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

AMENDMENT NO. 5 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)
12988 Valley View Road **Eden Prairie, Minnesota**	**55344**
(Address of principal executive offices)	(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

On January 27, 2012, we effected a reverse stock split of our common stock of 200 for 1. Except as otherwise indicated, all of the share and 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 had a six-month fiscal year that began on July 1, 2011 and ended 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, AU$ or A$ are to Australian Dollars, the lawful currency of the Commonwealth of Australia, and all references to $ or dollars are to U.S. Dollars.

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 of the C-Pulse implantation procedure and provide indications of the safety and

efficacy of the C-Pulse System in patients with moderate to severe heart failure. We expect to submit an investigational device exemption, or IDE, application to the FDA in early 2012 for approval to initiate 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. We have not implanted any additional patients, and currently do not have plans to implant any additional patients, permitted by this approval. If we implant any additional patients permitted by the FDA's April 2011 approval, the patients would be part of our feasibility trial and not included in the results for our planned pivotal trial. The additional centers approved by the FDA in April 2011 for our feasibility trial might participate in our planned pivotal trial, but the protocol for our planned pivotal trial remains subject to FDA approval and the inclusion of any particular center in the pivotal trial cannot be determined with certainty at this time.

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 C-Pulse implantation procedure and provide indications of safety and efficacy of the C-Pulse in patients with moderate to severe heart failure.

We expect to submit an IDE application to the FDA for approval to initiate 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 submitted data from our feasibility clinical trial and documentation relating to the design and manufacturing of our product to our notified body in January 2012. We anticipate that we will obtain CE Mark approval in the 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 balloon, driver unit, cuff and interface lead are provided by outside suppliers and tested by us in-house. Our suppliers include large and small U.S.-based manufacturers of medical device components. The components for our product do not require significant customization for use in our product or necessitate any raw materials for which we believe our suppliers could not readily find alternative sources. We purchase from our suppliers primarily on a purchase order basis. We do not "second source" any components of our product, although we believe we could find alternative suppliers for each component of our product other than the balloon without materially interrupting production of our products at current levels. If the manufacturer of the balloon used in our product was unwilling or unable to supply this component for any reason, however, our business could be adversely affected. If we obtain regulatory approvals necessary to commercialize our C-Pulse Heart Assist System, all of our outsourced manufacturers will need to increase their production of our product or we will need to develop capabilities to manufacture the product ourselves.

Intellectual Property

We have established an intellectual property portfolio through which we seek to protect our products and technology. As of January 27, 2012, our portfolio consisted of 29 issued patents, of which 11 were issued in the U.S. and 18 were issued in other countries including Australia, Canada, India, Japan and Mexico. We also have 29 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 the first half of 2012. Third party reimbursement requirements vary from country to country in Europe and we are not approved for reimbursement by any European third party payors at this time. Healthcare laws in the U.S. and other countries are subject to ongoing changes, including changes to the amount of reimbursement for hospital services. Legislative proposals can substantially change the way healthcare is financed by both governmental and private insurers and may negatively impact payment rates for our products. Also, from time to time there are a number of legislative, regulatory and other proposals both at the federal and state levels; it remains uncertain whether there will be any future changes that will be proposed or finalized and what effect, if any, such legislation or regulations would have on our business. However, in the U.S. and international markets, we expect that both government and third-party payors will continue to attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services.

Government Regulations

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

United States

In the U.S., the FDA regulates the design, manufacture, distribution and promotion of medical devices pursuant to the Federal Food, Drug, and Cosmetic Act, or FDCA, and its regulations. Our C-Pulse Heart Assist System is regulated as a medical device. To obtain FDA approval to market the C-Pulse, the FDA requires proof of safety and efficacy in human clinical trials performed under an IDE. An IDE application must contain pre-clinical test data supporting the safety of the product for human investigational use, information on manufacturing processes and procedures, proposed clinical protocols and other information. If the IDE application is approved, human clinical trials may begin. The trials must be conducted in compliance with FDA regulations and with the approval of institutional review boards. Clinical trials are subject to central registration requirements. The results obtained from these trials are submitted to the FDA in support of a 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 the first half of 2012.

Other Regulations

We are also subject to various federal, state and local laws and regulations relating to such matters as safe working conditions, laboratory and manufacturing practices and the use, handling and disposal of hazardous or potentially hazardous substances used in connection with our research and development and manufacturing activities. Specifically, the manufacture of our biomaterials is subject to compliance with federal environmental regulations and by various state and local agencies. Although we believe we are in compliance with these laws and regulations in all material respects, we cannot provide assurance that we will not be required to incur significant costs to comply with environmental laws or regulations in the future.

Employees

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

Corporate Information

Sunshine Heart, Inc. was incorporated in Delaware on August 22, 2002. We began operating our business through Sunshine Heart Company Pty Ltd, which currently is a wholly owned Australian subsidiary of Sunshine Heart, Inc., in November 1999. Since September 2004, Chess Depositary 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". Historically, each CDI represented one share of our common stock. In connection with the 200 for 1 reverse stock split we effected on January 27, 2012 we changed this ratio so that each CDI represents 1/200th of a share of our common stock.

Our principal executive offices are located at 12988 Valley View Road, Eden Prairie, Minnesota 55344, and our telephone number is (952) 345-4200. Our website address is www.sunshineheart.com. The information on, or that may be accessed through, our website is not incorporated by reference into and should not be considered a part of this 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 balloon, driver, cuff and interface lead. We primarily purchase our components and products on a purchase order basis and do not "second source" any components of our product. If the supplier of the balloon used in our product was unable or unwilling to meet our demand for this component, or if the components or finished products provided by any of our suppliers do not meet quality and other specifications, clinical trials or commercialization of our product could be delayed and increase our expenses. Alternatively, if we have to switch to a replacement manufacturer or replacement supplier for any of our product components, we may face additional regulatory delays, and the manufacture and delivery of our C-Pulse System could be interrupted for an extended period of time and become significantly more

expensive, which could delay completion of future clinical trials or commercialization of our C-Pulse System and adversely affect our results of operations. In addition, we may be required to use different suppliers or components to obtain regulatory approval from the FDA.

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

Intellectual property litigation could be costly and disruptive to us.

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

- stop 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 December 31, 2011, was approximately 1,261 shares. All of our shares of common stock that we have sold have been sold in reliance on exemptions from registration under the Securities Act of 1933, as amended, which we refer to as the Securities Act. As of February 8, 2012,

- 2,836,355 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;
- 988,953 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
- 2,451,230 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 1 million shares of our common stock issuable under our equity plans, there can be no assurance that a liquid public market for our shares will develop in the United States. If an active trading market does not develop in the United States, the market price and liquidity of our shares may be adversely affected.

The price of our common stock may fluctuate significantly.

Our common stock in the form of CDIs has been traded on the ASX in the form of CDIs since 2004. The price of our 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$6.00 to A$12.60 for the 12 months ended December 31, 2011. The price of our common stock could fluctuate significantly for many reasons, including the following:

- future announcements concerning us or our competitors;
- regulatory developments, enforcement actions bearing on advertising, marketing or sales, and disclosure regarding completed, ongoing or future clinical trials;
- quarterly variations in operating results, which we have experienced in the past and expect to experience in the future;
- introduction of new products;
- acquisition or loss of significant manufacturers, distributors or suppliers;

- business acquisitions or divestitures;
- changes in third party reimbursement practices;
- fluctuations of investor interest in the medical device sector; and
- fluctuations in the economy, world political events or general market conditions.

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

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

As of February 8, 2012, our executive officers and directors and entities affiliated with them beneficially owned, in the aggregate (including options or warrants exercisable currently or within 60 days of February 8, 2012), approximately 51.6% 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 of the C-Pulse implantation procedure and provide indications of the safety and efficacy of the C-Pulse System in patients with moderate to severe heart failure. We expect to submit an IDE application to the FDA in early 2012 to initiate 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 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 31, 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 lease a 10,000 square foot facility in Eden Prairie, Minnesota that previously housed our corporate headquarters and substantially all of our functional areas, with the exception of a portion of our research and development activities. The lease expires September 30, 2012 and requires a monthly payment of approximately $11,000. On October 21, 2011 we entered into a lease for a 23,000 square foot facility also located in Eden Prairie, Minnesota. The lease period commenced December 1, 2011 and extends through March 31, 2016. This facility houses substantially all of our functional areas and replaced our corporate headquarters previously located at the other facility we lease in Eden Prairie. Monthly rent and electricity for our new headquarters 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 February 8, 2012 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 February 8, 2012 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., 12988 Valley View Road, Eden Prairie, Minnesota 55344.

Name of Beneficial Owner	Number of Shares	Percent(1)
Dr. Geoffrey Brooke	1,458,954(2)	22.3%
Paul Buckman	2,922(3)	*
Nicholas Callinan	52,148(4)	*
Dr. Mark Harvey	1,879,222(5)	28.2%
Jeffrey Mathiesen	31,832(6)	*
Donal O’Dwyer	62,282(7)	1.0%
Dr. William Peters	84,610(8)	1.3%
David Rosa	77,113(9)	1.2%
Gregory Waller	974(10)	*
All directors, director nominees, named executive officers and other executive officers as a group (12 persons)	3,673,946(11)	51.6%

* Less than 1%.

(1) Based on 6,276,538 shares outstanding as of February 8, 2012.

(2) Includes 1,194,760 shares owned by GBS Bioventures II A/C and GBS Bioventures III A/C, which we collectively refer to as GBS; 3,285 shares subject to outstanding options exercisable within 60 days of February 8, 2012; 248,909 shares subject to outstanding options held by GBS exercisable within 60 days of February 8, 2012; and 12,000 shares acquirable upon exercise of outstanding warrants held by GBS exercisable within 60 days of February 8, 2012. 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 2,922 shares subject to outstanding options exercisable within 60 days of February 8, 2012.

(4) Includes 29,596 shares owned by Beraleigh Pty Ltd. and 22,501 shares subject to outstanding options exercisable within 60 days of February 8, 2012. Mr. Callinan is a director of Beraleigh Pty Ltd.

(5) Includes 750 shares owned by Dr. Harvey’s pension fund, for which he has the power to make investment and voting decisions; 1,500,712 shares owned by venture capital funds affiliated with CM Capital; 339,286 shares subject to outstanding options owned by CM Capital and its affiliated funds

exercisable within 60 days of February 8, 2012; 37,500 outstanding warrants held by CM Capital and its affiliated funds exercisable within 60 days of February 8, 2012; and 974 shares subject to outstanding options exercisable within 60 days of February 8, 2012. 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 13,144 shares subject to outstanding options exercisable within 60 days of February 8, 2012 and 4,313 shares acquirable on exercise of outstanding warrants exercisable within 60 days of February 8, 2012.

(7) Includes 8,146 shares held by a family trust, for which Mr. O'Dwyer serves as a trustee, 38,791 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 12,435 subject to outstanding options exercisable within 60 days of February 8, 2012.

(8) Includes 7,250 shares owned by Dr. William Peters and Szigetvary Trustee Services Ltd as trustees to Peters JAM Trust; 2,450 shares owned by Szigetvary Trustee Services Ltd; 35 shares owned by Dr. William Peters for the benefit of Ava Peters; 35 shares owned by Dr. William Peters for the benefit of Michael Peters; 53 owned by Dr. William Peters for the benefit of James Peters; 33,433 owned by Dr. William Peters and Apollo Trustees No. 1 Limited as trustees to Peters Apollo Trust; 1,400 shares acquirable upon exercise of outstanding warrants exercisable within 60 days of February 8, 2012; and 39,933 shares subject to outstanding options exercisable within 60 days of February 8, 2012.

(9) Includes 76,113 shares subject to outstanding options exercisable within 60 days of February 8, 2012.

(10) Includes 974 shares subject to outstanding options exercisable within 60 days of February 8, 2012.

(11) Consists of (i) 2,836,280 shares beneficially owned by the current directors and executive officers; and (ii) 837,591 shares issuable upon exercise of outstanding options or warrants that are exercisable within 60 days of February 8, 2012.

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 February 8, 2012. 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	1,455,669(2)	22.3%
Funds affiliated with CM Capital	1,877,498(3)	28.2%
Funds affiliated with Straus & Partners	653,059(4)	10.1%
New Emerging Medical Opportunities Fund LP	406,250(5)	6.4%

(1) Based on 6,276,538 shares outstanding as of February 8, 2012.

(2) Includes 248,909 shares subject to outstanding options exercisable within 60 days of February 8, 2012 and 12,000 shares acquirable upon exercise of outstanding warrants exercisable within 60 days of February 8, 2012. 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 339,286 shares subject to outstanding options exercisable within 60 days of February 8, 2012 and 37,500 shares acquirable upon exercise of outstanding warrants exercisable within 60 days of February 8, 2012. 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 114,052 shares subject to outstanding warrants held by Straus Healthcare Partners, L.P. 95,302 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 93,750 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	Senior Vice President, Technology & Operations
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	48	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 Senior Vice President of Technology and Operations, a position he has held since January 2012. From October 2010 until December 2011, Mr. Bassett served as our Vice President of Research, Development and Quality Assurance. 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 each person who served as one of our non-employee directors during the fiscal year ended December 31, 2011. During the fiscal years ended June 30, 2011 and December 31, 2011, we did not provide any separate compensation to our directors who were also employees.

