FORM S-1

General form of registration statement for all companies including face-amount certificate companies

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As filed with the Securities and Exchange Commission on January 28, 2013

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

SUNSHINE HEART, INC.

(Exact name of registrant as specified in its charter)

Delaware	**68-0533453**
(State or other jurisdiction of incorporation or organization)	IRS Employer Identification Number)

12988 Valley View Road
Eden Prarie, MN 55344
(952) 345-4200
(Address, including zip code, and telephone number, including area code, of registrant' s principal executive offices)

David A. Rosa
Chief Executive Officer
Sunshine Heart, Inc.
12988 Valley View Road
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(952) 345-4200
(Name, address, including zip code, and telephone number, including area code, of agent for service)

With a copy to:
Phillip D. Torrence, Esq.
Honigman Miller Schwartz and Cohn LLP
350 East Michigan Avenue, Suite 300
Kalamazoo, Michigan 49007
(269) 337-7702

Approximate date of commencement of proposed sale to public: From time to time after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box: ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering: ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering: ☐

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(d) under the Securities Act, check the following box: ☐

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☐
Accelerated filer☐
Non-accelerated filer☐
(Do not check if a smaller reporting company)
Smaller reporting company ☒

CALCULATION OF REGISTRATION FEE

Title of Each Class of Security Being Registered	Amount Being Registered(1)	Proposed Maximum Offering Price Per Security	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Shares of common stock, $.0001 par value per share	3,000,000	$ 5.80(2)	$ 17,400,000	$ 2,373.36

(1) Pursuant to Rule 416 under the Securities Act of 1933, as amended (the *"Securities Act"*), this Registration Statement shall also cover any additional shares of common stock which become issuable by reason of any stock dividend, stock split or other similar transaction effected without the receipt of consideration that results in an increase in the number of the outstanding shares of common stock of the registrant.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act, based upon the average of the high and low prices of the common stock on The NASDAQ Capital Market on January 25, 2013. Under a common stock purchase agreement, Aspire Capital Fund, LLC has agreed to purchase up to $25.0 million of shares of the Registrant' s common stock.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. The selling securityholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, dated January 28, 2013

PROSPECTUS

Relating to the Sale of up to
3,000,000 Shares of Common Stock, $0.0001 Par Value

SUNSHINE HEART, INC.

This prospectus relates to the sale of up to 3,000,000 shares of our common stock by Aspire Capital Fund, LLC. Aspire Capital is also referred to in this prospectus as the selling stockholder. The prices at which the selling stockholder may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive proceeds from the sale of the shares by the selling stockholder. However, we may receive gross proceeds of up to $25,000,000 from the sale of our common stock to the selling stockholder, pursuant to a common stock purchase agreement entered into with the selling stockholder on January 15, 2013, once the registration statement, of which this prospectus is a part, is declared effective.

The selling stockholder is an "underwriter" within the meaning of the Securities Act of 1933, as amended. We will pay the expenses of registering these shares, but all selling and other expenses incurred by the selling stockholder will be paid the selling stockholder.

Our common stock is listed on the NASDAQ Capital Market under the symbol "SSH." On January 25, 2013, the last reported sale price for our common stock was $5.89 per share.

Investing in our securities involves significant risks. We strongly recommend that you read carefully the risks we describe in this Prospectus and the risk factors that are incorporated by reference in this Prospectus from our filings made with the Securities and Exchange Commission. WE ARE AN "EMERGING GROWTH COMPANY" UNDER THE U.S. FEDERAL SECURITIES LAWS AND ARE SUBJECT TO REDUCED PUBLIC COMPANY REPORTING REQUIREMENTS. See "Risk Factors" beginning on page 8 before deciding whether to invest in our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this Prospectus. Any representation to the contrary is a criminal offense.

The date of this Prospectus is January 28, 2013.

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You should rely only on the information provided in this Prospectus or in any free writing Prospectus prepared by or on behalf of us or to which we have referred you. We have not authorized anyone to provide you with different information. The information contained in this Prospectus is accurate only as of the date of this Prospectus, regardless of the time of delivery of

this Prospectus or of any sale of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

Persons outside the United States who come into possession of this Prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this Prospectus outside of the United States.

