his opinion, significantly above or below the salaries of persons occupying similar positions at the companies consulted. Historically, our Chief Executive Officer has not targeted compensation at a specified point relative to the market information he has gathered or used studies or compilations of information prepared by third parties to evaluate salaries paid by our competitors.

Our Chief Executive Officer's evaluation of our company's performance is a subjective evaluation of our progress toward commercializing our product and meeting our business plan. The completion of enrollment of our feasibility clinical trial, commencement of exploration of possibilities to commercialize the C-Pulse System in Europe and commencement of preparations for our pivotal trial all favorably impacted our Chief Executive Officer's and board's evaluation of our performance during the year ended June 30, 2011.

Our Chief Executive Officer evaluates the contribution of the other named executive officers for the year by examining our progress in that officer's functional area. For the year ended June 30, 2011, Ms. Kridner's contributions were significant in light of the completion of enrollment of our feasibility clinical trial and preparations for our pivotal trial. Dr. Peters' contributions for the same period were significant in light of the development of a minimally invasive procedure to implant our product and progress made on developing a next-generation fully implantable device.

Based on the foregoing, our Chief Executive Officer recommended the salaries paid to Dr. Peters and Ms. Kridner for the year ended June 30, 2011, and our board agreed with Mr. Rosa's evaluation of the factors described and approved those salaries. Historically, our board has approved the salaries for other named executive officer's recommended by the Chief Executive Officer without material modification.

Ms. Kridner's non-equity incentive plan compensation award for the year ended June 30, 2011 provided for a payment of up to 20% of her annual salary, based on goals agreed upon by Ms. Kridner and our Chief Executive Officer. Ms. Kridner's goals were tied to completion of enrollment of our feasibility trial, obtaining CE Mark approval, and preparation for our pivotal trial. While we completed enrollment of our feasibility trial and began preparations for our pivotal trial, we are still seeking to obtain CE Mark approval. As a result, our board awarded Ms. Kridner an incentive payment of $22,500 for the year, approximately half of the maximum amount she could have earned.

The following table sets forth certain information concerning equity awards held by our named executive officers that were outstanding as of June 30, 2011.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

	Option Awards			
Name	Number of Securities Underlying Unexercisd Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)(1)	Option Expiration Date
David Rosa	5,000,000(2)	5,000,000	$ 0.049	11/29/20
William Peters, MD	797,881(3)	—	$ 0.0152	1/30/13
	776,000(3)	—	$ 0.0245	7/5/14
	440,000(3)	—	$ 0.176	11/1/16
	56,000(3)	—	$ 0.294	1/31/17
	600,000(3)	—	$ 0.294	4/18/17
	97,500(3)	—	$ 0.196	7/9/18
	675,165(4)	269,936	$ 0.078	8/20/18
Debra Kridner	—	—	n/a	n/a

(1) Amount converted from AUD to U.S. Dollars using a conversion rate of AUD1.00 to $0.98 U.S Dollar based upon bid rate on September 23, 2011.
(2) This option vested as to 50% of the shares on November 29, 2010, the date of grant, and 25% on November 1, 2011, and the remaining 25% will vest on November 1, 2012.

(3) Option fully vested as of June 30, 2011.
(4) This option vests as to 25% of the shares on the first anniversary of the date of grant, and 1/48 per month thereafter until fully vested.

Change in Control Agreements

We have entered into change in control agreements with each of our named executive officers that will require us to provide compensation to them in the event of a change in control of our company. Each agreement has a term that runs from its effective date through the later of (i) the five-year anniversary of the effective date or (ii) if a "change in control" occurs on or prior to the five-year anniversary, the one-year anniversary of the effective date

of the change in control. The agreements will be automatically extended for successive two-year periods until notice of non-renewal is given by either party at least 60 days prior to the end of the then-effective term.

Under the change in control agreements, "change in control" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events: (i) subject to certain exceptions, any person or group's acquisition, directly or indirectly, of more than 50% of the combined voting power of our outstanding securities other than by virtue of a merger, consolidation or similar transaction; (ii) the consummation of a merger, consolidation, or similar transaction involving our company and immediately after the consummation of such merger, consolidation or similar transaction, our stockholders immediately prior thereto do not directly own or beneficially own, either (A) outstanding voting securities representing more than 50% of the combined outstanding voting power of the surviving entity in such merger, consolidation or similar transaction; or (B) more than 50% of the combined outstanding voting power of the parent of the surviving entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their ownership of our outstanding voting securities immediately prior to such transaction; (iii) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of our company, other than a sale, lease, license or other disposition of all or substantially all of our consolidated assets to an entity, more than 50% of the combined voting power of the voting securities of which are owned by our stockholders in substantially the same proportions as their ownership of our outstanding voting securities immediately prior to such transaction; or (iv) individuals who, on March 17, 2011, were members of our board of directors cease to constitute at least a majority of the members of our board, provided that if the appointment, election or nomination for election of any new board member was approved or recommended by a majority of the members of the board as of March 17, 2011, the board member will be treated as being a board member as of March 17, 2011. Notwithstanding the foregoing, the term "change in control" will not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing our domicile.

Our change in control agreement with David Rosa, our Chief Executive Officer, provides that, if a change in control occurs during the term of his agreement and if Mr. Rosa's employment terminates anytime during the one year period after the effective date of the change in control and if such termination is involuntary at our initiative without cause or is due to a voluntary resignation for good reason, we will (1) pay in a lump sum his salary for 18 months and any other earned but unpaid compensation; (2) pay in a lump sum an amount equal to the incentive bonus payment received by Mr. Rosa for the fiscal year immediately preceding the fiscal year in which the termination occurs; and (3) provide healthcare benefits to him and his family for the shorter of (i) 18 months after his termination; or (ii) until the date Mr. Rosa is and/or Mr. Rosa's covered dependents are eligible to receive group medical and/or dental insurance coverage by a subsequent employer.

We have also entered into change in control agreements with each of our named executive officers other than Mr. Rosa, which provide that if a change in control occurs during the term of the officer's agreement and if the officer's employment terminates anytime during the one year period after the effective date of the change in control and if such termination is involuntary at our initiative without cause or is due to a voluntary resignation for good reason, we will (1) pay in a lump sum such officer's salary for 12 months and any other earned but unpaid compensation; (2) pay in a lump sum an amount equal to the incentive bonus payment received by such officer for the fiscal year immediately preceding the fiscal year in which the termination occurs; and (3) provide healthcare benefits to such officer and such officer's family for the shorter of (i) 12 months after the termination; or (ii) until the date the officer is and/or the officer's covered dependents are eligible to receive group medical and/or dental insurance coverage by a subsequent employer.

Additionally, if any named executive officer terminates employment with us (i) during the term of the officer's change in control agreement due to a voluntary resignation for good reason or due to an involuntary termination of an officer's employment by us without cause prior to a change in control and the expiration of the agreement's term (provided that the officer reasonably demonstrates that such termination arose in connection with or in anticipation of a change in control); (ii) a change in control occurs within 90 days after the officer's termination; and (iii) a change in control occurs within 90 days after the termination and occurs during the term of the officer's change in control agreement, then we will provide our named executive officers the applicable payments and health benefits described above.

Under the change in control agreements "cause" for termination exists upon the occurrence of any of the following events, if such event results in a demonstrably harmful impact on our business or reputation: (i) such officer's commission of any felony or any crime involving fraud, dishonesty or moral turpitude; (ii) such officer's attempted commission of, or participation in, a fraud or act of dishonesty against us; (iii) such officer's intentional, material violation of any contract or agreement between us and such officer or of any statutory duty owed to us; (iv) such officer's unauthorized use or disclosure of our confidential information or trade secrets; or (v) such officer's gross misconduct.