Name	Fiscal Year Ended	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	Total ($)
Geoffrey Brooke, MD	12/31/11	12,649	73,445	86,094
	6/30/11	—	—	—
Paul Buckman	12/31/11	25,963	76,626	102,589
	6/30/11	19,542	—	19,542
Nicholas Callinan	12/31/11	51,375	125,939	177,314
	6/30/11	103,234	—	103,234
Dr. Mark Harvey(2)	12/31/11	12,649	76,887	89,536
	6/30/11	—	—	—

Crispin Marsh(3)	12/31/11	8,129	73,445	81,574
	6/30/11	50,853	—	50,853
Donal O'Dwyer	12/31/11	12,649	73,445	86,094
	6/30/11	49,941	—	49,941
Gregory Waller(4)	12/31/11	21,042	74,784	95,826
	6/30/11	—	—	—

(1) 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.

(2) Dr. Harvey became a director of our company in September 2011.

(3) Mr. Marsh retired from our board of directors in September 2011.

(4) Mr. Waller became a director of our company in August 2011.

All amounts for cash payments 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 $267,500 based on a conversion rate of AUD1 to $1.07) in cash compensation for their service on our board of directors during the year ended June 30, 2011. 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. Our board of directors has the authority to allocate up to the maximum aggregate compensation among the directors in its discretion. For the fiscal year ended December 31, 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 cash compensation to our directors affiliated with venture capital funds in connection with their service on our board. However, effective October 1, 2011, we revised this policy so that our venture capital affiliated directors are compensated on the same basis as our other directors as described above.

Our board grants 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.

During our six-month fiscal year ended December 31, 2011, we granted stock options to each of our non-employee directors. The stock options granted to each of our non-employee directors other than Dr. Harvey and Mr. Waller have an exercise price of A$7.00 per share, representing a 20% premium to the closing price for one of our CDIs on the date the board approved the option grant, have a 10-year term and vest in equal monthly installments over a four-year period. Our stockholders approved these options grants at a special meeting held in August 2011. Prior to these option grants, the last time we granted stock options to non-employee directors generally was in July 2008. We also granted stock options to Mr. Waller and Dr. Harvey during our fiscal year ended December 31, 2011 in connection with their appointments to our board of directors in August and September 2011, respectively. Each of these options has an exercise price of A$8.20 per share, representing the closing price for one of our CDIs on the date the board approved the option grant, has a 10-year term and vests in equal monthly installments over a four-year period. Our stockholders approved these options grants at our annual meeting held in November 2011. Although we previously had a practice of granting stock options to our non-employee directors with a per share exercise price that was greater than the closing price of one of our CDIs on the date the board approved the option grant, which we believe is a typical practice for companies listed on the ASX, we intend to grant future stock options to our non-employee directors and other award recipients with exercise prices equal to the closing price of our common stock on the date of grant consistent with what we believe is common practice for public companies listed on a U.S. stock exchange.

As of December 31, 2011, each individual who served as a non-employee director during our fiscal year ended December 31, 2011 held options to purchase up to the aggregate number of shares of common stock indicated below:

- Dr. Brooke — 11,685 shares, 2,585 of which were unvested;
- Mr. Buckman 11,685 shares, 2,191 of which were unvested;
- Mr. Callinan — 36,705 shares, 21,101 of which were unvested;
- Dr. Harvey — 11,685 shares, 731 of which were unvested;
- Mr. Marsh — 16,734 shares, 7,634 of which were unvested;
- Mr. O'Dwyer — 11,685 shares, 2,585 of which were unvested; and
- Mr. Waller — 11,685 shares, 974 of which were unvested.

ITEM 6 — EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth certain information regarding compensation for the fiscal years ended June 30, 2011 and December 31, 2011, provided to our Chief Executive Officer and the two other most highly compensated executive officers who received remuneration exceeding $100,000 during the fiscal year ended December 31, 2011, who we refer to as our named executive officers.

Name and Principal Position	Fiscal Year Ended	Salary ($)	Option Awards ($)(1)	Non-Equity Incentive Plan	Total ($)

				Compensation ($)(2)	
David Rosa	12/31/11	156,550	1,012,821	79,825	1,249,196
Chief Executive Officer	6/30/11	280,000	47,146	70,000	397,146
William Peters, MD (3)	12/31/11	143,542(4)	529,493	28,663(4)	701,698
Chief Medical Officer	6/30/11	275,433(4)	—	—	275,433
Jeffrey Mathiesen (5)	12/31/11	106,667	344,766	44,000	495,433
Chief Financial Officer	6/30/11	59,879	—	—	59,879

(1) 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.

(2) Amounts shown for Mr. Rosa, Dr. Peters and Mr. Mathiesen for fiscal year ended December 31, 2011 represent non-equity incentive compensation earned during the 12-month calendar year ended December 31, 2011. As a result, the amounts shown for the fiscal year ended December 31, 2011 were earned over the course of two different fiscal years, the last six months of our fiscal year ended June 30, 2011 and the full six-month fiscal year ended December 31, 2011. Amount shown for Mr. Rosa for fiscal year ended June 30, 2011 represents non-equity incentive compensation earned during the 12-month calendar year ended December 31, 2010. As a result, the amounts shown for the fiscal year ended June 30, 2011 were earned over the course of two different fiscal years, the last six months of our fiscal year ended June 30, 2010 and the first six months of our fiscal year ended June 30, 2011.

Historically, Mr. Rosa has been awarded incentive compensation based on performance and milestones achieved during calendar years despite the fact that, until September 2011, our fiscal years ended on June 30. For Mr. Rosa, the material performance measures and milestones for calendar year 2010 related to development projects, relocation of our headquarters to Eden Prairie, Minnesota, development of a minimally invasive procedure to implant our product, and building our executive management team. The material performance measures and milestones for calendar year 2011 related to successful completion of our feasibility trial and progress on our planned pivotal trial, continued financing of our operations and product development. Until our fiscal year beginning July 1, 2010, we historically awarded our Australia-based employees, including Dr Peters, incentive compensation based on performance and milestones achieved during our fiscal years, which ended on June 30. Our fiscal years historically ended on June 30 (until we changed our fiscal year end in September 2011) because our operations previously were based in Australia, where a June 30 fiscal year end is more typical than in the U.S. due to the different seasons in the Southern Hemisphere (i.e., where June 30 falls in winter similar to December 31 falling in winter in the Northern Hemisphere). As we began establishing operations in the United States, we provided incentive compensation to our U.S.-based employees on a calendar year basis because we believed doing so was typical for U.S.-based companies.

Effective for our fiscal year beginning January 1, 2012 and ending December 31, 2012, our board decided to base all employee incentive compensation on performance and milestones achieved during calendar years, which, due to the change in our fiscal year effected in September 2011, will coincide with our fiscal year. As part of this transition of our compensation practices, we deferred the incentive compensation opportunity Dr. Peters otherwise would have received for the fiscal year ended June 30, 2011 to be based on performance and milestones achieved during the 12-month calendar year ended December 31, 2011 and Dr. Peters did not receive any incentive compensation based performance or milestones achieved during our fiscal year ended June 30, 2011. For Dr. Peters, the material performance measures and milestones for calendar year 2011 related to our clinical trial and research and development activities.

We chose the presentation format described above and reflected in the Summary Compensation Table to avoid any “gap” between consecutive periods for which incentive compensation is earned by our named executive officers and incentive compensation information is presented in the table above or in similar tables that we will include in future filings with the SEC.

(3) All amounts were paid to WSP Trading Limited, an entity that Dr. Peters owns.

(4) Amount was converted from Australian Dollars to U.S. Dollars using the conversion rate in effect on the date of payment.

(5) Mr. Mathiesen joined our company as Chief Financial Officer in March 2011.

Chief Executive Officer Employment Agreement and Compensation

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. 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. Effective January 1, 2011, the board increased Mr. Rosa’s salary to $310,000 per year in recognition of our company’s progress towards its goals during calendar year 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.

Historically, Mr. Rosa has been awarded incentive compensation based on our performance and milestones achieved during calendar years despite the fact that, until September 2011, our fiscal years ended on June 30. Beginning with 2012, our fiscal years will coincide with calendar years and with the

time periods for which we provide incentive compensation to Mr. Rosa and our other named executive officers.

Mr. Rosa's incentive compensation goals for calendar year 2010 related to development projects, relocation of our headquarters to Eden Prairie, Minnesota, development of a minimally invasive procedure to implant our product, and building our executive management team. 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. The non-equity incentive plan compensation earned by Mr. Rosa during calendar year 2010 is reflected in the Summary Compensation Table above for the fiscal year ended June 30, 2011 due to the discrepancy between our historic fiscal years and incentive compensation plan practices described above and in footnote 2 to the Summary Compensation Table.

For calendar year 2011, Mr. Rosa's goals related to successful completion of our feasibility trial and progress on our planned pivotal trial, continued financing of our operations and product 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 calendar year 2011. The non-equity incentive plan compensation earned by Mr. Rosa during calendar year 2011 is reflected in the Summary Compensation Table above for the fiscal year ended December 31, 2011 due to the discrepancy between our historic fiscal years and incentive compensation plan practices described above and in footnote 2 to the Summary Compensation Table. We chose the presentation format described above to avoid any "gap" between consecutive periods for which incentive compensation is earned by our named executive officers and incentive compensation information is presented in the Summary Compensation Table above or in similar tables that will be included in future filings with the SEC.

Mr. Rosa is entitled to participate in the benefit plans available to our employees generally. His employment agreement is terminable (i) by either party for any reason with one month's notice, by mutual agreement of us 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.

Our board of directors has granted Mr. Rosa stock options as part of this compensation from time to time. At a special meeting of our stockholders in August 2011, our stockholders approved stock option awards awarded to Mr. Rosa by our board during March 2011 and May 2011. The March 2011 stock option award covers 154,450 shares of our common stock and was granted with a per share exercise price of $7.49 (using a conversion rate of A$1.00 to $1.07 and representing a 20% premium to the closing price for our CDIs on the date the board approved the award). The May 2011 stock option award covers 29,210 shares of our common stock and was granted with a per share exercise price of $13.70 (using a conversion rate of A$1.00 to $1.07 and representing a 20% premium to the closing price for our CDIs on the date the board approved the award). At our annual meeting of our stockholders in November 2011, our stockholders approved a stock option award approved by our board to Mr. Rosa in November 2011. This November 2011 stock option award covers 50,000 shares of our common stock and was granted with a per share exercise price of $10.70 (using a conversion rate of A$1.00 to $1.07 and equaling the closing price for our CDIs on the date the board approved the award).

The ASX Listing Rules require stock options awarded to any of our directors, including Mr. Rosa, to be approved by our stockholders. For accounting purposes, stock options that are granted subject to stockholder approval are treated as granted in the period during which the necessary stockholder approval was obtained. Because we held our annual meeting of stockholders during our fiscal year ended June 30, 2011 before our board awarded the March 2011 and May 2011 stock options granted to Mr. Rosa, these stock options were approved by our stockholders at a special meeting in August 2011 and are treated as granted during our six-month fiscal year ended December 31, 2011 even though our board awarded the options, subject to stockholder approval, during our fiscal year ended June 30, 2011. Because Mr. Rosa also received a stock option award during November 2011 that was approved by our board and stockholders during the same month, there is a significant discrepancy between the value for accounting purposes of option awards granted to Mr. Rosa during our fiscal year ended June 30, 2011 compared to our six-month fiscal year ended December 31, 2011. In general, our board has awarded Mr. Rosa stock options with greater than annual frequency to gradually give him an equity position in our company that our board, in its discretion and based on its collective experiences, believes is appropriate for the chief executive officer of a development-stage public medical device company like ours. Other than the stock option awards described above, and as indicated in the Outstanding Equity Awards at Fiscal Year-End table below, we have granted Mr. Rosa only one other equity award. As indicated in the Beneficial Ownership of Directors and Executive Officers table above, as of February 8, 2012, Mr. Rosa beneficially owned approximately 1.2% of our common stock as calculated in accordance with SEC rules.

Salaries of Other Named Executive Officers

Our board determined the salary for Mr. Mathiesen pursuant to negotiations with Mr. Mathiesen in connection with his hiring in March 2011. Our board determined Dr. Peters' salary in effect during our fiscal years ended June 30, 2011 and December 31, 2011 primarily based on the salary recommendation our Chief Executive Officer made at the beginning of our fiscal year ended June 30, 2011. Historically, up to our fiscal year beginning July 1, 2011, we awarded our Australia-based employees, including Dr Peters, salary increases effective at the beginning of our fiscal years. Our Chief Executive Officer made his salary recommendation for Dr. Peters based on his subjective evaluation of our product development and clinical progress as of the beginning of our fiscal year ended June 30, 2011. Effective for our fiscal year beginning January 1, 2012 and ending December 31, 2012, our board decided to make annual adjustments to employees' salaries, regardless of location, effective at the beginning of each calendar year (which, beginning in 2012, will coincide with our fiscal year). As part of this transition of our compensation practices, we deferred salary adjustments that our Australia-based employees otherwise would have received effective July 1, 2011 to be effective as of January 1, 2012. Dr. Peters therefore was not awarded a salary increase during the periods covered by the Summary Compensation Table in connection with this transition in our compensation practices.