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PROSPECTUS SUMMARY

Because this is only a summary, it does not contain all of the information that may be important to you. You should carefully read the more detailed information contained in this prospectus and the information incorporated by reference carefully before you invest. Our business involves significant risks. You should carefully consider the information under the heading "Risk Factors" beginning on page 8.

As used in this prospectus, unless otherwise indicated, the terms ***"we," "us," "our company," "the Company"*** and ***"Sunshine Heart"*** refer to Sunshine Heart, Inc., a Delaware corporation.

All references in this prospectus to "$" are to U.S. Dollars and all references to "A$" are to Australian Dollars.

C-Pulse®, Sunshine®, Sunshine Heart™, C-Patch™ and other trademarks or service marks of Sunshine Heart appearing in this prospectus 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.

We obtained industry and market data used throughout this prospectus 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.

Our Company

Overview

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

We are in the process of pursuing regulatory approvals necessary to sell our system in the United States. We completed enrollment of our North American feasibility clinical trial in the first half of 2011. In November 2011, we announced the preliminary results of the six-month follow-up period for the feasibility study and we submitted the clinical data to the United States Food and Drug Administration, or FDA. In March 2012, the FDA notified us that it completed its review of the C-Pulse System feasibility trial data, concluded we met the applicable agency requirements, and indicated that we can move forward with an investigational device exemption, or IDE, application. In November 2012, the FDA provided us with unconditional approval to initiate a pivotal trial. We currently anticipate that enrollment of our pivotal trial will begin during the first half of 2013. We expect to complete enrollment of our pivotal trial by the end of 2015 and do not anticipate marketing our system in the United States before 2017.

We obtained CE Mark approval for the C-Pulse System in July 2012 and have taken initial steps to evaluate the market potential for our system in targeted countries that accept the CE Mark in anticipation of commencing commercial sales. In order to gain additional clinical data and support reimbursement in Europe, we also expect to initiate a post-market trial in Europe that will evaluate endpoints similar to those for our U.S. pivotal trial.

We incurred net losses of $16.2 million and $7.6 million in the years ended December 31, 2011 and 2010, respectively, and $10.0 million in the nine months ended September 30, 2012. Historically, we have

generated our revenue solely from sales of the C-Pulse System to hospitals and clinics pursuant to research arrangements and with appropriate regulatory approvals for sales in conjunction with our feasibility clinical trial. We expect to continue to incur significant net losses as we continue to conduct clinical trials, pursue commercialization and as we ramp up sales of our system.

Our Market Opportunity

Heart failure is one of the leading causes of death in the United States and other developed countries. The American Heart Association estimates that 5.7 million people in the United States 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 health care expense category.

Heart failure is a progressive disease caused by impairment of 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. The severity of heart failure depends on how well a person' s heart is able to pump blood throughout the body. A common measure of heart failure severity is the New York Heart Association, or NYHA, Class guideline. Patients are classified in Class I through Class IV based on their symptoms and functional limitations. Classes I and II include mild heart failure patients, Class III includes moderate heart failure patients, and Class IV includes severe heart failure patients.

Our C-Pulse 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 United States fall into this classification range, and we believe approximately 3.7 million patients in Europe are similarly affected.

Treatment alternatives currently available for Class III heart failure patients in the United States consist primarily of pharmacological therapies and pacing devices that are designed to address heart rhythm issues. Although these treatments may provide symptomatic relief and prolong the life of patients, they do not often 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 United States, and one product received FDA approval in the United States for Class IIIb patients although the device is not reimbursed by the Centers for Medicare and Medicaid Services, or CMS, 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 products are effective in increasing blood flow, these devices by design are in contact with the patient' s bloodstream, increasing the risk of adverse events, including thrombosis, bleeding and neurologic events.