Each named executive officer may tender resignation for "good reason" after any of the following are undertaken without such officer's written consent: (i) a significant diminution in officer's employment role with us as in effect immediately prior to the effective date of the change in control; (ii) a greater than 5% aggregate reduction by us in the officer's annual base salary, as in effect on the effective date of the change in control or as increased thereafter unless the reduction is pursuant to an across-the-board proportionate salary reduction for all officers, management-level and other salaried employees due to our financial condition, a greater than 10% aggregate reduction by us of the officer's annual base salary will be required for "good reason" to exist; (iii) any failure by us to continue in effect any benefit plan or program, including fringe benefits, incentive plans and plans with respect to the receipt of our securities, in which the officer is participating immediately prior to the effective date of the change in control, or any action by us that would adversely affect the officer's participation in or reduce his benefits under those benefit plans unless we offer a range of benefit plans and programs that, taken as a whole, is comparable to the benefit plans in effect in which the officer is participating immediately prior to the change in control; or (iv) a non-temporary relocation of the officer's business office to a location more than 50 miles from the location at which the officer performs duties as of the effective date of the

change in control, except for required travel by officer on our business to an extent substantially consistent with the officer's business travel obligations prior to the change in control.

In addition to the payments described above, the change in control agreements with the named executive officers provide that if a change in control occurs while such officer is actively employed by us, such change in control will cause the immediate acceleration of the vesting of 100% of any unvested portion of any stock option awards held by the officer on the effective date of such change in control.

We will not make any of the payments described above unless: (i) the named executive officer signs a full release of any and all claims in favor of us; (ii) all applicable consideration periods and rescission periods have expired; and (iii) as of the dates we provide any payments to the named executive officer, the officer is in strict compliance with the terms of the applicable change in control agreement and any proprietary information agreement the officer has entered into with us.

Compensation Committee Interlocks and Insider Participation

The board members who served on our Remuneration and Nomination Committee during the year ended June 30, 2011 were Dr. Geoffrey Brooke and Paul Buckman. During the year ended June 30, 2011, no person who served as a member of our Remuneration and Nomination Committee was, during such period, an officer or employee of our company, or has ever been one of our officers, and no such person had any transaction with us required to be disclosed in "Item 7 — Certain Relationships and Related Transactions" below. During the year ended June 30, 2011, (i) none of our executive officers served as a member of the compensation committee of another entity, one of whose executive officers served on our Remuneration and Nomination Committee; (ii) none of our executive officers served as a director of another entity, one of whose executive officers served on our Remuneration and Nomination Committee; and (iii) none of our executive officers served as a member of the compensation committee of another entity, one of whose executive officers served as one of our directors.

ITEM 7 — CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Director Independence

Our board of directors currently consists of eight directors. Our board of directors has determined that six of our eight directors are independent directors, as defined under the applicable rules of the Nasdaq Capital Market.

The independent directors are Dr. Geoffrey Brooke, Paul Buckman, Nicholas Callinan, Dr. Mark Harvey, Donal O'Dwyer, and Gregory Waller.

We are also subject to the corporate governance requirements of the ASX, which include guidelines for the determination of whether a director should be considered independent. Under these guidelines, in order for a director to be independent, the board should consider, among other things, whether the director is a "substantial shareholder" or an officer of, or otherwise directly associated with, a "substantial shareholder". The holdings of a shareholder are typically considered substantial if they exceed 5% of the voting securities. As a result, Dr. Geoffrey Brooke and Dr. Mark Harvey may not be considered independent for ASX purposes. However, our board has determined that these directors are independent notwithstanding their association with certain stockholders.

Related Party Transactions

Since July 1, 2008, we have entered into the following transactions with our directors, executive officers, holders of more than five percent of our voting securities, and affiliates of our directors, executive officers and five percent stockholders:

In September 2011, we sold 2,875,000 shares of our common stock to Jeffrey Mathiesen, our Chief Financial Officer, at the price of A$0.04 per share as part of a private placement.

In August, 2011, we entered into indemnification agreements with each of our directors and executive officers that provide, in general, that we will indemnify them to the fullest extent permitted by law in connection with their service to us or on our behalf.

We are party to an agreement with WSP Trading Limited pursuant to which WSP Trading Limited performs technical and medical advisory services for us and we pay WSP A$278,400 annually. This agreement requires that Dr. William Peters serve as our Medical Director and Chief Technical Officer. We make payments to WSP rather than to Dr. Peters directly for Dr. Peters' services to our company as Medical Director and Chief Technical Officer. Dr. Peters is a director of our company and WSP, and Dr. Peters owns all of the equity of WSP.

ITEM 8 — LEGAL PROCEEDINGS

We are not party to any material pending legal proceedings.

ITEM 9 — MARKET PRICE OF AND DIVIDENDS ON THE COMPANY'S COMMON STOCK AND RELATED STOCKHOLDER MATTERS

Market Information

Since September 2004, our shares of common stock have traded on the ASX in the form of CDIs under the symbol "SHC."

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 United States 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 Ending December 31, 2011:				

First Quarter	0.045	0.030	0.047	0.031
Second Quarter	0.063	0.039	0.068	0.042
Third Quarter	0.055	0.035	0.054	0.034
Fourth Quarter (through December 9, 2011)	0.047	0.034	0.046	0.033
Year Ended December 31, 2010:				
First Quarter	0.041	0.031	0.040	0.030
Second Quarter	0.037	0.029	0.031	0.024
Third Quarter	0.036	0.023	0.035	0.022
Fourth Quarter	0.039	0.023	0.040	0.024
Year Ended December 31, 2009:				
First Quarter	0.059	0.032	0.041	0.022
Second Quarter	0.068	0.042	0.055	0.034
Third Quarter	0.102	0.042	0.090	0.037
Fourth Quarter	0.052	0.033	0.047	0.030

As of December 9, 2011, we had 1,203,833,244 shares of common stock issued and outstanding, and there was one holder of record of our common stock, which was Chess Depositary Nominees, or CDN. CDN held shares of our common stock on behalf of approximately 1,200 CDI holders. As of December 9, 2011, there were outstanding options to purchase 418,750,471 shares of our common stock and warrants to purchase 60,624,227 shares of our common stock.

After this registration statement becomes effective, we intend to file with the SEC registration statements on Form S-8 covering approximately 205 million shares of our common stock.

We have not registered any of our outstanding shares of common stock under U.S. federal or state securities laws and all of our outstanding shares are restricted securities for purposes of Rule 144 under the Securities Act. As of December 9, 2011, 235,829,580 shares of our common stock could be sold by our existing stockholders who are not affiliates of our company without restrictions under U.S. federal securities laws pursuant to Rule 144. In addition, beginning 90 days after the effective date of this registration statement, under Rule 144 as in effect on the date this registration statement is filed with the SEC, a person who is not one of our affiliates at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months, would be entitled to sell an unlimited number of shares of our common stock provided current public information about us is available and, after owning such shares for at least one year, would be entitled to sell an unlimited number of shares of our common stock without restriction. Beginning 90 days after the date of this effective date of this registration statement, under Rule 144 as in effect on the date this registration statement is filed with the SEC, our affiliates who have beneficially owned shares of our common stock for at least six months would be entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- one percent of the number of shares of our common stock then outstanding; and
- the average weekly trading volume of our common stock on all national securities exchanges and/or reported through the automated quotation system of a registered securities exchange during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale, or if no such notice is required, the date of receipt of the order to execute the sale.

Sales under Rule 144 by our affiliates are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us.

We cannot estimate the number of shares of our common stock that our existing stockholders will elect to sell under Rule 144.

We have submitted a listing application to the Nasdaq Capital Market for listing of our common stock. There can be no assurance that the listing application will be approved or that a U.S. trading market for our common stock will develop.