Our current compensation practice is for our Chief Executive Officer to recommend salaries for the other named executive officers at the beginning of each calendar year for the salary to be paid for the that year based on our Chief Executive Officer's evaluation of three primary factors. 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 public 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 help determine whether the salaries he recommends for our other named executive officers are, in his opinion, significantly above or below the salaries of persons occupying similar positions at the companies consulted and that any variations to what the Chief Executive Officer considers to be a "market" salary are in his opinion justified. 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. As of January 1, 2012, salaries for our named executive officers were as follows: Mr. Rosa – $319,300; Dr. Peters – A$283,272; Mr. Mathiesen – $226,600. Future adjustments to the salaries for our named executive officers will be made using the process described above.

Incentive Compensation of Other Named Executive Officers

Dr. Peters' non-equity incentive plan compensation award for calendar year 2011 provided for a payment of up to 10% of his annual salary, based on goals agreed upon by Dr. Peters and our Chief Executive Officer. Dr. Peters' goals for calendar year 2011 were tied to our clinical trial and research and development activities. Based on Dr. Peters' work training and supporting physicians at sites participating in our feasibility trial, his work summarizing and presenting clinical trial data, the successful animal test for our next-generation fully implantable device and improvements to our existing product developed by Dr. Peters during the year, our board awarded Dr. Peters his maximum possible payment under the non-equity incentive plan. The non-equity incentive compensation earned by Dr. Peters during calendar year 2011 is reflected in the Summary Compensation Table above for the fiscal year ended December 31, 2011 due to the discrepancy between our historic fiscal years and the transition in our incentive plan practices described in footnote 2 to the Summary Compensation Table.

In connection with his hiring in March 2011, we decided that Mr. Mathiesen's incentive compensation would be based on the calendar year rather than our fiscal year in effect at that time. Mr. Mathiesen's non-equity incentive plan compensation award for calendar year 2011 provided for a payment of up to 20% of his annual salary. Our board determined that Mr. Mathiesen improved our financial reporting processes and successfully performed his duties for the year and awarded Mr. Mathiesen his maximum possible non-equity incentive payment. The non-equity incentive compensation earned by Mr. Mathiesen during calendar year 2011 is reflected in the Summary Compensation Table above for the fiscal year ended December 31, 2011 due to the discrepancy between our historic fiscal years and incentive compensation plan practices described above and in footnote 2 to the Summary Compensation Table.

Beginning in 2012, our fiscal years will coincide with calendar years and with the relevant periods for which we provide incentive compensation to our named executive officers.

Outstanding Equity Awards

The following table sets forth certain information concerning equity awards held by our named executive officers that were outstanding as of December 31, 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	37,500(2)	12,500	$ 10.70	11/29/20
	28,960(3)	125,490	$ 7.49	8/17/21
	—(5)	29,210	$ 13.70	8/17/21
	—(5)	43,000	$ 8.77	11/28/21
William Peters, MD	3,990(4)	—	$ 3.32	1/30/13
	3,880(4)	—	$ 53.50	7/5/14
	2,200(4)	—	$ 38.52	11/1/16
	280(4)	—	$ 64.20	1/31/17
	3,000(4)	—	$ 64.20	4/18/17
	488(4)	—	$ 42.80	7/9/18
	3,869(5)	857	$ 17.12	8/20/18
	80,745(3)	65,605	$ 7.49	8/17/21
Jeffrey Mathiesen	—(5)	52,575	$ 7.49	8/17/21
	—(5)	5,000	$ 8.77	11/1/21

(1) Amount converted from AUD to U.S. Dollars using a conversion rate of AU$1.00 to $1.07.
(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) This option vests as to 1/48th of the shares per month until fully vested.
(4) Option fully vested as of December 31, 2011.
(5) This option vests as to 25% of the shares on the first anniversary of the date of grant, and 1/48th of the shares 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 fiscal year ended December 31, 2011 were Dr. Geoffrey Brooke, Paul Buckman, Nicholas Callinan and Dr. Mark Harvey. During the fiscal year ended December 31, 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 fiscal year ended December 31, 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 February 2012, we sold 62,500 shares of our common stock and warrants to purchase 18,750 shares of our common stock to Funds affiliated with Straus & Partners for an aggregate purchase price of A$500,000 as part of a private placement. Funds affiliated with Straus & Partners beneficially own more than 5% of our common stock.

In September 2011, we sold 14,375 shares of our common stock to Jeffrey Mathiesen, our Chief Financial Officer, at the price of A$8.00 per share as part of a private placement.

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$283,272 annually effective as of January 1, 2012. 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, 2012:				
First Quarter (through February 7, 2012)	$ 8.40	7.20	$ 9.00	7.40
Year Ended December 31, 2011:				
First Quarter	9.00	6.00	9.40	6.20
Second Quarter	12.60	7.80	13.60	8.40
Third Quarter	11.00	7.00	10.80	6.80
Fourth Quarter	9.40	6.40	9.20	6.60
Year Ended December 31, 2010:				
First Quarter	8.20	6.20	8.00	6.00
Second Quarter	7.40	5.80	6.20	4.80
Third Quarter	7.20	4.60	7.00	4.40
Fourth Quarter	7.80	4.60	8.00	4.80

As of February 8, 2012, we had 6,276,538 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 February 8, 2012, there were outstanding options to purchase 2,123,128 shares of our common stock and warrants to purchase 387,710 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 1 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 February 8, 2012, 2,836,355 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 December 31, 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	887,425	$ 10.67	132,431
Equity compensation plans not approved by security holders	—	n/a	—
Total	887,425	10.67	132,431

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	1,226,795	Aug.-Sept. 2009	N/A	A$9,810,200
Institutional and high net worth Australian investors	Common Stock upon exercise of options	9,975	12/3/09	$A3.40 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	667,103 Common Shares 333,552 Warrants	11/15/10	A$5.60 per share purchase price for Common Stock A$6.40 per share exercise price for Warrants	A$3,735,774
Summer Street Research Partners	Warrants to purchase Common Stock	19,974 Warrants	11/13/10	A$5.60	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	3,525 Warrants	11/13/10	A$5.60	N/A
Institutional and high net worth Australian investors	Common Stock	1,701,473 Common Shares 850,737 Warrants	12/8/10	A$5.60	A$9,528,249
Institutional and high net worth Australian investors	Common Stock	17,858 Common Shares	1/25/11	N/A	A$100,000
Institutional and high net worth Australian investors	Common Stock	119 Common Shares	1/25/11	N/A	A$759
Institutional and high net worth Australian investors	Common Stock	140 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	6,900 Common Shares	5/9/11	N/A	A$44,157
Institutional and high net worth Australian investors	Common Stock	5,000 Common Shares	5/23/11	N/A	A$32,000
Institutional and high net worth Australian investors	Common Stock	53 Common Shares	6/6/11	N/A	A$335
Malcolm Legget	Common Stock	194 Common Shares	6/22/11	N/A	A$586
Accredited Investors party to Securities Purchase Agreement dated 7/25/11	Common Stock and Warrants to purchase Common Stock	572,222 Common Shares 171,667 Warrants	7/27/11	A$8.00 per share purchase price for Common Stock A$11.20 per share exercise price for Warrants	A$4,577,774

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	9,091 Warrants	7/27/11	A$8.00	N/A

Institutional and high net worth Australian investors	Common Stock and Warrants to purchase Common Stock	154,030 Common Shares 46,209 Warrants	9/9/11	A$8.00 per share purchase price for Common Stock A$11.20 per share exercise price for Warrants	A$1,232,240
Accredited Investors party to Securities Purchase Agreement dated 7/25/11	Common Stock and Warrants to purchase Common Stock	125,000 Common Shares 37,500 Warrants	9/13/11	A$8.00 per share purchase price for Common Stock A$11.20 per share exercise price for Warrants	A$1,000,000

Name or Class of Person to Whom Sold	Type of Securities	Amount of Securities	Date of Sale	Exercise Price per Share	Aggregate Offering Consideration
Accredited Investors party to Securities Purchase Agreement dated 7/25/11	Common Stock and Warrants to purchase Common Stock	70,414 Common Shares 21,125 Warrants	9/16/11	A$8.00 per share purchase price for Common Stock A$11.20 per share exercise price for Warrants	A$563,309
Summer Street Research Partners	Warrants to Purchase Common Stock	1,532 Warrants	9/16/11	A$8.00	N/A
Institutional and high net worth Australian Investors	Common Stock	2,581	9/23/11	N/A	A$16,514
Australian Investor under employee stock option agreement	Common Stock	266	9/23/11	N/A	A$1,858
Institutional and high net worth Australian Investors	Common Stock	86 Common Shares	11/2/11	N/A	A$549
Australian Investor under employee stock option agreement	Common Stock	591 Common Shares	11/2/11	N/A	A$4,136
Institutional Australian Investor	Common Stock and Warrants to purchase Common Stock	12,500 Common Shares 3,750 Warrants	2/8/12	A$8.00 per share purchase price for Common Stock A$11.20 per share exercise price for Warrants	A$100,00
Accredited Investors party to Securities Purchase Agreement dated 2/6/12	Common Stock and Warrants to purchase Common Stock	244,375 Common Shares 73,313 Warrants	2/8/12	A$8.00 per share purchase price for Common Stock A$11.20 per share exercise price for Warrants	A$1,955,000
Summer Street Research Partners	Warrants to purchase Common Stock	7,525 Warrants	2/8/12	A$8.00	N/A

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, September 16, 2011 and to the Accredited Investors on February 8, 2012 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, November 2, 2011 and to the Institutional Australian Investor on February 8, 2012 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	50,000	A$10.00
8/18/11	580,590	A$7.00
8/18/11	11,685	A$9.60
8/18/11	15,000	A$10.40
8/19/11	29,210	A$12.80
11/2/11	92,255	A$8.20
11/29/11	66,370	A$8.20
1/10/12	29,375	A$7.40

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 February 8, 2012, we had outstanding 6,276,538 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 February 8, 2012, we had outstanding options to acquire 2,836,355 shares of common stock held by employees, directors, consultants and investors granted options to purchase our common stock outside of our equity plans, as well as outstanding warrants to purchase 387,710 shares of common stock.

Common Stock

We are authorized to issue up to 100,000,000 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 Agreements

Pursuant to securities purchase agreements, dated July 21, 2011 and February 8, 2012, 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 applicable agreement through the first anniversary of the closing at which the applicable purchaser purchased our securities. 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 applicable 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 applicable securities purchase agreement for any subsequent placement of our securities. The preemptive right provided by each securities purchase agreement is subject to certain exceptions, including for securities issued pursuant to convertible securities issued prior to the date of the applicable securities purchase agreement, securities issued pursuant to certain commercial arrangements and securities issued under our Amended and Restated 2002 Stock Plan and our Amended and Restated 2011 Equity Incentive 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 transactions in our CDIs on the ASX is Link Market Services Limited, or Link. Link's address is Level 12, 680 George Street, Sydney NSW 2000, Australia, and its telephone number is +61 2 8280 7111. If our application to list on the Nasdaq Capital Market is approved, we intend to appoint American Stock Transfer & Trust Company, LLC, or AST, to serve as our transfer agent with respect to transfers of shares of our common stock. AST's address is 6201 15th Avenue, Brooklyn, New York 11219 and its telephone number is (800) 937-5449.

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. 5 to the registration statement to be signed on its behalf by the undersigned, thereunto duly authorized.

SUNSHINE HEART, INC.

Date: February 14, 2012

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.+
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	License, Supply & Manufacturing Agreement, dated April 26, 2010, by and between the registrant and DSM PTG, Inc.#
10.18	Lease Agreement, dated October 21, 2011, by and between the registrant and Silver Prairie Crossroads, LLC.+
10.19	Form of Securities Purchase Agreement, dated February 6, 2012.+
10.20	Form of Warrant to Purchase Common Stock issued to investors pursuant to Securities Purchase Agreement dated February 6, 2012.+
21	Subsidiaries of the registrant.+

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

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, except for Note 7 as to which the date is February 1, 2012

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 $0.0001 per share; authorized 100,000,000 shares; issued and outstanding 6,018,740, 5,063,968, and 2,695,392, respectively	506	270	602
Additional paid-in capital	59,581	47,822	67,690
Accumulated other comprehensive income:			
Foreign currency translation adjustment	995	372	1,040
Accumulated deficit	(48,993)	(41,393)	(59,954)
Total stockholders' equity	**12,089**	**7,071**	**9,378**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 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 Dec 31, 2010	Year ended Dec 31, 2009	Nine months ended September 30, 2011	Nine months ended 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	**$ (2.63)**	**$ (2.97)**	**$ (2.09)**	**$ (1.58)**
Weighted average shares outstanding - basic and diluted	**2,885**	**1,798**	**5,249**	**2,695**

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	**1,459**	**$ 146**	**$ 39,868**	**$ (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	1,237	124	7,826			7,950
Balance December 31, 2009	**2,696**	**270**	**47,822**	**372**	**(41,393)**	**7,071**
Comprehensive loss:						
Net loss					(7,600)	(7,600)
Foreign currency translation adjustment				623		623
Total comprehensive loss						(6,977)
Stock based compensation			78			78
Issuance of common stock, net	2,368	236	11,681			11,917
Balance December 31, 2010	**5,064**	**506**	**59,581**	**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	955	96	7,554			7,650
Balance September 30, 2011 (unaudited)	**6,019**	**$ 602**	**$ 67,690**	**$ 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 1,310,987, 78,790, 2,216,615 and 174,790 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. See Note 7, *Subsequent Events* for additional information.

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

In 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 1,225,825 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 2,368,576 shares of common stock (in the form of CDIs) for proceeds, net of transaction costs, of $11,917.