Our Strategy

Our goal is to become a market leader in the treatment of heart failure patients through the commercialization of our C-Pulse System, and to continue the development of the system to make it safer and more convenient for patients and physicians. We believe that our technology will provide us with a competitive advantage in the market for treating specific segments of heart failure patients. To achieve our objectives, we intend to:

- conduct a pivotal trial in the United States;
- conduct a post-market trial in Europe to gather additional clinical data;
- prepare for the commercial launch of the C-Pulse System in Europe; and
- continue to enhance the C-Pulse System.

Our System

The C-Pulse 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 sustain the patient' s current condition or, in some cases, reverse the heart failure process, thereby potentially preventing the need for later-stage heart failure devices, such as LVADs, artificial hearts or transplants. It may also provide relief from the symptoms of Class III and ambulatory Class IV heart failure and improve quality of life and cardiac function. Based on the patient results from our feasibility trial, we also believe that some patients treated with our C-Pulse System will be able to stop using the device due to sustained improvement in their conditions as a result of the therapy.

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 via the coronary arteries. Just before the heart pumps, the C-Pulse cuff deflates to reduce the heart' s workload through pressure changes, 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 abdominal wall to connect to a power driver outside the body. The system' s single unit driver and battery source are contained inside a carrying bag.

Surgeons in the feasibility phase of our clinical trial initially implanted the C-Pulse System in patients via a full sternotomy. We have developed a procedure to allow the C-Pulse System to be implanted via a mini thoracotomy using a small pacemaker-like incision between the patient' s ribs and sternum, rather than through a full sternotomy, and the first implant using this less invasive procedure was completed in 2010. Patients implanted via our minimally invasive procedure typically require a hospital stay of four to seven days in connection with implantation of the C-Pulse System, after which they return home. This compares to an average hospital stay of 14 days for patients implanted with the C-Pulse System via a full sternotomy. Further, final clinical data from two LVAD studies indicate median hospital stays of 19 and 25 days for patients implanted via a full sternotomy. Therefore, we believe this less invasive approach can reduce procedural time, hospital stays, overall cost and patient risk as compared to treatment options that require a full sternotomy.

The C-Pulse System distinguishes itself from other mechanical heart failure therapies in two important respects, which we believe differentiate our system from other products addressing moderate to severe heart failure patients:

- **The C-Pulse System is Placed Outside 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

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function inside the vascular system. Because it rests outside the vasculature, it also does not require blood thinning agents that are necessary for patients with devices that are in contact with the bloodstream. As with any implanted device, patients using our system have a risk of infection from the implantation procedure, and any untreated sternal infection arising from the implantation procedure or otherwise could result in erosion of the aortic wall or an aortic rupture in connection with using our system. Because our system has been implanted in a limited number of patients to date, the potential competitive disadvantages and risks associated with the use of our system are not fully known at this time.

- **The C-Pulse System Can be Safely Turned On or Off at Any Time.** The C-Pulse System does not need to be in constant operation for patients once implanted, and the device can be safely turned on or off at any time. This feature allows patients intervals of freedom to perform certain activities such as showering. Patients are not required to visit a medical facility when turning our device on or off or using the device. However, patients are advised to turn off the C-Pulse System only for short periods of time and for specified activities to maximize the benefit from the system. If the C-Pulse System is not used as directed, patients might experience a return of their heart failure symptoms, a loss of any improvement in their condition resulting from use of our system or an overall worsening of their heart failure symptoms compared to when they began using our system.

Clinical Development

We completed enrollment and implantation of 20 patients in our North American feasibility trial in the first half of 2011. The feasibility phase of our clinical trial was primarily designed to assess safety and provide indications of performance of the C-Pulse System in moderate to severe heart failure patients who suffer from symptoms such as shortness of breath and reduced mobility. In November 2011, we announced the preliminary results of the six-month follow-up period for the feasibility study and we submitted the clinical data to the FDA. In July 2012 we completed two-year follow-up for a patient implanted with our system during our feasibility trial. A summary of the results from the six-month follow-up data as well as the twelve-month data can be found under "Business−Clinical Development" beginning on page 45 of this prospectus.