Dividends

We currently intend to retain any earnings to finance research and development and the operation and expansion of our business and do not anticipate paying any cash dividends for the foreseeable future. The declaration and payment of any dividends in the future by us will be subject to the sole discretion of our board of directors and will depend upon many 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.

Equity Compensation Plan Information

The following table provides information as of June 30, 2011 with respect to our equity compensation plans. See Note 3 to our consolidated financial statements included elsewhere is this registration statement for further information.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)

Equity compensation plans approved by security holders	24,125,719	$ 0.013	—
Equity compensation plans not approved by security holders	—	n/a	152,000,000
Total	24,125,719	n/a	152,000,000

As of June 30, 2011, the maximum number of shares of our common stock that could be granted under our Amended and Restated 2002 Stock Plan, which we refer to as our 2002 Plan, was 12,037,306. As of that date, we had issued or had outstanding options to purchase 24,125,719 shares of our common stock under the 2002 Plan. A copy of the 2002 Plan is included as Exhibit 10.2 to this registration statement. Each outstanding option in excess of the authorized shares under the 2002 Plan incorporates by reference the terms of the 2002 Plan. In September 2011, our board amended the 2002 Plan to increase the number of shares issuable thereunder to 25,000,000.

In August 2011, our stockholders approved our 2011 Equity Incentive Plan, which we refer to as the 2011 Plan. A copy of the 2011 Plan is included as Exhibit 10.4 of this registration statement. The 2011 Plan became effective in March 2011 when it was adopted by our board of directors, but no award under the 2011 Plan could be exercised (or, in the case of a restricted stock award, restricted stock unit award, or other award of stock, no such award could be granted) unless and until the 2011 Plan was approved by our stockholders. Our board and stockholders subsequently approved an amendment and restatement of the 2011 Plan to increase the number of shares issuable thereunder to 180,000,000. Below is a description of the material features of the 2011 Plan.

General

Our board may terminate or suspend the 2011 Plan at any time, and incentive stock options may not be granted more than 10 years after the effective date of the plan.

Share Reserve

Subject to the provisions of the plan and applicable stock exchange rules, the aggregate number of shares that may be issued under the 2011 Plan is a total of 180,000,000 shares plus the number of any shares underlying outstanding stock awards granted under the 2002 Plan that expire or terminate for any reason prior to exercise or settlement or are forfeited because of the failure to meet a contingency or condition required to vest such shares. The aggregate maximum number of shares of common stock that may be issued pursuant to the exercise of incentive stock options is 180,000,000 shares. The maximum number of shares that may be granted to any participant in a calendar year attributable to performance stock awards must not exceed 37,500,000 shares of common stock.

If an award expires or otherwise terminates without all of the shares covered by such award having been issued, or if the award is settled in cash, such expiration, termination or settlement will not reduce (or otherwise offset) the number of shares that may be available for issue under the 2011 Plan. Similarly, if any shares issued pursuant to an award are forfeited back to our company because of the failure to meet a contingency or condition required to vest such shares in the participant, then the shares that are forfeited will revert to and again become available for issue under the 2011 Plan.

Administration

The 2011 Plan is administered by our board, which may delegate some or all of the administration of the 2011 Plan to a committee or committees. Subject to the terms of the plan, the board has the authority to, among other things, determine which of the persons eligible under the plan will be granted awards, determine when and how each award will be granted, determine the number and type of stock awards to be granted, determine the provisions of each award granted, accelerate the time of exercisability and vesting of awards, suspend or terminate the plan at any time, and subject to any necessary stockholder approval, amend the plan as it deems necessary or advisable.

To the extent permitted by law, our board may also determine that the delivery of shares or the payment of cash upon the exercise, vesting or settlement of an award may be deferred.

Eligibility

Our employees, directors, and certain consultants are eligible to receive awards under the 2011 Plan. However, incentive stock options may be granted only to our employees. Further, no incentive stock option may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our company's total combined voting power or that of any affiliate unless the following conditions are satisfied: (i) the option exercise price must be at least 110% of the fair market value of the stock subject to the option on the date of grant; and (ii) the term of any incentive stock option award must not exceed five years from the date of grant.

Awards

Pursuant to the 2011 Plan, we may grant an eligible person incentive stock options, stock appreciation rights, performance stock awards, performance cash awards, and other stock awards. Other than as expressly set out in the 2011 Plan or as permitted under applicable stock exchange rules, a stock award does not give a participant any right to vote, receive dividends or participate in any new issue of shares. A stock award does not grant a participant any other rights as a stockholder of our company until such time as the participant has satisfied all requirements for the exercise of the award and (if applicable) the issuance of shares subject to the award has been entered into the books and records of our company. Unless otherwise provided in the stock award agreement, if our company is dissolved or liquidated, all outstanding stock awards (except those consisting of vested and outstanding shares not subject to a forfeiture condition or a right of repurchase) will terminate immediately prior to the completion of such dissolution or liquidation, and the shares subject to our company's repurchase rights or subject to a forfeiture condition may be repurchased or reacquired by our company. The Board may, however, cause some or all stock awards to become fully vested, exercisable and/or no longer subject to repurchase or forfeiture before the dissolution or liquidation is completed, but contingent on its completion. The following is a summary of awards that can be granted under the 2011 Plan:

- *Stock Options.* Stock options permit the holder to purchase a specified number of shares of our common stock at a set price. Options granted under the plan may be either incentive or nonstatutory stock options. Subject to the provisions of the plan, the term of each option granted under the 2011 Plan will be exercisable for a period of 10 years from the date of grant or such shorter period as specified in the award agreement. If the option is not exercised within the specified period, the option will terminate. The exercise price of options granted

under the 2011 Plan may be no less than 100% of the fair market value of the shares subject to the option on the date the option is granted, unless an option is granted pursuant to an

assumption of or substitution for another option pursuant to a corporate transaction. The total number of shares subject to an option may vest and become exercisable in periodic instalments. If the aggregate fair market value (as determined at the time of grant) of shares with respect to which incentive stock options are exercisable for the first time by any optionholder during any calendar year exceeds $100,000, the options that exceed such limit will be treated as nonstatutory stock options. Our board may further determine the terms and conditions of options granted under the plan, including the exercise price and vesting and exercisability terms.

- *SARS.* Stock appreciation rights, or SARs, provide for payment to the holder for all or a portion of the excess of the fair market value of a specified number of shares of our common stock on the date of exercise over a specified exercise price. Subject to the provisions of the plan, the term of each SAR granted under the 2011 Plan will be exercisable for a period of 10 years from the date of grant or such shorter period as specified in the award agreement. If the SAR is not exercised within the specified period, the SAR will terminate. The exercise price of each SAR may be no less than 100% of the fair market value of the shares subject to SAR on the date SAR is granted, unless an option is granted pursuant to an assumption of or substitution for another SAR pursuant to a corporate transaction. The total number of shares subject to a SAR may vest and become exercisable in periodic instalments. The SARs may be subject to other terms and conditions on the time or times when it may be exercised as deemed appropriate by our board.

- *Performance Awards.* Performance awards under the 2011 Plan may be performance stock awards or performance cash awards. A performance stock award is a stock award that may vest or may be exercised contingent upon the attainment of certain goals during a performance period and may require the completion of a specified period of continuous service as determined by our board. A performance cash award is a cash award, the payment of which may be contingent upon the attainment of certain performance goals during a performance period, and may also require the completion of a specified period of continuous service as determined by our board. Our board may specify the form of payment of a performance cash award, which may be cash or other property.

- *Other.* Other forms of stock awards valued in whole or in part with reference to shares may be granted under the 2011 Plan at the sole discretion of our board.