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

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

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

Stock Options

The Company recognized share-based compensation expense related to stock options and grants of common stock to employees, directors and consultants of $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 Outstanding	Weighted Average Exercise price	Remaining Average Contractual Term (Years)	Aggregate Intrinsic Value

Outstanding, December 31, 2008	147,241	$	39.71			
2009 Grants	—		—			
2009 Exercises	10,945		3.10			
2009 Forfeitures/expiration	57,507		49.12			
Outstanding, December 31, 2009	78,789		37.94			
2010 Grants	50,000		10.72			
2010 Exercises	—		—			
2010 Forfeitures/expiration	2,091		36.70			
Outstanding, December 31, 2010	126,698		28.00	7.26	$	819
Exercisable at December 31, 2010	90,427		6.94	6.54		819
2011 Grants (unaudited)	610,590		6.10			
2011 Exercises (unaudited)	969		12.95			
2011 Forfeitures/expiration (unaudited)	28,231		10.33			
Outstanding, September 30, 2011 (unaudited)	708,088	$	9.93	1.11	$	1,485
Exercisable at September 30, 2011 (unaudited)	143,729	$	20.86	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 564,359 non vested options, 56 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 $10.72. No options were issued during 2009. During the nine months ended September 30, 2011, the weighted-average fair value of stock options granted was $6.10.

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

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 850,737 warrants to purchase common stock at an exercise price of AU$6.40 per share. The warrants have a stated life of four years.

As part of the private placement completed during 2011, the Company issued 10,622 warrants to purchase common stock at an exercise price of AU$8.20 per share and 276,500 warrants to purchase common stock at an exercise price of AU$11.20 per share. The warrants have a stated life of four years.

Additional warrants to purchase common stock were issued in connection with the issuance of $800 convertible promissory notes in June 2004, which were issued as a bridging loan prior to the initial public offering of the Company's CDIs on the ASX. These warrants were issued to related party entities affiliated with certain directors of the Company and to one unrelated party. The warrants entitle the holders to receive 16,000 shares at an exercise price of AU$5.00. The warrants have an exercise period of ten years and expire in June 2014. No warrants were exercised during the year.

During the nine months ended September 30, 2011, 14,282 warrants were exercised at a price of AU$6.40 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 Events

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.

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

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.

LICENSE, SUPPLY & MANUFACTURING AGREEMENT

THIS LICENSE, SUPPLY and MANUFACTURING AGREEMENT ("Agreement"), dated as of the 26, day of April 2010 (the "Effective Date") by and between DSM PTG, Inc., a DSM Biomedical company, with its principal place of business at 2810 Seventh St., Berkeley, CA 94710 ("DSM PTG") on the one hand, and Sunshine Heart, Inc. a Delaware Corporation and its subsidiary Sunshine Heart Company, Pty Ltd (collectively "SHC") with its principal place of business at 7651 Anagram Drive Eden Prairie, MN 55344 on the other hand, (together, the "Parties").

RECITALS

WHEREAS, DSM PTG is the owner of the Subject Technology, as defined below; and

WHEREAS, SHC desires to obtain an exclusive license to and under the Subject Technology for use in the manufacture and sale of Assemblies and Licensed Products in the Field; and

WHEREAS, DSM PTG is willing to grant an exclusive license to and under the Subject Technology to SHC subject to the terms set forth herein; and

WHEREAS, DSM PTG desires to supply and manufacture Assemblies using Subject Technology to meet SHC's requirements.

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual promises contained in this Agreement, the Parties agree as follows:

AGREEMENT

In addition to the Agreement itself this Agreement includes the following Exhibits:

Exhibit "A" Related DSM PTG Patents

Exhibit "B" Price Model and Payment Schedule ***

Exhibit "C" List of SHC Products

Exhibit "D" Initial12 Month Rolling Forecast

Exhibit "E" Approved Vendor List- Initial

Exhibit "F" Intentionally Left Blank

*** Portions of this page have been omitted pursuant to a request for confidential treatment filed separately with the commission.

Exhibit "G" DMRs for SHC Products

Exhibit "H" Industry Standards

Exhibit "I" SHC Owned Equipment-Initial

Exhibit "J" Material Model

Exhibit "K" Intentionally Left Blank

Exhibit "L" Intentionally Left Blank

Exhibit "M" Sunshine Heart Quality Agreement (separate Agreement incorporated herein by reference but not attached)

Exhibit ''N" Form Certificate of Compliance

Exhibits A through N shall form a part of this Agreement as if set forth at length herein.

1. DEFINITIONS OF TERMS

As used in this Agreement the following terms shall have the following meanings:

"Affiliate" of a person or entity means any individual, sole proprietorship, firm, partnership, corporation, trust, joint venture or other entity, which directly or indirectly controls, is controlled by or is under common control with such person or entity. As used in this definition, "control" means the possession, directly or indirectly, of the power to direct or cause the direction of the policies and management of a person or entity, whether by the ownership of stock, by contract or otherwise.

“Approved Vendor List (AVL)” shall collectively mean all suppliers as have or shall be selected by SHC or DSM PTG and approved by SHC with respect to any Materials and Services used in Assemblies. They are the manufacturers or service providers approved to supply Materials and Services in the Approved Vendor List.

“Assembly or Assemblies” shall mean components and mechanical systems that DSM PTG will manufacture for SHC as specified in Attachment 4 to Exhibit M, for inclusion by SHC in a Licensed Product.

“Bill of Materials” shall mean all Material, materials, assembly aids, packaging materials etc required to complete the Assembly as it is provided by DSM PTG and approved by SHC.

“Components” shall mean any and all Material, material, assembly aids, packaging materials, etc used in the manufacture of Assemblies.

“Confidential Information” shall mean any and all information, both technical and non-technical, relating to a Party’s and its Affiliates’ respective businesses and affairs, finances, sales, Assemblies, customers, processes, strategies, techniques, trade secrets, research, development, inventions, testing procedures and marketing that has been or hereafter may be provided or

shown to the one Party (the receiving Party) by the other party (the disclosing Party), irrespective of the form of the communication, and also includes all notes, analyses, compilations, studies, summaries and other materials prepared by the receiving Party containing, or based or derived, in whole or in part, on or from, any information of the disclosing Party included in the foregoing. Confidential Information includes samples and other materials and the results of any testing or analysis thereof.

“Defect” means that an Assembly does not meet Specifications.

“DHR” means Device History Record. An FDA term pertaining to the entire manufacturing record of a device, a comprehensive listing of all materials, processes and inspections performed during manufacture and assembly that are required for the subject (device). As used herein this term shall only refer to the manufacturing history of the component to be manufactured by DSM PTG defined herein as an “Assembly.”

“DSM PTG Materials” or “Material” shall mean DSM PTG’s proprietary Materials comprised of Bionate® 90A UR PCU Part FP 70062, Bionate® 75A UR PCU Part FP70064 and BioSpan® SPU Part FP70001 for use in Assemblies and Licensed Products.

“ECN” means a direction in the form of an engineering change order to make a change to an Assembly including a change to the design, manufacture or test procedure for an Assembly or a component or Material.

“Effective Date” shall mean the date designated as such in the preamble to this Agreement.

“Field” shall mean the manufacture, sale and use of SHC’s C-Pulse Cuff Devices for the field of Cardiac Assistance.

“Forecast” shall mean a rolling, written or electronic forecast that sets forth the quantities of the Assemblies and that SHC, in good faith, estimates it will order during the 12-month period beginning on the Effective Date and updated on a rolling quarterly basis.

“Invoice” shall mean any invoice delivered by DSM PTG to SHC in accordance with this Agreement.

“Licensed Product(s) or “Products” shall mean all Products of SHC for use in the Field that incorporate, or are made with DSM PTG Materials and Assemblies as set forth in Exhibit C.

“Manufacturing Discontinuance” If either SHC or DSM PTG stops the manufacturing of a Material, Assembly or Product.

“Order Acknowledgment” shall mean a written or electronic notice delivered by DSM PTG to SHC in accordance with this Agreement to the effect that DSM PTG has received and accepted a Purchase Order.

“Purchase Order” shall mean any written or electronic purchase order delivered by SHC to DSM PTG in accordance with this Agreement.

“Quarterly Business Review (QBR)” shall mean a strategic business meeting between DSM PTG and SHC for the purpose of discussing current business issues and opportunities.

“SHC Owned Equipment” shall mean the manufacturing, assembly, or test equipment described on Exhibit “I”

“SHC” or SHI or Sunshine Heart shall have the same meaning in the Purpose of this Agreement as Sunshine Heart, Inc.

“Specifications” shall mean, with respect to any Assembly, all specifications and requirements as documented by DSM PTG or SHC and approved by SHC as drawings, designs and manufacturing and test specifications for the Assembly, as approved in writing by both Parties and set forth in a separate Quality Agreement referenced as Exhibit M.

“Subject Technology” shall mean all inventions, compounds, know-how, methods, and, materials necessary to make or use DSM PTG Materials which were developed as of the Effective Date and which include but are not limited to all inventions which are covered by any claim of any of the patents identified on Exhibit A hereto together all pending and issued reissues, re-examinations, divisions, continuations, continuations-in-part, renewals, extensions and additions thereto, and all foreign counterparts and applications for foreign counterparts of the foregoing (collectively, the “Patents”).

"Supplier" shall mean any vendor, including SHC that provides Components or Services to DSM PTG.

"Term" shall mean the period commencing with the Effective Date and ending at the time prescribed by Section 17 hereof.

2. GRANT OF LICENSE

2.1 License Grant. DSM PTG hereby grants to SHC for the Term of this Agreement, unless terminated as provided herein, an exclusive, worldwide, right and license in and to the Subject Technology to make, have made, use, market, sell and offer for sale Licensed Products solely in the Field during the Term. SHC shall not use or permit anyone else to use the Subject Technology or any DSM PTG Materials for any other purpose.

2.2 No Implied Rights. DSM PTG shall retain all other rights to the Subject Technology. Except as is expressly provided in this Agreement, neither Party shall be deemed to have granted to the other, and there shall not arise by implication or otherwise, any rights whatsoever by reason of the execution or performance of this Agreement.

2.3 Access to Master Files. Upon SHC's request at any time during the term of this Agreement, DSM PTG shall authorize SHC's approved regulatory body to have access to, at no charge other than the fees specifically provided for herein, DSM PTG's material master files maintained by regulatory authorities to support any approval applications submitted by the SHC for Licensed Products or as otherwise reasonably necessary to exercise SHC's rights hereunder.

3. PAYMENTS *

3.1 Grant of License. As consideration for the rights conveyed by DSM PTG under this Agreement, SHC shall pay DSM PTG *** according to the schedule of payments described in Exhibit "B" which shall include but not be limited to fees associated with the license granted herein, certain services, and other consideration afforded SHC by DSM. ***.

3.2 No Implied Rights. DSM PTG shall retain all other rights to the Subject Technology. Except as is expressly provided in this Agreement, neither Party shall be deemed to have granted to the other, and there shall not arise by implication or otherwise, any rights whatsoever by reason of the execution or performance of this Agreement.

4. SUBLICENSES

4.1 SHC shall have no sub-license rights, but shall have the conditional rights, if any, granted under the terms below hereto.

4.2 Should DSM PTG be unable to satisfy at least seventy five percent (75%) set forth in SHC's or its Affiliates of Purchase Orders (as defined herein) as SHC (hereinafter "SHC") for Assemblies made with Materials for six (6) consecutive months, as defined in this Agreement, in accordance with the Purchase Orders, SHC shall have the right to terminate the Agreement upon thirty (30) days notice to DSM PTG and DSM PTG shall to the extent of its authority to do so, license SHC, for the term of this Agreement, to the limited extent necessary to enable SHC to make or procure its requirements for such Materials to make Assemblies, use and sell Licensed Products for use in the Field from other sources without otherwise adversely affecting DSM PTG's rights. Should SHC necessarily make or procure its requirements for Assemblies using Materials from a source other than DSM PTG, SHC shall continue to make *** payments to DSM PTG according to Exhibit "B ', and DSM PTG shall make all required processes and/or formulations available to SHC so that SHC's requirement for Assemblies made with Materials can be satisfied, provided that SHC and such source execute and deliver to DSM PTG a confidentiality agreement in such form as DSM PTG may reasonably request.

5. PURCHASE ORDERS

5.1 Purchase Orders. Upon the terms and subject to the conditions set forth in this Agreement, DSM PTG shall manufacture and sell to SHC the Assemblies that SHC orders by the delivery of a Purchase Order, and SHC shall purchase those Assemblies from DSM PTG. Such purchase orders shall be binding in terms of and shall set forth the SHC part number, price, quantity and delivery date ("Purchase Order") and shall be provided to DSM PTG on the first business day of each calendar quarter. On the Effective Date, SHC shall provide DSM PTG with firm and binding Purchase Orders for the first two (2) calendar quarters. Thereafter, SHC shall provide firm and binding Purchase Orders on a rolling quarterly basis such that DSM PTG shall always have two (2) binding quarterly Purchase Orders to be filled. By way of explanation; SHC shall provide binding Purchase Orders for Q1 and Q2. Upon delivery of Assemblies pursuant to the Q1 Purchase Order, SHC shall provide DSM PTG with a firm and binding Purchase Order for Q3.

*** Portions of this page have been omitted pursuant to a request for confidential treatment filed separately with the commission.