We believe the results of the six-month and 12-month follow-up demonstrate the feasibility of the C-Pulse System implantation procedure and provide indications of safety and efficacy of the C-Pulse System in patients with moderate to severe heart failure necessary to proceed with a pivotal trial. In March 2012, the FDA notified us that it completed its review of the C-Pulse System feasibility trial data, concluded we met the applicable agency requirements, and indicated that we can move forward with an IDE application. In November 2012, the FDA provided us with unconditional approval to initiate a pivotal trial. We currently anticipate that enrollment of our pivotal trial will begin during the first half of 2013, and we expect to complete our pivotal trial enrollment by the end of 2015. In July 2012, we obtained CE Mark approval for the C-Pulse System and have taken steps to initiate a post-market trial in Europe that will evaluate endpoints similar to those for our U.S. pivotal trial.

Corporate Information

Sunshine Heart, Inc. was incorporated in Delaware on August 22, 2002. We began operating our business in November 1999 through Sunshine Heart Company Pty Ltd., which currently is a wholly owned Australian subsidiary of Sunshine Heart, Inc. 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 affected on January 27, 2012, we changed this ratio so that each CDI represents 1/200th of a share of our common stock.

On September 30, 2011, we filed a Form 10 registration statement with the SEC, which was declared effective on February 14, 2012. The Form 10 registered our common stock under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our common stock began trading on the Nasdaq Capital Market on February 16, 2012.

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 prospectus or the registration statement of which it is a part.

We qualify as an "emerging growth company" as defined in the Jumpstart our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to U.S. public companies. These provisions include:

- a requirement to have only two years of audited financial statements and only two years of related Management' s Discussion and Analysis of Financial Condition and Results of Operations disclosure; and

- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002.

We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1.0 billion in annual revenue, have more than $700 million in market value of our shares of common stock held by non-affiliates, or issue more than $1.0 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these reduced burdens. The JOBS Act permits emerging growth companies to take advantage of an extended transition period to comply with new or revised accounting standards applicable to U.S. public companies. We have elected to take advantage of the benefits of this extended transition period, and as a result of this election, our financial statements may not be comparable to those of companies that comply with new or revised accounting standards for U.S. public companies.

THE OFFERING

Common stock covered hereby:	Up to 3,000,000 shares, including 80,257 shares currently outstanding.
Common stock outstanding as of January 25, 2013:	9,362,981 shares.

Use of proceeds:	Aspire Capital will receive all of the proceeds from the sale of the shares offered for sale by it under this prospectus. We will not receive proceeds from the sale of the shares by Aspire Capital. However, we may receive up to $25.0 million in proceeds from the sale of our common stock to Aspire Capital under the Common Stock Purchase Agreement described below, which we currently intend to use for working capital and general corporate purposes. See "Use of Proceeds."
Risk factors:	The shares of common stock offered hereby involve a high degree of risk. See "Risk Factors" beginning on page 8.
Dividend policy:	We currently intend to retain any future earnings to fund the development and growth of our business. Therefore, we do not currently anticipate paying cash dividends on our common stock.
Trading Symbol:	Our common stock currently trades on the Nasdaq Capital Market under the symbol "SSH." Our shares of common stock have also traded in the form of CDIs on the Australian Stock Exchange under the symbol "SHC" since September 2004.

On January 15, 2013, we entered into a common stock purchase agreement (referred to in this prospectus as the ***"Purchase Agreement"***), with Aspire Capital Fund, LLC, an Illinois limited liability company (referred to in this prospectus as ***"Aspire Capital"*** or the ***"selling stockholder"***), which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $25.0 million of shares of our common stock over the approximately 24-month term of the Purchase Agreement, should we elect to sell shares to Aspire Capital. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital 80,257 shares of our common stock, which we refer to as the Commitment Shares, as a commitment fee. Concurrently with entering into the Purchase Agreement, we also entered into a registration rights agreement with Aspire Capital, which we refer to as the Registration Rights Agreement, pursuant to which we agreed to file one or more registration statements, including the registration statement of which this prospectus is a part, as permissible and necessary to register under the Securities Act of 1933, as amended, or the Securities Act, the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the Purchase Agreement.