Transferability

Our board may impose restrictions on the transferability of options and SARs. Otherwise, an option or SAR may be transferred only by will or pursuant to a domestic relations order. In any event, however, an optionholder may designate a beneficiary who may exercise the option following the optionholder's death.

Termination of Service

Unless otherwise provided in a participant's award or other agreement, upon termination of an award recipient's service for cause with our company, all options or SAR will terminate on the date of such participant's termination of continuous service and the participant will be prohibited from exercising his or her option or SAR from and after the time of such termination. If an award recipient's service with our company terminates other than for cause or upon the participant's death or disability, then the participant may exercise his or her option or SAR, to the extent he or she was entitled to exercise such award as of the date of termination, by no later than the earlier of three months following the date of termination of service or the expiration of the term of option or SAR. If an award recipient's service with our company terminates as a result of the participant's disability, then the participant may exercise his or her option or SAR, to the extent he or she was entitled to exercise such award as of the date of termination, by no later than the earlier of the date 12 months following such termination or the expiration of the term of the option or SAR. If an award recipient's service with our company terminates as a result of the participant's death, then the option or SAR may be exercised to the extent the participant was entitled to exercise such award as of the date of death by the participant's designated beneficiary or representative. The option or SAR must be exercised by no later than the earlier of 18 months following the date of death or the expiration of the term of the option or SAR.

Change in Control; Corporate Transaction

In the event of a change in control, disposition of all or substantially all of our assets, consummation of a disposition of at least 90% of our outstanding securities or consummation of a merger, consolidation or similar transaction following which we are not the surviving corporation or we are the surviving corporation but our shares of common stock are converted or exchanged into other property, a stock award will be subject to additional acceleration of vesting and exercisability as provided in the relevant stock award agreement or provided in any other written agreement between our company or any affiliate and the participant. In the absence of such a provision, no acceleration of vesting or exercisability will occur. In the event of such a corporate transaction, unless otherwise provided by our board or otherwise specified in the agreement evidencing the award, our board must take one or more of the following actions with respect to a stock award, contingent upon the closing or completion of the contemplated transaction, including: arrange for the acquiring corporation to assume or continue the stock award (or substitute a similar stock award), arrange for the assignment of any reacquisition or repurchase rights held by our company in respect of shares issued pursuant to the stock award to the acquiring corporation, accelerate the vesting of the stock award to a date prior to the effective time of such corporate transaction as determined by our board, arrange for a lapse of any reacquisition or repurchase rights held by our company with respect to the stock award, cancel or arrange for the cancellation of the stock award to the extent not vested or exercised prior to the

effective time of the corporate transaction, or make a payment, in such form as determined by our board, equal to the excess (if any) of the value of the property the participant would have received on the exercise of the stock award over any exercise price payable by such holder in connection with such exercise.

Adjustment of Awards

In the event that there is a specified type of change in our company's capital structure not involving the receipt of consideration by our company, such as a stock split or stock dividend, the number of shares reserved under the 2011 Plan and the number of shares and exercise price or strike price, if applicable, of all outstanding stock awards will be appropriately adjusted by our board.

Amendment and Termination

Our board has the authority to amend or terminate the 2011 Plan. No amendment or termination of the 2011 Plan will adversely affect any rights under awards already granted to a participant under the 2011 Plan unless agreed to by the affected participant. Our Board will obtain stockholder approval of any amendment to the 2011 Plan as required by applicable law or stock exchange requirements. Suspension or termination of the 2011 Plan will not impair the rights and obligations of any award granted while the 2011 Plan is in effect, except with the written consent of the affected participant.

ITEM 10 — RECENT SALES OF UNREGISTERED SECURITIES

In the three years preceding the filing of this registration statement, we issued the securities indicated below that were not registered under the Securities Act.

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	245,358,998	Aug.-Sept. 2009	N/A	A$9,810,200
Institutional and high net worth Australian investors	Common Stock upon exercise of options	1,994,923	12/3/09	$A0.017 per share purchase price for Common Stock	A$34,019
Accredited Investors party to Securities Purchase Agreement dated 9/15/10	Common Stock and Warrants to purchase Common Stock	133,420,518 Common Shares 66,710,259 Warrants	11/15/10	A$0.028 per share purchase price for Common Stock A$0.032 per share exercise price for Warrants	A$3,735,774
Summer Street Research Partners	Warrants to purchase Common Stock	3,994,760 Warrants	11/13/10	A$0.028	N/A

Name or Class of Person to Whom Sold	Type of Securities	Amount of Securities	Date of Sale	Exercise Price per Share	Aggregate Offering Consideration
Matthew Dormer	Warrants to Purchase Common Stock	704,958 Warrants	11/13/10	A$0.028	N/A
Institutional and high net worth Australian investors	Common Stock	340,294,600 Common Shares 170,147,300 Warrants	12/8/10	A$0.028	A$9,528,249
Institutional and high net worth Australian investors	Common Stock	3,571,429 Common Shares	1/25/11	N/A	A$100,000
Institutional and high net worth Australian investors	Common Stock	23,716 Common Shares	1/25/11	N/A	A$759
Institutional and high net worth Australian investors	Common Stock	27,840 Common Shares	2/22/11	N/A	A$891

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	1,379,921 Common Shares	5/9/11	N/A	A$44,157
Institutional and high net worth Australian investors	Common Stock	1,000,000 Common Shares	5/23/11	N/A	A$32,000
Institutional and high net worth Australian investors	Common Stock	10,536 Common Shares	6/6/11	N/A	A$335
Malcolm Legget	Common Stock	38,800 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	114,444,346 Common Shares 34,333,306 Warrants	7/27/11	A$0.04 per share purchase price for Common Stock A$0.056 per share exercise price for Warrants	A$4,577,774

Name or Class of Person to Whom Sold	Type of Securities	Amount of Securities	Date of Sale	Exercise Price per Share	Aggregate Offering Consideration
Summer Street Research Partners	Warrants to purchase Common Stock	1,818,052 Warrants	7/27/11	A$0.04	N/A
Institutional and high net worth Australian investors	Common Stock and Warrants to purchase Common Stock	30,806,000 Common Shares 9,241,800 Warrants	9/9/11	A$0.04 per share purchase price for Common Stock A$0.056 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	25,000,000 Common Shares 7,500,000 Warrants	9/13/11	A$0.04 per share purchase price for Common Stock A$0.056 per share exercise price for Warrants	A$1,000,000

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	14,082,730 Common Shares 4,224,819 Warrants	9/16/11	A$0.04 per share purchase price for Common Stock A$0.056 per share exercise price for Warrants	A$563,309
Summer Street Research Partners	Warrants to Purchase Common Stock	306,250 Warrants	9/16/11	A$0.04	N/A
Institutional and high net worth Australian Investors	Common Stock	516,064	9/23/11	N/A	A$16,514
Australian Investor under employee stock option agreement	Common Stock	53,084	9/23/11	N/A	A$1,858
Institutional and high net worth Australian Investors	Common Stock	17,143 Common Shares	11/2/11	N/A	A$549

Australian Investor under employee stock option agreement	Common Stock	118,167 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 November 15, 2010 and July 27, 2011 transactions. 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 November 15, 2010, 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 during August and September 2009 and on each of December 3, 2009, December 8, 2010, January 25, 2010, February 22, 2011, May 9, 2011, May 23, 2011, June 6, 2011, June 22, 2011, September 9, 2011 September 23, 2011 and November 2, 2011 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 agreed 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 the 2002 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 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 three years preceding the filing of this registration statement.