DSM PTG shall accept each Purchase Order by the delivery to SHC of an Order Acknowledgment prior to the close of business on the fifth business day after the receipt of the Purchase Order. Neither SHC nor DSM PTG shall have any rights or obligations with respect to any Purchase Order unless and until DSM PTG has accepted the Purchase Order.

6. FORECASTS, COMMITMENTS

6.1 Forecasts. (a) Periodically (but no less frequently than Quarterly), SHC shall deliver to DSM PTG a twelve month rolling Forecast. The initial twelve month rolling Forecast is set forth on Exhibit "D". SHC may modify any Forecast at any time by the delivery to DSM PTG of notice to such effect. Within thirty (30) business days after receipt of a rolling Forecast, or otherwise promptly, DSM PTG shall notify SHC of any prospective problems that DSM PTG is aware of that is likely to prevent DSM PTG from meeting SHC's forecasted requirements.

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8. MANUFACTURING

8.1 Specifications. Materials and Approved Vendors. DSM PTG shall manufacture each Assembly in accordance with the Specifications for the Assembly as defined herein. DSM PTG shall uniquely identify the Materials to distinguish the Materials from any materials held by DSM PTG to incorporate into other DSM PTG products. DSM PTG shall purchase the materials for Assembly manufacturing only from (i) SHC or (ii) Approved Vendors for the Materials. DSM PTG agrees to supply SHC with Assemblies manufactured in compliance with ISO 13485. DSM PTG further agrees to provide SHC with non-sterile samples of Assemblies as set forth in Exhibit B.

8.2 Upon the receipt of a copy of the current version of the Approved Vendor List ("AVL"), or an ECN changing a supplier on the Approved Vendor List DSM PTG shall acknowledge receipt thereof. SHC shall use reasonable commercial efforts to approve DSM PTG as an Approved Vendor for any materials for which DSM PTG is not already an Approved Vendor in accordance with SHC's standard approval procedures. Exhibit "E" Approved Vendor List provides the now current list of Approved Vendors. SHC may from time to time change the AVL in its sole discretion by providing a revised AVL or ECN to DSM PTG. If DSM PTG wishes to revise the AVL a written request shall be provided to SHC for consideration. Acceptance shall be indicated by revision of the AVL or ECN. DSM PTG shall not be responsible for any supply issues, or the consequences thereof, that arise as a result of any delay, negligence or other action or inaction by any vendor on the AVL, or the inability of a vendor on the AVL to meet DSM PTG's requirements. DSM PTG shall provide prompt notice to SHY of any event that is likely to lead to a delay in the shipment of Assemblies.

8.3 Manufacturing Sites. (a) DSM PTG shall manufacture each Assembly only at manufacturing sites approved by SHC for the manufacture of the Assembly in accordance with SHC's standard approval procedures. If DSM PTG proposes to manufacture any Assembly at any manufacturing site not approved by SHC for the manufacture of the Assembly, then DSM PTG shall deliver to SHC notice to such effect. Within 90 calendar days after the receipt of such notice, SHC shall (i) evaluate the proposed manufacturing site in accordance with SHC's

standard approval procedures and (ii) deliver to DSM PTG a notice that sets forth (A) SHC's approval of the proposal or (B) SHC's rejection of the proposal and the reasons therefore. If SHC rejects any such proposal, then SHC and DSM PTG shall jointly review the reasons therefore. SHC hereby approves the manufacture of its Assemblies at the Berkeley CA Facility, subject to the final satisfaction of SHC's standard approval procedures. SHC shall use reasonable commercial efforts to complete such procedures with respect to the Berkeley CA Facility as promptly as practicable after the date hereof.

8.4 Certifications. DSM PTG shall maintain applicable certifications specially: ISO 13485 - 2003 as listed in Exhibit "H".

(a) **Certificate of Compliance.** Each delivery of Licensed Product shall be accompanied by DSM PTG's certificate of compliance in the form attached hereto as Exhibit N, as mutually agreed to by the Parties.

(b) **Rejection.** Except as provided herein, SHC shall accept all Licensed Product delivered in accordance with the terms and conditions of this Agreement. SHC (a) may reject any portion of any shipment of Licensed Product if such shipment (i) was not manufactured in material compliance with ISO 13485 and/or (ii) does not conform in all material respects with the product Specifications. In order to reject a shipment, SHC must give DSM PTG, within thirty (30) days of receipt of shipment, a reasonably detailed statement of its reasons for rejection and Licensed Product samples demonstrating the purported nonconformance and requesting that DSM PTG either remedy or provide a reasonable plan to promptly remedy such nonconformance. If no such statement is received by DSM PTG then SHC shall be deemed to have accepted the shipment of Licensed Product. In the event of timely rejection by SHC, DSM PTG shall, within thirty (30) business days after receipt thereof, notify SHC of whether it accepts SHC's notice of nonconformity or it shall be deemed to accept such notice.

(c) **Disagreement.** If DSM PTG disagrees with any purported nonconformity issue raised by SHC, then both parties agree to cooperate in good faith and make every reasonable effort to resolve the disagreement. If DSM PTG confirms SHC's rejection under (i) or (ii) above in Section 8.4(b), or if SHC's rejection is otherwise due to (iii) above in Section 8.4(b), then DSM PTG shall, at its sole expense and option, and in a reasonably prompt manner, but in no event more than sixty (60) days after receipt of SHC's rejection statement, either replace the nonconforming Licensed Product with conforming Licensed Product or refund to SHC the purchase price thereof or credit such amounts if not already paid. Licensed Product shall not be returned to DSM PTG without DSM PTG's prior permission, and then only in a manner and to the destination prescribed by DSMPTG.

(d) **Dispute Resolutions.** If the parties hereto fail to agree as to whether a delivered quantity of Licensed Product meets its agreed product Specifications, then the parties shall cooperate to have the Licensed Product in dispute analyzed by a qualified independent testing laboratory selected by DSM PTG to which SHC does not have reasonable objection. The following provisions shall apply with respect to the results indicated by such independent laboratory:

(i) If the Licensed Product is determined to have met its product

Specifications, then SHC shall bear the costs of the independent laboratory testing and shall accept the shipment of such Licensed Product and promptly pay for such Licensed Product if not yet paid; or

(ii) If the Licensed Product is determined not to meet its product Specifications, then DSM PTG promptly shall bear the cost to replace the affected quantity, or refund amounts paid or credit such amounts if not yet paid, as outlined in Section 8.4(b) and DSM PTG shall bear the costs of the independent laboratory testing.

(e) **Regulatory Audit.** In the event of a regulatory audit at SHC, which involves any Licensed Product, SHC shall notify DSM PTG of such audit promptly after receiving notice thereof but no less than within one week thereof. Pursuant to such notice of audit, DSM PTG shall supply SHC with documents required to be reviewed as part of a regulatory audit, related to the Licensed Product, within three business days from a request by SHC (or alternatively, DSM PTG shall agree to provide any proprietary information directly to such agency or body within ten business days, and shall respond to any inquiries regarding such information with such agency or body).

(f) **Plant Inspection.** DSM PTG shall promptly notify SHC whenever a request for a plant inspection is received from the FDA that relates in any way to Licensed Product, and shall promptly advise SHC of any scheduled or unscheduled FDA inspection and the results thereof. A copy of Form 483 observations or other applicable reports, which apply to Licensed Product and redacted as deemed necessary by DSM PTG to protect proprietary information, shall be supplied to SHC upon its request, within ten business days of the request. DSM PTG shall promptly take steps to remedy any valid deficiencies found by the FDA inspectors relating to the manufacture, sterilization and packaging of Licensed Product, and to respond in writing to the Form 483 observations. DSM PTG shall provide SHC with a copy of its responses to any Form 483 observations relating to the Licensed Product in advance of their submission to FDA, redacted of any proprietary information, and shall notify SHC of the date such responses are filed with the FDA.

(g) **Recall.** In the event that SHC determines that a recall of any one or more Licensed Products is necessary for any reason, DSM PTG shall reasonably cooperate in such recall efforts. DSM PTG's liability with respect to any recall shall be limited as set forth in this Agreement.

(h) **Access.** DSM PTG shall provide SHC access to its sites and quality system records for the purpose of auditing the sites for compliance with the requirements of Section 8.1. Any information obtained by SHC as a result of such access shall be subject to the provisions of Section 18 hereof. To the extent that DSM PTG reasonably believes that providing SHC with access to such sites would compromise DSM PTG's obligations of confidentiality to third parties or require the disclosure of trade secrets, DSM PTG shall grant such access to an independent third party designated by SHC in its reasonable discretion, and reasonably acceptable to DSM PTG, to conduct such audit. Any report furnished by such third party to SHC shall be subject to the provisions of Section 18 herein and DSM PTG shall have the right to review any such report and delete any information it deems a trade secret or the disclosure of which would violate such confidentiality obligations, prior to the release of said report to SHC.

(i) **Cooperation.** DSM PTG shall cooperate with SHC to provide any authorizations, documents or information in DSM PTG's possession, or take such other actions, which SHC may reasonably request in order to obtain or maintain any registration, approval, clearance, certification or other authorization with or from any federal, state, local or foreign government agency or any self-regulatory body (or alternatively, DSM PTG shall agree to provide any proprietary information directly to such agency or body in the form of a master file or comparable document, and shall respond directly to any inquiries regarding such information with such agency or body).

(j) **Records.** Each Party shall keep and maintain complete and accurate records necessary for regulatory compliance for a period of at least five (5) years after the expected life of the Licensed Product or ten (10) years from the date of creation (whichever is less), including all records that ensure the ability to perform complete lot tracing of Licensed Product

8.5 Quality-Assurance Program. DSM PTG shall implement and maintain a comprehensive process and quality-assurance program in accordance with a Quality Agreement as referenced in Exhibit M and included as part of this Agreement. DSM PTG shall deliver or make available to SHC any documentation with respect to DSM PTG's Quality-Assurance Program and the DHRs generated by DSM PTG as is outlined in Exhibit "G" that SHC reasonably requests to verify compliance therewith. Upon the written request of SHC on at least ten business days notice, DSM PTG shall define a mutually agreeable date for SHC to have access during normal business hours to the facilities of DSM PTG and the records of its subcontractors for the purpose of inspecting DSM PTG's quality-assurance-program compliance, and DSM PTG shall reasonably cooperate with SHC in connection therewith. Upon the request of DSM PTG in connection with any such inspection, SHC shall cause its directors, officers, employees and agents to execute and deliver to DSM PTG an appropriate nondisclosure agreement.

8.6 Tooling and SHC Owned Equipment

(a) All tooling produced or obtained by DSM PTG for the Assemblies to be delivered hereunder have been or shall be provided for by SHC. Tooling shall become and remain the property of SHC at the time payment in full is received by DSM PTG. SHC may also consign tooling to DSM PTG for the manufacture of the Assemblies.

(b) All SHC Owned Equipment shall be used by DSM PTG only for the benefit of SHC, and shall be delivered to SHC upon request. DSM PTG will not cause to occur any lien or encumbrance on any such SHC Owned Equipment in DSM PTG possession. DSM PTG will insure any SHC Owned Equipment in DSM PTG possession at the replacement value thereof under the terms of DSM PTG's then current insurance policies. Upon reasonable notice and written request, DSM PTG shall provide SHC with certificate(s) of insurance, which name SHC as loss payee, as proof of all such risk insurance for the SHC Owned Equipment at DSM PTG. Such certificate(s) shall be endorsed to contain a provision requiring the insurers to endeavor to provide SHC with thirty (30) days written notice of any cancellation in such insurance.

(c) DSM PTG shall maintain all SHC Owned Equipment according to a mutually agreed maintenance schedule and repair, calibrate, or upgrade SHC Owned Equipment; provided, however, SHC shall not be responsible for any repair or replacement of any SHC Owned

Equipment that is damaged as a result of DSM PTG's misuse. SHC will pay for any such services on a time and materials basis. Labor charges will be billed at DSM PTG's then current billing rate. Replacement parts for SHC owned equipment will be charged at DSM PTG cost plus 10%.

(i) (d) If SHC requests the return of any SHC Owned Equipment from DSM PTG and the return of such SHC Owned Equipment prevents DSM PTG from providing Assemblies to SBC, then DSM PTG shall be relieved of such obligations. In the event that SHC Owned Equipment requires replacement, or additional tooling or equipment is required to manufacture Assemblies; DSM PTG shall provide SHC written notice of such requirement with an estimate of the costs of such new equipment which must be approved by SHC in writing prior to DSM PTG's replacement. SHC shall provide such equipment or tooling, or authorization to DSM PTG to purchase such equipment or tooling at SHC's expense, within thirty (30) days of the date of such written notice. If failure to acquire such tooling or equipment is due to SHC's failure to supply or approve the purchase of same; and the consequence is that DSM PTG cannot meet Purchase Orders for Assemblies, DSM PTG shall be relived of such obligation. If the parties hereto fail to agree as to whether a such new equipment is required, then the parties shall cooperate to have the issue as to whether new equipment is required analyzed by a qualified independent organization selected by DSM PTG to which SHC does not have reasonable objection to obtain and independent opinion as to whether new equipment is required. The cost of this independent evaluation shall be borne equally by both parties.

(e) All SHC Owned Equipment are listed on Exhibit "I". If SHC delivers to DSM PTG any new assembly or test equipment, then (i) attachment shall automatically be amended to include the new equipment, and (ii) SHC shall promptly deliver to DSM PTG a copy of the amended Schedule.