As of January 25, 2013, there were 9,362,981 shares of our common stock outstanding (6,525,105 shares held by non-affiliates) excluding the 2,919,743 shares offered that may be issuable to Aspire Capital pursuant to the Purchase Agreement. If all of the 3,000,000 shares of our common stock offered hereby

were issued and outstanding as of January 25, 2013, such shares would represent 24% of the total common stock outstanding, or 32% of the non-affiliate shares of common stock outstanding as of January 25, 2013. The number of shares of our common stock ultimately offered for sale by Aspire Capital is dependent upon the number of shares purchased by Aspire Capital under the Purchase Agreement.

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we are registering under the Securities Act 3,000,000 shares of our common stock, which includes the Commitment Shares that have already been issued to Aspire Capital. All 3,000,000 shares of common stock are being offered pursuant to this prospectus.

Under the Purchase Agreement, we have the right, but not the obligation, to sell more than the 3,000,000 shares of common stock offered in this prospectus. The Purchase Agreement provides that the number of shares that may be sold pursuant to the Purchase Agreement shall be limited to 1,298,653 (the ***"Exchange Cap"***), which represents 13.99% of our outstanding shares as of January 14, 2013, unless shareholder approval or an exception pursuant to the rules of the Australian Stock Exchange (the ***"ASX"***) is obtained to issue more than 13.99%, to be in compliance with the applicable listing maintenance rules of the ASX. If at any time during the term of the Purchase Agreement, our securities cease to be listed on the ASX, the Exchange Cap will be reset to 1,856,616 shares, or 19.99% of our outstanding stock as of the date of the Purchase Agreement, to be in compliance with the applicable maintenance rules of the Nasdaq Capital Market. The Nasdaq limitation shall not apply if, at any time the Exchange Cap is reached and at all times thereafter, the average price paid for all shares issued and sold under the Purchase Agreement is equal to or greater than $6.10, a price based on the closing sale price of our common stock on January 14, 2013. We are not required or permitted to issue any shares of common stock under the Purchase Agreement if such issuance would breach our obligations under the rules or regulations of the ASX or the Nasdaq Capital Market.

After the SEC has declared effective the registration statement of which this prospectus is a part, Aspire Capital will make an initial purchase of $1,000,000 (the "***Initial Purchase"***) of an amount of our common stock equal to $1.0 million divided by the average closing share price for the five consecutive trading days preceding the Commencement Date (as defined in the Purchase Agreement). Thereafter, we have the right, in our sole discretion, to present Aspire Capital with a purchase notice (each, a ***"Purchase Notice"***), directing Aspire Capital (as principal) to purchase up to 50,000 shares of our common stock per trading day, provided that the aggregate price of such purchase shall not exceed $1,000,000 per trading day, up to an additional $24.0 million of our common stock in the aggregate at a per share price (the ***"Purchase Price"***) calculated by reference to the prevailing market price of our common stock (as more specifically described below).

In addition, on any date on which we submit a Purchase Notice to Aspire Capital in an amount equal to 50,000 shares, we also have the right, in our sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice (each, a ***"VWAP Purchase Notice"***) directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company' s common stock traded on The Nasdaq Capital Market on the next trading day (the ***"VWAP Purchase Date"***), subject to a maximum number of shares we may determine (the ***"VWAP Purchase Share Volume Maximum"***) and a minimum trading price (the ***"VWAP Minimum Price Threshold"***) (as more specifically described below). The purchase price per Purchase Share pursuant to such VWAP Purchase Notice (the ***"VWAP Purchase Price"***) is calculated by reference to the prevailing market price of our common stock (as more specifically described below).

The Purchase Agreement provides that in no event will any shares of common stock be sold if the closing price of our common stock is less than $1.00, or the Floor Price. This Floor Price and the respective prices and share numbers in the preceding paragraphs shall be appropriately adjusted for any

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reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction. Additionally, the Purchase Agreement provides that the Company and Aspire Capital shall not effect any sales under the Purchase Agreement if such shares proposed to be issued and sold, when aggregated with all other shares of the Company' s common stock that Aspire Capital and its affiliates beneficially own, would result in Aspire Capital and its affiliates beneficially owning more than the Exchange Cap.