Date of Issuance	Number of Options Granted	Exercise Price per Share
11/29/10	10,000,000	A$0.05
8/18/11	116,118,000	A$0.035
8/18/11	2,337,000	A$0.048
8/18/11	3,000,000	A$0.052
8/19/11	5,842,000	A$0.064
11/2/11	18,451,000	A$0.041
11/29/11	13,274,000	A$0.041

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 the 2002 Plan or our 2011 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 2001 Stock Option Plan and our 2011 Plan qualify as a compensatory benefit plans.

ITEM 11 — DESCRIPTION OF SECURITIES TO BE REGISTERED

General

The following description of our capital stock is a summary only and is qualified in its entirety by reference to our certificate of incorporation, as amended, and amended and restated bylaws, which are included as Exhibits 3.1 and 3.2 of this registration statement.

As of December 9, 2011, we had outstanding 1,203,833,244 shares of our common stock held by one holder of record, which was CDN. CDN held shares of our common stock on behalf of approximately 1,200 CDI holders. As of December 9, 2011, we also had outstanding options to acquire 418,750,471 shares of common stock held by employees, directors and consultants and warrants to purchase 60,624,227 shares of common stock.

Common Stock

We are authorized to issue up to 1,960,000,000 shares of common stock, with a par value of $0.0001 per share.

Holders of our common stock are entitled to receive dividends when and as declared by our board of directors out of funds legally available.

Holders of our common stock are entitled to one vote for each share on each matter properly submitted to our stockholders for their vote; provided however, that except as otherwise required by law, holders of our common stock will not be entitled to vote on any amendment to our certificate of incorporation (including any certificate of designation filed with respect to any series of preferred stock) that relates solely to the terms of a series of outstanding preferred stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon by law or pursuant to our certificate of incorporation (including any certificate of designation filed with respect to any series of preferred stock).

Subject to the voting restrictions described above, holders of our common stock may adopt, amend or repeal our bylaws and/or alter certain provisions of our certificate of incorporation with the affirmative vote of the stockholders of at least 66 $^{2}/_{3}$% of the voting power of all of the then-outstanding shares of our capital stock entitled to vote generally in the election of directors, voting together as a single class, in addition to any vote of the holders of a class or series of our stock required by law or our certificate of incorporation. The provisions of our certificate of incorporation that may be altered only by the super-majority vote described above relate to:

- the number of directors on our board of directors, the classification of our board of directors and the term of the members of our board of directors;
- the limitations on removal of any of our directors described below under "—Anti-Takeover Effects of Certain Provisions of Delaware Law and Our Certificate of Incorporation and Bylaws";
- the ability of our directors to fill any vacancy on our board of directors by the affirmative vote of a majority of the directors then in office under certain circumstances;
- the ability of our board of directors to adopt, amend or repeal our bylaws and the super-majority vote of our stockholders required to adopt, amend or repeal our bylaws described above;
- the limitation on action of our stockholders by written action described below under "—Anti-Takeover Effects of Certain Provisions of Delaware Law and Our Certificate of Incorporation and Bylaws";
- the choice of forum provision described below under "—Choice of Forum";

- the limitations on director liability and indemnification described below under the heading "Item 12. Indemnification of Directors and Officers"; and
- the super-majority voting requirement to amend our certificate of incorporation described above.

Holders of our common stock do not have any conversion, redemption or preemptive rights pursuant to our organizational documents. In the event of our dissolution, liquidation or winding up, holders of our common stock are entitled to share ratably in any assets remaining after the satisfaction in full of the prior rights of creditors and the aggregate of any liquidation preference pursuant to the terms of any certificate of designation filed with respect to any series of preferred stock. The rights, preferences, and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

All outstanding shares of our common stock are fully paid and non-assessable.

Preferred Stock

We are authorized to issue up to 40,000,000 shares of preferred stock, with a par value of $0.0001 per share. We may issue any class of preferred stock in any series. Our board of directors has the authority to establish and designate series, and to fix the number of shares included in each such series and to determine or alter for each such series, such voting powers, designation, preferences, and relative participating, optional, or other rights and such qualifications, limitations or restrictions thereof. Our board of directors is not restricted in repurchasing or redeeming such stock while there is any arrearage in the payment of dividends or sinking fund installments. Our board of directors is authorized to increase or decrease the number of shares of any series subsequent to the issuance of shares of that series, but not below the number of shares of such series then outstanding. The number of authorized shares of preferred stock may be increased or decreased, but not below the number of shares thereof then outstanding, by the affirmative vote of the holders of a majority of the common stock, without a vote of the holders of the preferred stock, or of any series thereof, unless a vote of any such holders is required pursuant to the terms of any certificate of designation filed with respect to any series of preferred stock.

CDIs

In order for our shares of common stock in the form of CDIs to trade electronically on the ASX, we participate in the electronic transfer system known as the Clearing House Electronic Subregister System, or CHESS, operated by ASX Settlement and Transfer Corporation Pty Limited, or ASTC. ASTC provides settlement services for ASX markets to assist participants and issuers to understand the operation of the rules and procedures governing settlement facilities. The ASX Settlement Operating Rules form part of the overall listing and market rules which we are required to comply with as an entity listed on ASX.

CHESS is an electronic system which manages the settlement of transactions executed on ASX and facilitates the paperless transfer of legal title to ASX quoted securities. CHESS cannot be used directly for the transfer of securities of companies domiciled in certain jurisdictions outside of Australia, such as the United States. Accordingly, to enable our shares of common stock to be cleared and settled electronically through CHESS, we have issued and will continue to issue depositary interests called CDIs.

CDIs confer the beneficial ownership in the shares of common stock on the CDI holder, with the legal title to such shares held by CDN, a subsidiary of ASX, to act as our Australian depositary and issue CDIs.

A holder of CDIs who does not wish to have their trades settled in CDIs may request that their CDIs be converted into shares of common stock, in which case legal title to the shares of common stock will be transferred to the holder of CDIs and stock certificates representing the shares of common stock will be issued.

Anti-Takeover Effects of Certain Provisions of Delaware Law and Our Certificate of Incorporation and Bylaws

Certificate of Incorporation and Bylaws

Certain provisions of our certificate of incorporation and bylaws may be considered as having an anti-takeover effect, such as those provisions:

- providing for our board of directors to be divided into three classes with staggered three-year terms, with only one class of directors being elected at each annual meeting of our stockholders and the other classes continuing for the remainder of their respective three-year terms;
- authorizing our board of directors to issue from time to time any series of preferred stock and fix the voting powers, 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 $^{2}/_{3}$% super-majority stockholder approval in order for stockholders to alter, amend or repeal certain provisions of our certificate of incorporation;

- requiring a 66 $^{2}/_{3}$% super-majority stockholder approval in order for stockholders to adopt, amend or repeal our bylaws;
- providing that, subject to the rights of the holders of any series of preferred stock to elect additional directors under specified circumstances, neither the board of directors nor any individual director may be removed without cause;
- creating the possibility that our board of directors could prevent a coercive takeover of the Company due to the significant amount of authorized, but unissued shares of our common stock and preferred stock;
- providing that, subject to the rights of the holders of any series of preferred stock, the number of directors shall be fixed from time to time exclusively by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- providing that any vacancies on our board of directors under certain circumstances will be filled only by a majority of our board of directors then in office, even less than a quorum, and not by the stockholders.

Delaware Law

We are also subject to Section 203 of the Delaware General Corporation Law, which in general prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder, unless:

- prior to that date, our board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of our voting stock outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned by (i) persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to that date, the business combination is approved by our board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 $^{2}/_{3}$% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines an interested stockholder as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by any of these entities or persons.

The above-summarized provisions of the Delaware General Corporation Law and our certificate of incorporation and bylaws could make it more difficult to acquire us by means of a tender offer, a proxy contest or otherwise, or to remove incumbent officers and directors. These provisions are expected to discourage certain types of coercive takeover practices and takeover bids that our board of directors may consider inadequate and to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging takeover or acquisition proposals because, among other things, negotiation of these proposals could result in an improvement of their terms.