(f) SHC hereby grants to DSM PTG a non-exclusive, fully paid-up license to use any loaned software solely with the SHC Owned Equipment in the Field. Notwithstanding any provision of this Agreement to the contrary, DSM PTG may make copies of any such Software only to the extent reasonably necessary for backup and archival purposes. DSM PTG shall not disassemble, reverse compile or reverse engineer any such Software. Upon the request of SHC, DSM PTG shall deliver to SHC all copies of any such Software in accordance with SHC's instructions.

(g) Discontinuance of Manufacturing If SHC decides to End-of-Life any Product, then SHC shall deliver to DSM PTG a notice that sets forth the expected discontinuation date in advance of at least nine (9) months, If DSM PTG decides to stop the manufacturing any of the Material or Assemblies, DSM PTG will inform SHC at least nine (9) months prior to the date of Manufacturing Discontinuance of the Material or Assembly in order to give SHC a chance to place art end-of life order before the discontinuation.

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10. INVENTORY MANAGEMENT

10.1 Change Consequences on Inventory. Should SHC make any changes to the

Specifications, Quality Agreement, or Approved Vendor List; SHC shall reimburse DSM PTG for the cost and expense associated with any materials or services that are excess or obsolete as a consequence of such change including those in inventory as well as those on order. DSM PTG shall use reasonable efforts to mitigate the cost and expense associated with such change.

11. SUPPLY-CHAINMANAGEMENT

11.1 AVL Changes. If SHC modifies the Approved Vendor List or an Approved Vendor, then SHC shall promptly deliver to DSM PTG a copy of the Modified Exhibit "E" or other Specification that identifies vendors. If DSM PTG proposes to modify the Approved Vendor List, then DSM PTG shall deliver to SHC a proposal that describes the modification in detail and sets forth any change in the purchase price or delivery schedule of any Assembly. If SHC desires to accept any such proposal, then within thirty (30) calendar days after the receipt of the proposal, SHC shall deliver to DSM PTG notice to such effect and a copy of the modified Approved Vendor List. If SHC fails to deliver to DSM PTG such a notice within such 30-calendar-day period, then SHC shall be deemed to have rejected the proposal. DSM PTG shall not implement any proposal to modify the Approved Vendor List unless and until SHC has accepted the proposal.

11.2 Other Services. Upon the request of SHC, DSM PTG shall perform testing and other mutually agreed services with respect to any materials of SHC (other than the Assemblies) upon mutually agreed prices, terms and conditions.

12. PURCHASE AND SALE

12.1 Prices.

(a) The initial purchase price of each SHC Assembly is set forth on Exhibit "B". All prices are exclusive of freight and exclusive of foreign and domestic federal, state and local excise, sales, use and similar taxes. Such taxes, when applicable, will be billed as separate, additional items on DSM PIG's invoices. ***

(b) Payment. Upon the shipment of any Assembly, DSM PTG shall deliver to SHC an Invoice that sets forth the date, the name and address of DSM PTG, the related Purchase Order number, a detailed description of the Assemblies shipped (including the SHC part number and description) and, the quantity shipped, the delivery destination, the method of shipment, the purchase price in effect on the shipping date (including an itemization of all applicable freight, insurance, packing and other charges), the payment terms, the country of origin, the number of packages, the way bill number and a reference to this Agreement. Payment shall be due within

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thirty (30) days of the shipment date.

(c) Delivery and Shipping. All shipments shall be F.O.B. DSM PIG's shipping dock. SHC's Purchase Orders shall specify the carrier or means of transportation or routing, and DSM PTG shall comply with SHC's instructions. If SHC fails to provide shipping instructions, DSM PTG will make the selection. DSM PTG will make delivery within five (5) business days of the date set forth in the Purchase Order for all deliveries to US locations. DSM PTG will make no representation or warranty as to delivery date for any shipment outside the US. DSM PTG may make deliveries in installments. Partial shipments will be billed as made, and payments therefore are subject to the terms of payment set forth herein. All delivery indications are estimates and are dependent upon prompt receipt of all necessary information to service an order. DSM PTG reserves the right to allocate inventories and production when such allocation becomes necessary. DSM PTG's obligations under this Agreement are subject to the export administration and control laws and regulations of the U.S. Government. SHC shall comply fully with such laws and regulations in the export, resale or disposition of Assemblies.

(d) Title, Risk of Loss and Reserved Security Interest. Title and risk of loss or damage to the Assemblies shall pass to SHC at the time DSM PTG delivers possession thereof to the carrier. Notwithstanding passage of title, DSM PTG reserves, and SHC grants, a security interest in, and right of

repossession of, all Assemblies to secure all of SHC's payment obligations under this Agreement. SHC agrees to execute additional documents and papers in furtherance of this right if requested by DSM PTG.

(e) Packaging. DSM PTG shall package or cause to be packaged each Assembly in accordance with SHC's packaging specifications. DSM PTG shall provide a certification of compliance with each shipment in accordance with Section 8.4(a).

(f) Inspection and Acceptance. Prior to the delivery of any Assembly to SHC, DSM PTG shall inspect and test the Assembly in accordance with a test plan approved by SHC and referenced as Exhibit M. Upon the request of SHC, DSM PTG shall deliver or make available to SHC the DHR with respect to any Assembly to verify compliance with requirement. Upon at least ten business days notice from SHC, DSM PTG shall permit SHC to have access during normal business hours to the facilities of DSM PTG for the purpose of inspecting any Assembly, and DSM PTG shall reasonably cooperate with SHC in connection therewith.

(g) Warranty. DSM PTG warrants that all Assemblies sold to SHC will be in compliance with the Specifications established under this Agreement and defined in Exhibit M. The warranties contained herein extend only to SHC, and SHC shall affirmatively disclaim all liability of DSM PTG to any end users of Products, which disclaimer shall be satisfactory to DSM PTG in its sole discretion. The sole and exclusive remedy for any breach of warranty or certification of compliance with respect to any Assembly shall be replacement of that Assembly or refund of the payment price of such Assembly. The warranty contained herein shall not be deemed to have failed of its essential purpose so long as DSM *PTG* is making good faith efforts to correct defects under the terms of the warranty, or has made the replacements provided for.

EXCEPT AS SET FORTH HEREIN, NO OTHER WARRANTIES, EXPRESS OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE, INCLUDING WITHOUT LIMITATION THE

WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND INFRINGEMENT, ARE MADE BY DSM PTG, UNDER THIS AGREEMENT AND ALL SUCH OTHER WARRANTIES ARE HEREBY EXPRESSLY DISCLAIMED. THE PARTIES ACKNOWLEDGE THAT SHC PROVIDED OR DETERMINED THE SPECIFICATIONS FOR THE COMPOSTION OF THE MATERIAL, ASSEMBLIES, VENDOR APPROVAL, AND PRODUCTS AND THE PERFORMANCE AND OTHER SPECIFICATIONS THEREFOR, AND THAT DSM PTG HAS NO RESPONSIBILITY FOR SHC'S DETERMINATION TO USE THE MATERIALS OR ASSEMBLIES IN THE PRODUCTS.

(i) Limitation of Liability. Neither Party will be liable for a delay in performance of or failure to perform an obligation under this Agreement where such failure to perform any duty or obligation has been directly or indirectly caused by any act of God, fire, war, or any other cause outside the reasonable control of that party, and occurring without its fault or negligence, including without limitation, strikes, lock-outs or other industrial disturbances; acts of terrorists or other public enemies; orders of any civil or military authority; insurrection; civil disturbances, sabotage; epidemics; seismic or meteorological events and their consequences; fires or explosions; partial or entire failure of utilities; fuel shortage or unavailability of supplies. NEITHER PARTY SHALL BE LIABLE TO THE OTHER OR TO THE OTHER'S AFFILIATES FOR INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES ARISING OUT OF THIS AGREEMENT OR ITS TERMINATION, OR ANY OTHER CAUSE OF ACTION WHETHER LIABILITY IS ASSERTED IN TORT OR CONTRACT, AND IRRESPECTIVE OF WHETHER THE PARTIES HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. ALL MONETARY REMEDIES OF THE PARTIES SHALL BE LIMITED TO DIRECT DAMAGES.

13. RELATIONSHIP MANAGEMENT

13.1 Meetings.

(a) SHC and DSM PTG shall cause their respective employees to hold Quarterly Business Reviews (QBR) to review and discuss strategic issues such as but not limited to: business trends effecting both the SHC and DSM PTG, price increase, forecasted quantity requirements, delivery performance, quality performance, payment performance, Assembly pricing, manufacturing capacity, compliance issues, and any other matter relating to the business relationship of the parties.

(b) Other Recurring Communications. SHC shall permit its cross-functional team to communicate directly with DSM PTG's program management team, and DSM PTG shall permit its program management team to communicate directly with SHC's cross-functional team, with respect to quality, MRP, operations, purchasing, engineering, and any other matters relating to the transactions contemplated by this Agreement. SHC shall cause its operations, purchasing, engineering, and other applicable personnel to communicate as directly as reasonably possible with their respective counterparts at DSM PTG, and DSM PTG shall cause its MRP, operations, purchasing, engineering, and other applicable personnel to communicate as directly as reasonably possible with their respective counterparts at SHC.

14. ASSEMBLY MANAGEMENT

(a) Assembly Changes: If SHC desires to modify the Specifications or Bill of Materials for any Assembly, then SHC shall work with DSM PTG and deliver or cause to deliver to DSM PTG either an Engineering Change Notice in writing that describes the modification in detail or a revision of the affected Document that includes the changes as set forth at Exhibit M. However; DSM PTG shall determine the effects of such Change at the time of submission and provide notice to SHC of such effects thereof. If SHC desires to implement any such modification, then within 30 calendar days after the receipt of the related notice, SHC shall deliver the signed and approved Engineering Change Notice to DSM PTG for execution. If SHC fails to deliver to DSM PTG such notice within such 30-calendar-day period, then SHC shall be deemed to have elected not to implement the modification. DSM PTG shall implement any such modification approved by SHC in accordance with a mutually agreed schedule.

(b) If DSM PTG proposes to modify the Specifications or Bill of Materials for any Assembly, then DSM PTG shall deliver to SHC a proposed Engineering Change Notice that describes the modification in detail and sets forth (i) any change in the purchase price or delivery schedule of the related Assembly and (ii) a description of any Materials relating to the Assembly that will be rendered obsolete as a result of the implementation of such modification and DSM PTG's standard material cost therefore. If SHC desires to accept any such proposal, then within 30 calendar days after the receipt of the proposed

Engineering Change Notice, SHC shall deliver to DSM PTG notice to such effect. If SHC fails to deliver to DSM PTG such notice within such 30-calendar-day period, then SHC shall be deemed to have rejected the proposal. If SHC rejects any such proposal, then SHC and DSM PTG shall jointly review the reasons therefore. DSM PTG shall not implement any proposal to modify the Specifications or Bill of Materials for any Assembly unless and until SHC has accepted the proposal.

15. INSURANCE AND INDEMNIFICATION

15.1 Insurance and Indemnification. SHC shall cause DSM PTG and its Affiliates, and their respective agents, employees, officers, employees, shareholders and contractors ("Indemnitees"), to be named as additional insureds on policies of general commercial liability and Assemblies liability insurance covering SHC, which coverage shall have limits of liability which are commercially reasonable. Within five (5) days of the beginning of each policy period SHC shall supply DSM PTG with a certificate evidencing the coverage required hereby and the amount thereof. Such coverage shall be maintained for not less than five (5) years following termination of this Agreement, or, if such coverage is of the "claims made" type, for ten (10) years following termination of this Agreement. SHC shall indemnity, defend and hold harmless DSM PTG and the other Indemnitees from and against all losses, liabilities, claims, causes of action, and expenses (including attorneys' fees and litigation costs), resulting from bodily injury (including death), or property damage arising out of or related to, or asserted to arise from, any Material or Assembly which is the subject of this Agreement, unless it is determined in a court of competent jurisdiction that the loss, damage or claim is the consequence of the negligence or willful act of DSM PTG. DSM PTG shall defend, indemnity and hold harmless SHC against all loss, damages or claims caused by the negligence or willful acts of DSM PTG with total aggregate indemnification obligations of DSM PTG capped at one (1) times annual sales to SHC in the initial year of this Agreement. The insurance referred to above shall provide contractual liability

coverage covering SHC's obligations under the preceding sentence.

16. PATENTS AND INFRINGEMENT

16.1 Patents. DSM PTG may, but shall have no obligation to, prosecute applications and maintain patents covering Subject Technology or DSM PTG Materials. If it elects to do so, DSM PTG shall be responsible for any of its expenses, including attorney's fees that DSM PTG incurs in order to obtain or maintain the patent(s).

16.2 Notice of lnfringement. SHC shall promptly inform DSM PTG of any suspected infringement of any claims in any Patent or misuse, misappropriation, theft or breach of confidence of other proprietary rights in the Subject Technology or any DSM PTG Materials by a third party.

16.3 Warranty. DSM PTG warrants that, to the best of its knowledge, the DSM PTG Materials, components thereof and their materials and manufacturing processes and the Subject Technology, as the same may exist as of the Effective Date, do not infringe any third party patents or other intellectual property rights, and each party shall reasonably cooperate with the other in any investigations undertaken to determine any potential infringement.

16.4 Remedy. In the event of a breach of the warranty given by DSM PTG in Section 16.3, DSM PTG shall take any one or more of the following actions, simultaneously or sequentially: (a) attempt to redesign the allegedly infringing Assembly so as to make it non-infringing, and (b) if such redesign is impossible or impracticable, attempt to obtain for itself and the benefit of SHC a license to manufacture and sell the allegedly infringing Assembly, or (c) only after attempting, in good faith, to take the aforementioned actions and failing, terminate this Agreement, including without limitation, all licenses granted hereunder and all payment obligations of SHC hereunder.

16.5 Invalidity. DSM PTG warrants to SHC that: (a) it is unaware of any prior art which would render any of the patents under the Subject Technology invalid; (b) it has not received a third party claim of invalidity or unenforceability of any of the Patents under the Subject Technology; (c) it is unaware of any third party allegations of misappropriation of third party trade secrets by DSM PTG; and (d) that it is unaware of any third party claim of ownership of or invalidity of any of the Subject Technology. To the best of DSM PIG's knowledge, the license of the Subject Technology hereunder by DSM PTG to SHC pursuant to this Agreement will not violate any right of any third party and DSM PTG has the right and authority to enter into this Agreement and to grant the license granted herein.

17. TERMANDTERMINATION

17.1 Term. The Term of this Agreement shall commence on the Effective Date and terminate on the third (3rd) anniversary of the Effective Date upon receipt of ninety (90) days written notice from either Party of their intent to terminate. After the third anniversary of the Effective Date, this Agreement shall continue on a year to year basis until terminated by written notice as set forth above. This Agreement may also be terminated pursuant to its terms, including under section 4.2, 17.2 or 17.3 of this Agreement. SHC shall ***, despite any expiry of a Patent listed on Exhibit A, in which case the License granted under Section 3.1 shall be a license in and to all Subject Technology except the

*** Portions of this page have been omitted pursuant to a request for confidential treatment filed separately with the commission.

Patent. ***

17.2 Termination by Consent or for Breach. This Agreement may be terminated at any time by the mutual written agreement of the Parties. In addition, either Party may terminate the Agreement, after providing written notice and sixty (60) days' opportunity to cure, if the other Party breaches a material provision of this Agreement. DSM PTG shall have the right, at its option, to cancel and terminate this Agreement in the event that SHC shall (i) cease to purchase all its requirements of Assemblies meeting the description and Specifications set forth at Exhibit M, or (ii) become involved in insolvency, dissolution, bankruptcy or receivership proceedings affecting the operation of its business or (iii) make an assignment of all or substantially all of its assets for the benefit of creditors, or in the event that (iv) a receiver or trustee is appointed for SHC and SHC shall, after the expiration of thirty (30) days following any of the events enumerated above, have been unable to secure a dismissal, stay or other suspension of such proceedings. The failure of any party to exercise any

right of termination or other right shall not be deemed to be a waiver of any right such party might have to exercise or enforce that right, upon any subsequent breach.

17.3 Effect of Termination. Any termination of this Agreement shall automatically terminate all licenses granted hereunder unless otherwise set forth herein. Termination of this Agreement shall not, however, terminate the rights and obligations of the Parties under Sections 3, 12, 15, 17 and 18 hereof.

18. CONFIDENTIAL INFORMATION

18.1 Protection of Information. In the performance of this Agreement DSM PTG and SHC may exchange certain Confidential Information. The Parties shall use such information of the other only for the purposes of this Agreement. A party shall disclose the Confidential Information of the other only to those of its employees, directors, agents or associates who have a reasonable need for such Confidential Information in connection with the permitted use of such Confidential Information. The receiving Party of Confidential Information shall inform, its employees, directors, agents or associates who receive such Confidential Information of the terms of this Agreement , and shall take all necessary and appropriate actions to preserve the confidentiality of such Confidential Information, including, without limitation, placing suitable confidentiality legends on all Confidential Information so disclosed and using the same degree of care receiving Party exercises to protect its own proprietary or confidential information (but which in any event shall be not less than a reasonable standard of care). All documents, discs and other materials containing Confidential Information shall remain the sole property of the disclosing Party. The receiving Party shall promptly return all such materials on request, but such return shall not affect the continuing obligations of the receiving Party hereunder. The provisions of this Section 18 are in addition to, and not in lieu of, the obligations of the Parties under the Mutual Confidentiality Agreement dated December 16,2009 executed by the Parties or their Affiliates, the terms of which shall remain in effect.

18.2 Permitted Use. Nothing contained in this Agreement shall in any way restrict either Party's right to use, disclose or otherwise deal with any Confidential Information which: (a) at the time of disclosure is generally available to the public, or thereafter becomes generally

*** Portions of this page have been omitted pursuant to a request for confidential treatment filed separately with the commission.

available to the public through no act of the receiving Party in violation of this Agreement; (b) was in the possession of the receiving Party prior to the time of disclosure and such possession is documented by written evidence in existence at the time of such disclosure and was not acquired, directly or indirectly, from the disclosing Party; (c) is independently made available as a matter of right to the receiving Party by a third party lawfully entitled to possess such Confidential Information, provided such third party did not violate any legal obligation to the disclosing Party or any other person or acquire such Confidential Information directly or indirectly from the disclosing Party, or (d) the receiving Party is required to disclose under applicable laws or regulations or a court or other governmental order, provided that (i) except where impracticable, the receiving Party provides the disclosing Party with reasonable advance notice of such disclosure requirement and affords the disclosing Party opportunity to oppose or limit, secure confidential treatment for, such required disclosure, and (ii) the recipient discloses only that portion of the Confidential Information that the receiving Party is legally required to disclose.

19. GENERAL

19.1 Governing Law. This Agreement shall be governed by the laws of the State of New York without regard to conflicts of law principles. The Parties also agree that the United Nations Convention on Contracts for the International Sale of Goods does not apply to this Agreement.

19.2 Complete Agreement; Modification; Waiver. This Agreement, including its Exhibits, which are hereby incorporated by reference, and any other agreement or Mutual Confidentiality Agreement referred to herein are intended as the complete, final and exclusive statement of the terms of the agreement between the Parties with regard to the subject matter hereof, and supersedes any and all agreements between them relating to the subject matter hereof. No modification, change, or amendment to this Agreement, or any waiver of any rights in respect hereto, shall be effective unless in writing signed by the Party to be charged. The waiver of any breach or default hereunder shall not constitute the waiver of any subsequent breach or default.

19.3 Notices. Any notice or report required or permitted by this Agreement shall be deemed given if delivered personally or if sent by either Party to the other by registered or certified mail, postage prepaid, or internationally recognized courier, for overnight delivery, or by electronic transmission (e.g. E-mail or facsimile). If by personal delivery or by courier, delivery shall be effective on receipt. If by electronic transmission, delivery shall be effective on the day after transmission. If by mail, delivery shall be effective on the third business day after mailing. Notices shall be transmitted as follows:

If to DSM PTG:

President / CEO DSM PTG
2810 7th Street, Berkeley, California 94710 USA
Attn: Robert S. Ward
Phone 510 841 8800
Fax: (510) 841-7800

If to SHC:

Sunshine Heart, Inc. Attn: Dave Rosa, CEO
14413 Westridge Drive
Eden Prairie, Minnesota 55347

19.4 Assignment and Successors. Neither Party shall assign this Agreement or any rights hereunder, or delegate any obligations hereunder, without the prior written consent of the other Party, except as expressly permitted hereby. Either Party shall be entitled to assign its interest in this Agreement and to delegate its obligations under this Agreement, in whole but not in part, in connection with a merger or other business combination in which it is not the

surviving entity or to a party which acquires substantially all of the business and assets of the transferring Party which are related to the line of business which is the subject of this Agreement and which assumes in writing the transferring Party's obligations hereunder. Such assignment or delegation shall not relieve the transferring Party of its obligations hereunder, and such Party shall remain secondarily liable therefore. Subject to the foregoing, this Agreement shall bind and inure to the benefit of the Parties and their respective successors and assigns.

19.5 Severability. In the event any provision of this Agreement is found to be invalid, illegal, or unenforceable, the validity, legality, and enforceability of any of the remaining provisions shall not in any way be affected or impaired thereby.

19.6 Arbitration. Any dispute arising under or relating to this Agreement shall be decided by binding arbitration as follows. The Parties shall use all reasonable efforts to resolve the dispute through direct discussions within 30 days of written notice that there is such a dispute. If no amicable settlement is reached as a result of the discussions, the matter shall be finally settled by arbitration conducted expeditiously by a single neutral arbitrator in accordance with the applicable rules of the American Arbitration Association. No arbitrator may serve who has had at any time a material personal or financial relationship with any participant to the dispute or any Affiliate of any such participant. The place of arbitration shall be in the county in which is located the principal place of business of the respondent. The arbitrator is not empowered to modify the terms of this Agreement. The arbitrator shall award costs and attorneys' fees to the prevailing Party. The dispute resolution proceedings contemplated by this provision shall be as confidential and private as permitted by law. To that end, the Parties shall not disclose the existence, content or results of any proceedings conducted in accordance with this provision, and materials submitted in connection with such proceedings shall not be admissible in any other proceeding; provided, however, that this confidentiality provision shall not prevent a petition to vacate or enforce an arbitral award, and shall not bar disclosures required by law. The Parties agree that any decision or award resulting from proceedings in accordance with this dispute resolution provision shall have no preclusive effect in any other matter involving third parties. Notwithstanding the foregoing, if the enforcement of any right under this Agreement reasonably requires recourse to the equitable remedies provided by a court, due to the immediacy or nature of the remedy sought (for example, a preliminary injunction or a temporary restraining order), then either Party may pursue such equitable remedies in a court of competent jurisdiction if otherwise permissible by law pending submission of the matter to arbitration.

19.7 Compliance with Laws. SHC shall at all times during the term of this Agreement and for

so long as it shall sell Licensed Products comply with all laws and regulations that apply to import, export, manufacture, use, sale, marketing, distribution and other commercial exploitation of Licensed Products or any other activity undertaken pursuant to this Agreement.

19.8 Non-Waiver. The parties covenant and agree that if a party fails or neglects for any reason to take advantage of any of the terms provided for the termination of this Agreement or if a party, having the right to declare this Agreement terminated, shall fail to do so, any such failure or neglect by such party shall not be a waiver or be deemed or be construed to be a waiver of any cause for the termination of this Agreement subsequently arising, or as a waiver of any of the terms, covenants or conditions of this Agreement or of the performance thereof. None of the terms, covenants and conditions of this Agreement may be waived by a party except by its written consent.

19.9 Independent Contractors. The Parties hereby acknowledge and agree that each is an independent contractor and that neither Party shall be considered to be the agent, representative, master or servant of the other Party for any purpose whatsoever, and that neither Party has any authority to enter into a contract, to assume any obligation, or to give warranties or representations on behalf of the other party. Nothing in this relationship shall be construed to create a relationship of joint venture, partnership, fiduciary or other similar relationship between the Parties.

19.10 Publicity. During the Term and thereafter, except as required by applicable law, neither Party shall, without securing the prior written consent of the other Party, release the terms of this Agreement to any third party, publicly announce the terms of this Agreement or otherwise use the name of the other Party in any website, publication or press release without the prior written consent of the other Party.

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IN WITNESS WHEREOF, the Parties hereby execute this Agreement effective as of the Effective Date.

DSM PTG, INC.

Name: Rob Evans

Title: Vice President Global Sales & Marketing

Signature: /s/ Rob Evans

Date: 4/22/10

Name: Robert Ward

Title: President

Signature: /s/ Robert S. Ward

Date: 4/26/10

SUNSHINE HEART, INC.

Name: Dave Rosa

Title: CEO

Signature: /s/ Dave Rosa

Date: 4/14/10

EXHIBIT "A"

RELATED DSM PTG PATENTS

Patents covering Bionate materials

- Patent entitled "Crack- Resistant Polycarbonate Urethane Polymer Prostheses" U.S. Patent Serial No. 5,133,742 granted July 28, 1992
- Patent entitled "Crack-Resistant Polycarbonate Urethane Polymer Prostheses, and the Like, U.S. Patent Serial No. 5,229,431 granted July 20, 1993

Applications related to the foregoing two patents:

- Canada- Application No. 2,038,605
- Europe- Application No. 0461375
- Germany -Application No. 9117117
- Spain- Application No. 2077104
- Japan- Application No. 4226119

Patent entitled "Surface-Modifying End Groups for Biomedical Polymers, Ward et al U.S. Patent Serial No. 5,589,563_December 31, 1996

"Self-Assembling Monomers and Oligomers as Surface Modifying End-groups for polymers"

International application number: PCT/US2006/046586, filing date: 7 December 2006

Related Sunshine Heart Patents

US Patents covering the Heart Assist Field include Devices, Systems and Methods. Sunshine has a number of applications pending for worldwide coverage in the areas related to our research and development. Listed below are only the US patents and applications, the complete portfolio of patents and applications is considered included in this contract. There is a specific type of device known as an Actuator which includes the inflatable Balloon and Wrap.

- A patent titled "Heart Assist Devices Systems and Methods" US Patent Number 6,808,484
- A patent titled "Heart Assist Devices Systems and Methods" US Patent Number 7,357,771
- A patent titled "Heart Assist Device utilising Aortic Deformation" US Patent Number 7,347,8111

Applications pending but not yet approved

- A patent titled "Heart Assist Devices Systems and Methods" US Application 12/035,247
- A patent titled "Heart Assist Device utilising Aortic Deformation" US Application 12/044,853
- A patent titled "Actuator for a heart assist device" US Application 10/595605
- A patent titled "A wrap" US Application 10/595602

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Exhibit "B"

PAYMENT SCHEDULE OF LICENSE FEES

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*** Two pages have been omitted pursuant to a request for confidential treatment filed separately with the commission.