Preemptive Right Pursuant to Securities Purchase Agreement

Pursuant to a securities purchase agreement, dated July 21, 2011, between us and the purchasers party thereto, the purchasers have a preemptive right to purchase equity or equity-based securities we offer after the date of the agreement through July 25, 2012. Prior to our offering any equity or equity-based securities during this time, or within 30 days after the closing of any sale of such securities, we must offer to issue to the purchasers, on the terms we are offering the securities to third parties, an aggregate of 25% of the securities we are offering. The number of offered securities which each purchaser will have a right to subscribe for will be based on the purchaser's pro rata portion of the aggregate number of common shares purchased under the securities purchase agreement by all purchasers party thereto. If a purchaser fails to purchase its pro rata share of the securities subject to the preemptive right, then such holder will no longer have preemptive rights pursuant to the securities purchase agreement for any subsequent placement of our securities. The preemptive right provided by the securities purchase agreement is subject to certain exceptions, including for securities issued pursuant to convertible securities issued prior to the date of the securities purchase agreement, securities issued pursuant to certain commercial arrangements and securities issued under the 2002 Plan and the 2011 Plan.

Choice of Forum

Our certificate of incorporation provides that, unless we consent in writing otherwise, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any (i) derivative action or proceeding brought on our behalf; (ii) action asserting a breach of fiduciary duty owed by any of our directors, officers or other employees or any of our stockholders; (iii) action asserting a claim pursuant to the Delaware General Corporation Law; or (iv) action asserting a claim that is governed by the internal affairs doctrine.

Listing

We have applied to list our common stock on the Nasdaq Capital Market under the symbol of "SSH". Our shares of common stock in the form of CDIs are listed on the ASX under the symbol "SHC".

Transfer Agent and Registrar

The transfer agent and registrar for our common stock and CDIs is Link Market Services Limited. The transfer agent's address is Level 12, 680 George Street, Sydney NSW 2000, Australia, and the telephone number is +61 2 8280 7111. If our application to list on the Nasdaq Capital Market is approved, we will appoint a transfer agent registered with the SEC.

ITEM 12 — INDEMNIFICATION OF DIRECTORS AND OFFICERS

Our certificate of incorporation limits the liability of our directors to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for any:

- breach of their duty of loyalty to us or our stockholders;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares as provided in Section 174 of the Delaware General Corporation Law; or
- transaction from which the directors derived an improper personal benefit.

These limitations of liability do not apply to liabilities arising under federal securities laws and do not affect the availability of equitable remedies such as injunctive relief or rescission.

Our bylaws provide that we will indemnify and advance expenses to our directors and officers to the fullest extent permitted by law or, if applicable, pursuant to indemnification agreements. They further provide that we may choose to indemnify our other employees or agents from time to time. Subject to certain exceptions and procedures,

our bylaws also require us to advance to any person who was or is a party, or is threatened to be made a party, to any proceeding by reason of the person's service as one of our directors or officers all expenses incurred by the person in connection with such proceeding.

Section 145(g) of the Delaware General Corporation Law and our bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to us, regardless of whether our bylaws permit indemnification. We maintain a directors' and officers' liability insurance policy.

We entered into indemnification agreements with each of our directors and executive officers that provide, in general, that we will indemnify them to the fullest extent permitted by law in connection with their service to us or on our behalf and, subject to certain exceptions and procedures, that we will advance to them all expenses that they incur in connection with any proceeding to which they are, or are threatened to be, a party.

At present, there is no pending litigation or proceeding involving any of our directors or officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission this indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

ITEM 13 — FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See our consolidated financial statements beginning on page F-1.

ITEM 14 — CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 15 — FINANCIAL STATEMENTS AND EXHIBITS

(a) Financial Statements

See our consolidated financial statements beginning on page F-1.

(b) Exhibits

Refer to the Exhibit Index immediately following the signature page of this report, which is incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the registrant has duly caused this amendment no. 2 to the registration statement to be signed on its behalf by the undersigned, thereunto duly authorized.

SUNSHINE HEART, INC.

Date: December 29, 2011

By: /s/ Jeffrey Mathiesen
Name: Jeffrey Mathiesen
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
3.1	Certificate of Incorporation, as amended.+
3.2	Amended and Restated Bylaws.+
4.1	Specimen stock certificate.+
10.1	Form of Indemnity Agreement between the registrant and each of its officers and directors.*+
10.2	Sunshine Heart, Inc. Amended and Restated 2002 Stock Plan.*+
10.3	Form of Notice of Stock Option Grant and Option Agreement for Amended and Restated 2002 Stock Plan.*+
10.4	Amended and Restated Sunshine Heart, Inc. 2011 Equity Incentive Plan.*+
10.5	Form of Stock Option Grant Notice and Option Agreement for 2011 Equity Incentive Plan.*+
10.6	Form of Senior Management Stock Option Grant Notice and Option Agreement for 2011 Equity Incentive Plan.*+
10.7	Form of Change in Control Agreement for the registrant's executive officers.*+
10.8	Form of Warrant to Purchase Common Stock issued to investors pursuant to Securities Purchase Agreement dated September 15, 2010.+
10.9	Form of Warrant to Purchase Common Stock issued to Summer Street Research Partners.+
10.10	Form of Securities Purchase Agreement, dated July 21, 2011, between the registrant and the purchasers party thereto.+
10.11	First Amendment to Securities Purchase 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.+
10.13	Form of Warrant to Purchase Common Stock issued to Matthew Dormer and Summer Street Research Partners.+
10.14	Employment Agreement, dated November 1, 2009, by and between the registrant and David A. Rosa.*+
10.15	Letter Agreement, dated August 3, 2004, between the registrant and WSP Trading Limited.*+
10.16	Lease Agreement, dated September 15, 2010, by and between the registrant and CSM Properties, Inc.+
10.17	Sublease Agreement, dated February 19, 2010 by and between the registrant and Australian Surgical Design & Manufacture Pty, Limited.+
10.18	Lease Agreement, dated October 21, 2011, by and between the registrant and Silver Prairie Crossroads, LLC.+
21	Subsidiaries of the registrant.+

* Indicates management contract or compensatory plan or arrangement.
+ Previously filed.

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, 2010 and 2009, 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, 2010 and 2009, 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
September 30, 2011

SUNSHINE HEART, INC. AND SUBSIDIARY

Consolidated Balance Sheets

Dollars in thousands, except per share amounts	Dec 31, 2010	Dec 31, 2009	September 30, 2011 (unaudited)
Current assets			
Cash and cash equivalents	$ 12,350	$ 7,028	$ 10,344
Accounts receivable, net	247	124	—
Other current assets	182	88	191
Total current assets	**12,779**	**7,240**	**10,535**
Property, plant and equipment	**120**	**145**	**121**
TOTAL ASSETS	**$ 12,899**	**$ 7,385**	**$ 10,656**
Current liabilities			
Accounts payable	$ 696	$ 230	$ 968
Accrued salaries, wages, and other compensation	114	84	310
Total current liabilities	**810**	**314**	**1,278**
Total liabilities	**810**	**314**	**1,278**
Stockholders' equity			
Preferred stock as of September 30, 2011, December 31, 2010 and December 31, 2009, $0.0001 par value per share; authorized 40,000,000 shares	—	—	—
Common stock as of September 30, 2011, December 31, 2010 and December 31, 2009, par value $0.0001 per share; authorized 1,960,000,000 shares; issued and outstanding 1,203,747,934, 1,012,793,468, and 539,078,350, respectively	924	455	931
Additional paid-in capital	59,163	47,637	67,361
Accumulated other comprehensive income:			
Foreign currency translation adjustment	995	372	1,040
Accumulated deficit	(48,993)	(41,393)	(59,954)
Total stockholders' equity	**12,089**	**7,071**	**9,378**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 12,899**	**$ 7,385**	**$ 10,656**