Exhibit "C"

List of SHC Products

Catalog number	Description
93020	C-Pulse Cuff, Small
93021	C-Pulse Cuff, Small Not for Human Use
94020	C-Pulse Cuff, Medium
94021	C-Pulse Cuff, Medium Not for Human Use
95020	C-Pulse Cuff, Large
95021	C-Pulse Cuff, Large Not for Human Use

Exhibit "D"

Initial Twelve Month Rolling Forecast

Forecast to be provided within 45 days of the Effective date.

Exhibit "E"

Initial Approved Vendor List

Suppliers for the program are identified on the Bill of Materials (BOM) document(s) which are provided as part of the requirements and specifications constitute the AVL.

Number FRM-061-A Approved Vendor List

Approved Suppliers List

Number: FRM-061 **Notes:** **Rev. A**
ECN: 012 **Contacts are for reference purposes only and are subject to change**

Key components may only be sourced from Approved Suppliers according to requirements at FM-002 *Supplier Evaluation*

Spec No.	Status	Supplier Name	Manufacturer	Distributor	Address	Phone	Fax	E-Mail	Contact*	Approval Date	Next Assessment Due
		PTG								17-Oct-08	17-Apr-09
		ASDM								17-Oct-08	17-Apr-09
		Nusil								17-Oct-08	17-Apr-09
		LSO			830 Challenger St. Brea, CA 92821	714 672 1090	714 672 1093			17-Oct-08	17-Apr-09
		Bard PV								17-Oct-08	17-Apr-09
		Centurion								17-Oct-08	17-Apr-09
		Calmont Wire and Cable								17-Oct-08	17-Apr-09
		Fischer Connectors								17-Oct-08	17-Apr-09
		Fort Wayne Metals								17-Oct-08	17-Apr-09
		Russell Symes								17-Oct-08	17-Apr-09
		Macam Rubber								17-Oct-08	17-Apr-09
		REIM								17-Oct-08	17-Apr-09
		Nelson Laboratories								17-Oct-08	17-Apr-09
	Conditional Approval	Plexus TG and EA								17-Oct-08	17-Apr-09
		W.L. Gore								17-Oct-08	17-Apr-09
		House of Packaging			13170 Temple Ave.Industry, CA 91746	626 369 3371	626 333 6115			17-Oct-08	17-Apr-09
		Formrite								17-Oct-08	17-Apr-09
		Steritech								17-Oct-08	17-Apr-09
		Oliver-Tolas Healthcare			445 6th St. NW Grand Rapids, MI 49504 USA	616 456 7711	616 456 5820			17-Oct-08	17-Apr-09

Packaging							
	U-Line		**2105 S. Lakeside Dr. Waukegan, IL 60085**	**1800 958 5463**	**1800 295 5571**		
	Rite Pak		**29 Huntingwood Dr. Huntingwood, NSW 2148, Australia**	**(02) 9672 7887**	**(02) 9672 7515**		**Anita Baker**
	Bard Peripheral Vascular		**1625 West 3rd Street P.O. Box 1740, Tempe, AZ 85280- 1740, USA**	**(+1) 480 303 2695**	**(+1) 480 966 7062**	**susan.moore@crbard.com**	**Susan B. Moore**
	Specialist Medical Supplies		**4/2 Moore Avenue, West Lindfield, NSW 2070, Australia**	**(02) 9880 7311**	**(02) 9880 7355**		
	Pacific Container, Inc		**Suite 122, 2192 Dupont Dr, Irvine, CA 92612-1328, USA**	**949 476 0484**	**949 955 3951**		
	B. Braun Australia Pty Ltd		**Norwest Business Park, 17 Lexington Drive, Bella Vista NSW 2153, Australia**	**(02) 9629 0200**	**1800 628 045**	**David.Chuck@bbraun.com**	**David Chuck**
	B. Braun OEM Division B. Braun Medical Inc.		**824 Twelfth Ave, Bethlehem, PA, 18018, USA**	**866 822 7286**	**610 691 6715**	**contact-usa@bbraunoem.com**	
	NuSil Technology LLC		**1050 Cindy Lane, Carpinteria, CA, 93013**	**(+1) 805 684 4118**	**(+1) 805 566 9905**		
		EIM Medical Consulting Pty Limited	**P.O. Box 1495, Mona Vale NSW 1660, Australia**	**(+61) 2 9979 9448**	**(+61) 2 9997 5646**	**eim.med@bigpond.net.au**	**Bozana Beric**

Exhibit “F”

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To be jointly created by SHC & DSM PTG

Exhibit “G”

DMR documents for* SHC *Products

DMR (Device Master Record) documents are listed below for the Assemblies covered by this agreement. The revision of each DMR shall be the latest version not necessarily the revision cited below. The DMR includes all subordinate documents contained therein.

DMR Number & Rev	Title
DMR 93020-G	C-Pulse Cuff, Small
DMR 94020-H	C-Pulse Cuff, Medium
DMR 95030-H	C-Pulse Cuff, Large

DHR document types

A DHR typically consist of one or more of the following document types. The list may not be inclusive or use identical terminology for all Vendors

Work Order Templates
Travelers
Procedures for Manufacturing, Assembly, Test, Inspection, etc.
Certificate of Compliance or Analysis (CofC) templates
Inspection results/forms
Test Data sheets/forms
etc

Exhibit “H”

Industry Standards and Certifications

CERTIFICATIONS

ISO 13485

ISO 9001

and all successor standards to ISO 13485 and ISO 9001.

Exhibit "I"

SHC Provided and Owned Equipment, Tooling, and Material

Equipment and Tooling

Qty	Part#	Rev	Description
			BALLON MANDRELS AND J HOOKS
5	01338		Mandrel, Balloon, EABe, Small
5	01340		Mandrel, Balloon, EABe, Medium
5	01342		Mandrel, Balloon, EABe, Large
5	01346		Assembly J-Hook, Dipping
1	?		Dispensing Robot (BFD)
4	01684	A	Balloon Bushing Bonding Jig (See below for individual items)
1			Stand for Balloon Bushing bonding (01703 & 01704)
1	01703	A	Stand Bushing Bonding plate
3	01704	A	Post, Bushing Balloon Bonding
3	01712	A	Guide Post , Bushing Balloon Bonding Jig
4	01688	A	Base, Bushing Balloon bonding jig
2	01685	B	Bushing Balloon bonding clamp plate, Small
2	01708	B	Bushing Balloon bonding clamp plate, Medium
8	01699	A	Slider plate, Bushing Balloon bonding
24		-	Screws for assembly (M4 thumbscrews x9, M6x12, M4x3)
2	01684	A	Balloon Bushing Bonding Jig (See below for individual items)
2	01688	A	Base, Bushing Balloon bonding jig
4	01699	A	Slider plate, Bushing Balloon bonding
2	01709	B	Bushing Balloon bonding clamp plate, Large
14	------	-	Screws for assembly and spares (M4 thumbscrews x6, M6 x8)
3	01556		Hot Knife Tip
			HELIX CUTTING TEMPLATES
1	01400		Cutting Template, Upper, Bard Tube, 38
1	01401		Cutting Template, Inner, Bard Tube, 38
1	01402		Cutting Template, Lower, Bard Tube, 38
2	01582		Baseplate, Clamp, 1 with SS Spring Pin
2	01583		Lockplate, Clamp
4	01584		Pin, Clamp
1	01588		Cutting Template, Upper, Bard Tube, 36
1	01586		Cutting Template, Inner, Bard Tube, 36
1	01587		Cutting Template, Lower, Bard Tube, 36
2	01582		Baseplate, Clamp, 1 with SS Spring Pin
2	01583		Lockplate, Clamp
4	01584		Pin, Clamp
multiple	01585		Center Support
			WRAP PATTERN CUTTING TEMPLATES
1	01514		Wrap, EABe Cutting Template, Small
1	01351		Wrap_, EABe, Cutting Template, Medium
1	01352		Wrap, EABe, Cutting Template, Large
			TAIL GLUING JIGS CENTRAL
1	01678		Glue Template, Wrap Center, Small

1	01679		Glue Template, Wrap Center, Medium
1	01680		Glue Template, Wrap Center, Large
1	01692		Central Tail Glue Jig
2	(CL-51-TC)		Toggle Clamp with Fasteners
8			M4x10 SS Pan Head (Philips)
1	01693		Clamp Disk
			TAIL GLUING JIGS SIDE
1	01681		Glue Template, Wrap Tail
1	01690		Glue Clamp, Wrap Tail
1	01691		Base Plate, Gluing WrapTail
4	{CL-250HTC-S)		Toggle Clamp with Fasteners
16			M4x10 SS Pan Head (Philips)
multiple	01693		Clamp Disk
			WRAP HEAT SHAPING
1	01659		Baseplate, Heat Shaper Nests
2			M4x20mm SS Countersunk Screw
1	01615		Heat Shaping Arbor, Small
1	01616		Heat Shaping, Nest, Small

1	01657	Clamp, Heat Shaping Nest, Small
2		M4x12mm SS Socket Head Cap Screw
2	01617	Arbor Clip
4		M4x10mm SS Socket Head Cap Screw
1	01659	Baseplate, Heat Shaper Nests
2		M4x20mm SS Countersunk Screw
1	01628	Heat Shaping Arbor, Medium
1	01629	Heat Shaping, Nest, Medium
1	01626	Clamp, Heat Shaping Nest, Medium
2		M4x12mm SS Socket Head Cap Screw
2	01617	Arbor Clip
4		M4x10mm SS Socket Head Cap Screw
1	01659	Baseplate, Heat Shaper Nests
2		M4x20mm SS Counter Sunk
1	01631	Heat Shaping Arbor, Large
1	01632	Heat Shaping, Nest, Large
1	01658	Clamp, Heat Shaping Nest, Large
2		M4xl2mm SS Socket Head Cap Screw
2	01617	Arbor Clip
4		M4x10mm SS Socket Head Cap Screw
		PORT GLUING JIGS
1	01635	Clamp, Base, Small
1	01636	Clamp, Top, Small
1		M4x10mm SS Thumb Screw
1	01638	Clamp, Base, Medium
1	01639	Clamp, Top, Medium
1		M4x10mm SS Thumb Screw
1	01641	Port Glue Clamp, Base, Large
1	01642	Port Glue Clamp, Top, Large
1		M4x10mm SS Thumb Screw
		BUCKLE CLEANING AND ATTACHMENT
1	01697	Buckle Location Template
1	(8464A63)	Multi-position vice
1	01800	Buckle Template Clamp Base
1	01801	Buckle Template Clamp Brace

1	01802	Buckle Template Clamp Bushing
1		MS Wingnut
2		M5x14 Phillips CSK Screw
1		M5x16 Phillips CSK Screw
		IN-PROCESS TAG
1	01702	Cutting Template, In-Process Label

Inventory Items

Part#	Description	Quantity
044938	Bard woven polyester tubing (wrap material) 38mm wide	35
01425-E	C-Pulse Buckle	330
N/A	Completed Wraps	1 tray
N/A	In process cuff wrap tails	1 bag
N/A	Sterilization pouches - assorted	1 bag
SPM 01330-B	Prolene suture	1 bag
SPM 01707-A	Ethibond polyester Suture, 4-0	1 bag
SPM 01330-A	Prolene Suture	1 bag
01425-E	Buckle, C-Pulse	1 bag

Miscellaneous Items - Instruments Consumables Etc.

Description	Quantity
various wrap offcuts	1 bag
Folder containing various labels	1 folder
1 Box of forceps, tools for cutting wrap, and 1 Box of cutting tools with divider Incl: · Dividers · Spatula · No.3 scapel	2 boxes

· Size 11 blades · Rule 150mm · Razor blades · Needle drivers · Tweezers · Babcock Tissue Forceps · Pen	
Box ofEFD dispensing accessories kit Incl: · NPT to Barrel elbows (907P) multiple · 3cc barrel reservoirs (5109LL-B) multiple · White pistons for 3cc barrels (5109PE-B) multiple · Snap tight cap for 3cc reservoirs multiple (51 09EC-B) · Orange Tip Caps (5113-B) multiple · Dispenser tips green smooth flow (5118TT-B) multiple	1 box with multiple parts

Exhibit "M"

Quality Agreement

Specifications Inspection Documents:

Balloon:

QCT 40079 REV E QCT 40080 REV E QCT 40081 REV E

Subassembly:

QCT 40094 REV E QCT 40095 REV E QCT40096 REV E

Final Assembly:

QCT 90042 REV B QCT 90043 REV B QCT 90044 REV B

Exhibit "N"

Form of Certification of Compliance

Print on DSM PTG Letterhead

CERTIFICATE OF COMPLIANCE

To: Sunshine Heart Company P/L

Purchase Order No.:

DSM PTG Part No.: Revision:

SHC Part No.: Revision:

Description:

Quantity:

DSM PTG Lot Number:

DSM PTG Date of Manufacture:

DSM PTG hereby certifies that products completed under the above purchase order were produced in conformance to requirements contained in the DSM PTG-SHC Quality Documentation. It is further certified that all manufacturing records are on file and readily available for review at DSM PTG upon request.

Authorized Signature: _____ Date: _____

DSMPTG

Printed Name: _____

Title of Signature: _____