See notes to the consolidated financial statements

SUNSHINE HEART, INC. AND SUBSIDIARY

Consolidated Statements of Operations

In thousands, except per share amounts	Year ended		Nine months ended	
	Dec 31, 2010	Dec 31, 2009	September 30, 2011	September 30, 2010

				(unaudited)
Net sales	**$ 407**	**$ 224**	**$ —**	**$ 354**
Operating expenses				
Selling, general and administrative	2,598	2,232	3,250	1,537
Research and development	6,229	3,425	7,939	3,851
Total operating expenses	8,827	5,657	11,189	5,388
Loss from operations	**(8,420)**	**(5,433)**	**(11,189)**	**(5,034)**
Interest income	150	91	228	113
Loss before income taxes	**(8,270)**	**(5,342)**	**(10,961)**	**(4,921)**
Income tax expense/(benefit)	**(670)**	—	—	**(670)**
Net loss	**$ (7,600)**	**$ (5,342)**	**$ (10,961)**	**$ (4,251)**
Basic and diluted loss per share	**$ (0.01)**	**$ (0.01)**	**$ (0.01)**	**$ (0.01)**
Weighted average shares outstanding - basic and diluted	**577,024**	**359,686**	**1,049,888**	**539,078**

See notes to the consolidated financial statements

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, 2008	**291,724**	**$ 242**	**$ 39,772**	**$ (477)**	**$ (36,051)**	**$ 3,486**
Comprehensive loss:						
Net loss					(5,342)	(5,342)
Foreign currency translation adjustment				849		849
Total comprehensive loss						(4,493)
Stock based compensation			128			128
Issuance of common stock, net	247,354	213	7,737			7,950
Balance December 31, 2009	**539,078**	**455**	**47,637**	**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	473,715	469	11,448			11,917
Balance December 31, 2010	**1,012,793**	**924**	**59,163**	**995**	**(48,993)**	**12,089**
Comprehensive loss:						
Net loss					(10,961)	(10,961)
Foreign currency translation adjustment				45		45
Total comprehensive loss						(10,916)
Stock based compensation			555			555
Issuance of common stock, net	190,955	7	7,643			7,650
Balance September 30, 2011 (unaudited)	**1,203,748**	**$ 931**	**$ 67,361**	**$ 1,040**	**$ (59,954)**	**$ 9,378**

See notes to the consolidated financial statements

SUNSHINE HEART, INC. AND SUBSIDIARY

Consolidated Statements of Cash Flows

(In thousands)	Year ended Dec 31, 2010	Year ended Dec 31, 2009	Nine months ended September 30, 2011 (unaudited)	Nine months ended September 30, 2010 (unaudited)
Reconciliation of net loss to net cash provided by (used in) operations				
Net loss	$ (7,600)	$ (5,342)	$ (10,961)	$ (4,251)
Adjustments to reconcile net loss to cash flows from operating activities:				

Depreciation and amortization	32	11	25	35
Loss on disposal of equipment	—	—	6	—
Stock based compensation expense	78	128	555	42
Changes in asset and liabilities:				
Accounts receivable	(123)	(118)	259	(211)
Other current assets	(94)	(12)	(24)	(785)
Accounts payable and accrued expenses	496	(477)	480	67
Net cash used in operations	**(7,210)**	**(5,810)**	**(9,660)**	**(5,103)**
Cash flows used in investing activities:				
Purchase of property and equipment	(7)	(3)	(34)	(3)
Net cash used in investing activities	**(7)**	**(3)**	**(34)**	**(3)**
Cash flows provided by financing activites:				
Net proceeds from the sale of common stock	11,917	7,950	7,650	—
Net cash provided by financing activities	**11,917**	**7,950**	**7,650**	**—**
Effect of exchange rate changes on cash	623	849	38	139
Net increase (decrease) in cash and cash equivalents	5,322	2,986	(2,006)	(4,967)
Cash and cash equivalents - beginning of period	7,028	4,042	12,350	7,028
Cash and cash equivalents - end of period	**$ 12,350**	**$ 7,028**	**$ 10,344**	**$ 2,061**

See notes to the consolidated financial statements

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 (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, 2010 and 2009, and the nine months ended September 30, 2011, 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 September 30, 2011, we had an accumulated deficit of $60.0 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.

Unaudited Interim Consolidated Financial Information: The interim balance sheet as of September 30, 2011, statements of operations and cash flows for the nine months ended September 30, 2011 and 2010 and stockholders' equity (deficit) for the nine months ended September 30, 2011 and related interim information contained in the notes to these financial statements are unaudited. In the opinion of management, such unaudited interim consolidated information has been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and includes all adjustments consisting of normal recurring accruals necessary for the fair presentation of this interim information when read in conjunction with the audited financial statements and notes thereto. Results for the nine months ended September 30, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011 or any other interim period or for any other future year.

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.

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 September 30, 2011, December 31, 2010 or December 31, 2009.

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	10-15 years
Computer equipment	3-4 years
Laboratory and research equipment	3-15 years

Depreciation expense was $32, $11, $25, and $35 for the years ended December 31, 2010 and 2009, and for the nine months ended September 30, 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 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, 2010 and 2009, or for the nine months ended September 30, 2011.

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 US based parent company is the US dollar. Prior to that date the functional currency of both the US 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 US 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 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 262,197,208, 15,757,816, 443,322,951 and 34,957,816 for the years ended December 31, 2010 and 2009 and the nine months ended September 30, 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 $6,229, $3,425, $7,939, and $3,851 for the years ended December 31, 2010 and 2009, and for the nine months ended September 30, 2011 and 2010, respectively.

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.

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 January 2010, FASB issued Accounting Standards Update, or ASU, 2010-06, *Improving Disclosure about Fair Value Measurements*, or ASU 2010-06. ASU 2010-06 revises two disclosure requirements concerning fair value measurements and clarifies two others. It requires separate presentation of significant transfers into and out of Levels 1 and 2 of the fair value hierarchy and disclosure of the reasons for such transfers. It also requires the presentation of purchases, sales, issuances and settlements within Level 3 on a gross basis rather than a net basis. The amendments also clarify that disclosures should be disaggregated by class of asset or liability and that disclosures about inputs and valuation techniques should be provided for both recurring and non-recurring fair value measurements. ASU 2010-06 is effective for interim and annual reporting periods beginning after December 15, 2009, except for certain Level 3 activity disclosure requirements that will be effective or reporting periods beginning after December 15, 2010.

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.

Note 2 - Balance Sheet Information

Property, Plant and Equipment

Property, plant and equipment were as follows:

	Dec. 31, 2010	Dec. 31, 2009	September 30, 2011 (unaudited)
Library	$ 1	$ 1	$ 1
Office Furniture & Fixtures	90	79	91
Leasehold Improvements	78	69	76
Software	28	25	35
Production Equipment	179	157	173
Computer Equipment	65	51	84
Total	$ 441	$ 382	$ 460
Accumulated Depreciation	(321)	(237)	(339)
	$ 120	$ 145	$ 121

Note 3 - Equity

Private Placement

In August and September 2009, the Company placed 245,164,998 shares of common stock (in the form of CDIs) for proceeds, net of transaction costs, of $7,915.

In November and December, 2010, the Company placed 473,715,118 shares of common stock (in the form of CDIs) for proceeds, net of transaction costs, of $11,917.

In January 2011, the Company placed 3,571,429 shares of common stock (in the form of CDIs) for proceeds, net of transaction costs, of $99.

In July 2011, the Company placed 114,444,346 shares of common stock (in the form of CDIs) for proceeds, net of transaction costs, of $4,597.

In September 2011, the Company placed 69,888,730 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 $78, and $128 during the years ended December 31, 2010 and 2009, respectively, and $555 and $42 during the nine month periods ended September 30, 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, 2010 and 2009 and the nine months ended September 30, 2011 and 2010:

	Dec 31, 2010	Dec 31, 2009	September 30, 2011	September 30, 2010 (unaudited)
Selling, general and administrative	$ 55	$ 96	$ 385	$ 25
Research and development	23	32	170	17
Total	$ 78	$ 128	$ 555	$ 42

As of September 30, 2011 and December 31, 2010 the total compensation cost related to all nonvested awards not yet recognized was $3,552 and $94, respectively. This amount is expected to be recognized over the remaining weighted-average period of 1.11 years as of September 30, 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 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 September 30, 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, 2010 and 2009, and for the nine months ended September 30, 2011.

	Options	Weighted	Remaining	Aggregate

	Outstanding	Average Exercise price	Average Contractual Term (Years)	Intrinsic Value
Outstanding, December 31, 2008	29,448,121	$ 0.20		
2009 Grants	—	—		
2009 Exercises	2,188,923	0.02		
2009 Forfeitures/expiration	11,501,382	0.25		
Outstanding, December 31, 2009	15,757,816	0.19		
2010 Grants	10,000,000	0.05		
2010 Exercises	—	—		
2010 Forfeitures/expiration	418,167	0.18		
Outstanding, December 31, 2010	25,339,649	0.14	7.26	$ 819
Exercisable at December 31, 2010	18,085,236	0.16	6.54	819
2011 Grants (unaudited)	122,118,000	0.03		
2011 Exercises (unaudited)	193,601	0.03		
2011 Forfeitures/expiration (unaudited)	5,646,162	0.06		
Outstanding, September 30, 2011 (unaudited)	141,617,886	$ 0.05	1.11	$ 1,485
Exercisable at September 30, 2011 (unaudited)	28,745,607	$ 0.10	3.44	$ 161

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, 2010 and 2009 and for the nine months ended September 30, 2011 and 2010 was $0, $48, $4 and $0, respectively. Of the 112,872,279 non vested options, 11,130 are held by consultants, the majority of which vest in 2012. Total cash proceeds from exercised options were $0, $34, $1, and $0 for the years ended December 31, 2010 and 2009 and the nine months ended September 30, 2011 and 2010, respectively.

The weighted-average fair value of stock options granted during the year December 31, 2010 was $0.01. No options were issued during 2009. During the nine months ended September 30, 2011, the weighted-average fair value of stock options granted was $0.03.

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 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 term 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 , 2010 and 2009, and for the nine months ended September 30, 2011 and 2010.

	Year ended December 31		Nine Months ended September 30,	
	2010	2009	2011	2010
Expected dividend yield	0%	N/A	0%	N/A
Risk-free interest rate	4.97%	N/A	1.43%	N/A
Expected volatility	65%	N/A	100%	N/A
Expected life (in years)	5	N/A	6.5	N/A

Warrants

On November 10, 2010, the Company issued 71,409,997 warrants at an exercise price of $0.03 and a term of 4 years as part of the private placements previously described.

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

Also, as part of the private placements completed during 2010, the Company issued 170,147,300 warrants to purchase common stock at an exercise price of $0.03 per share. The warrants have a stated life of four years.

As part of the private placement completed during 2011, the Company issued 2,124,302 warrants to purchase common stock at an exercise price of $0.04 per share and 55,299,925 warrants to purchase common stock at an exercise price of $0.05 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 3,200,000 shares at an exercise price of AU$0.25. The warrants have an exercise period of ten years and expire in June 2014. No warrants were exercised during the year.

During the nine months ended September 30, 2011, 2,856,360 warrants were exercised at a price of $0.03 for total proceeds of $99.

Note 4 - Income Taxes

The components of income tax expense for the years ended December 31, 2010 and 2009, and the nine months ended September 30, 2011, consist of the following:

	December 31, 2010	December 31, 2009	September 30, 2011 (unaudited)
Income tax provision:			
Current:			
U.S. and state	—	—	—
Foreign	(670)	—	—
Deferred:			
U.S. and state	—	—	—
Foreign	—	—	—
Total income tax expense	(670)	—	—

Actual income tax expense differs from statutory federal income tax benefit for the years ended December 31, 2010 and 2009 and the nine months ended September 30, 2011 as follows:

	December 31, 2010	December 31, 2009	September 30, 2011 (unaudited)
Statutory federal income tax benefit	(2,812)	(1,816)	(3,726)
State tax benefit, net of federal taxes	(417)	(259)	(595)
Foreign tax	225	199	147
R&D tax credit rebate	(670)	—	—
Nondeductible expenses	—	—	(4)
Valuation allowance increase	3,033	1,787	3,999
Other	(29)	89	179
Total income tax expense	(670)	—	—

Deferred taxes as of December 31, 2010 and 2009, and September 30, 2011, consist of the following:

	December 31, 2010	December 31, 2009	September 30, 2011 (unaudited)
Deferred tax assets (liabilities):			
Accrued expenses	120	84	153
Stock based compensation	385	332	487
Capitalized patent costs	140	132	130
Other	7	7	8
Net operating losses	16,210	11,852	20,644
	16,862	12,407	21,422
Less: valuation allowance	(16,862)	(12,407)	(21,422)
	—	—	—

As of September 30, 2011, we had U.S. net operating loss (NOL) carryforwards of approximately $11,004 for U.S. income tax purposes, which expire in 2023 through 2031, and NOLs in the Commonwealth of Australia of approximately $52,670 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 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 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, 2010 and 2009, and the nine months ended September 30, 2011, the valuation allowance increased by $4,455, $4,663 and $4,560, 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 September 30, 2011, December 31, 2010 or December 31, 2009.

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, 2010 and 2009, and the nine months ended September 30, 2011, we recorded no accrued interest or penalties related to uncertain tax positions.

The fiscal tax years ended June 30, 2007 through June 30, 2011 remain open to examination by the Internal Revenue Service. For the states of California and Minnesota, the fiscal tax year ended June 30, 2006 is also still 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 September 2012. Rent expense related to operating leases was approximately $186, $151, $176 and $129 for the years ended December 31, 2010 and 2009, and the nine months ended September 30, 2011 and 2010, respectively. Future minimum lease payments under non-cancelable operating leases as of September 30, 2011 were approximately $59 through December 31, 2011, and $99 for the year ending December 31, 2012. At September 30, 2011 we did not have any significant lease obligation beyond 2012. See Note 7 for additional discussion.

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, 2010 and 2009, and for the nine months ended September 30, 2011 and 2010, the Company incurred expense of $64, $57, $64, and $44, respectively.

Note 6 — Related Party Transaction

During the year ended December 31, 2010 and 2009, and the nine month periods ended September 30, 2011 and 2010, we paid $4, $5, $0, 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 September 30, 2011 or December 31, 2010. At December 31, 2009, we had outstanding accounts payable of $5 due to the related party. In September 2011, we sold 2,875,000 shares of our common stock to Jeffrey Mathiesen, our Chief Financial Officer, at the price of A$0.04 per share as part of a private placement.

Note 7 — Subsequent Event

On October 21, 2011 we entered into a lease for a 23,000 square foot facility in Eden Prairie, Minnesota. The lease period commenced December 1, 2011 and extends through March 31, 2016. This facility will house substantially all of our functional areas and will replace our current corporate headquarters. We expect to move our operations to this facility in late December 2011. Monthly rent and electricity for this facility total approximately $21,000.

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 Australia.