There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Aspire Capital. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as we direct in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us.

RISK FACTORS

Any investment in our common stock involves a high degree of risk. Investors should carefully consider the risks described below, together with all of the other information included in this prospectus, before deciding whether to purchase shares of our common stock. Each of the following risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our company. This prospectus also contains forward-looking statements that involve risks and uncertainties. Our operating results could differ materially from those anticipated in these forward-looking statements as a result of certain risk factors, including the risks we face as described below and elsewhere in this prospectus.

Risks Relating to Our Business

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

We are an early-stage company with a history of incurring net losses. We have incurred net losses since our inception, including net losses of $16.2 million and $7.6 million for the years ended December 31, 2011 and 2010, respectively, and $10.0 million for the nine months ended September 30, 2012. As of September 30, 2012, our accumulated deficit was $75.2 million. We do not have any products that have been approved for marketing in the United States, we have not established any sales capability outside of the United States, 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 research and development programs, seek regulatory approvals, expand our sales and marketing capabilities, increase manufacturing of our system and comply with the requirements related to being a U.S. public company listed on the ASX and the Nasdaq Capital Market. To become and remain profitable, we must succeed in developing and commercializing products with significant market potential. This will require us to succeed in a range of challenging activities, including conducting clinical trials, obtaining regulatory approvals, manufacturing products and marketing and selling commercial products. There can be no assurance that we will 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.

We have no products currently available for commercial sale, and to date we have generated only limited revenue from our feasibility study. In addition, the report of our independent registered public accounting firm includes an explanatory paragraph with regard to our ability to continue as a going concern in connection with its audit of our financial statements for the fiscal year ended December 31, 2011. After completion of this offering, 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 research and development programs, seek regulatory approvals, expand our sales and marketing capabilities, increase manufacturing of our system and comply with the requirements related to being a U.S. public company listed on the ASX and the Nasdaq Capital Market. Additional funding will likely be needed after the sale of shares anticipated by the Purchase Agreement with Aspire Capital and may not be available on terms favorable to us, or at all. 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, require us to use our cash to make payments under such 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 development programs and our commercialization efforts would be delayed, reduced or eliminated, our relationships with our suppliers and manufacturers may be harmed, and we may not be able to continue our operations.

Our near-term prospects are highly dependent on the development of a single product, our C-Pulse System. If we fail to obtain the regulatory approvals necessary to sell the C-Pulse System or fail to successfully commercialize this system, our business and prospects would be harmed significantly.

Our near-term prospects are highly dependent on the development of a single product, our C-Pulse System, and we have no other product candidates in active development at this time. We are in the process of pursuing regulatory approvals necessary to sell our system in the United States. We completed enrollment of our North American feasibility clinical trial in the first half of 2011. In November 2011, we announced the preliminary results of the six-month follow-up period for the feasibility study and we submitted the clinical data to the FDA. In March 2012, the FDA notified us that it completed its review of the C-Pulse System feasibility trial data, concluded we met the applicable agency requirements, and indicated that we can move forward with an IDE application. In November, 2012, the FDA provided us with unconditional approval to initiate a pivotal trial. We currently anticipate that enrollment of the pivotal trial will begin in the first half of 2013. We expect to complete enrollment of our pivotal trial by the end of 2015 and do not anticipate marketing our system in the United States before 2017.

There can be no assurance that we will be able to obtain the regulatory approvals necessary to sell our system. In addition, even if we obtain such regulatory approvals, there can be no assurance that we will be able to successfully commercialize our system. If we fail to obtain the regulatory approvals necessary to sell our system or fail to successfully commercialize our system, our business and prospects would be harmed significantly.

We currently have no sales, marketing or distribution operations and will need to expand our expertise in these areas.

We currently have no sales, marketing or distribution operations and, in connection with the expected commercialization of our system, will need to expand our expertise in these areas. To increase internal sales, distribution and marketing expertise and be able to conduct these operations, we would have to invest significant amounts of financial and management resources. In developing these functions ourselves, we could face a number of risks, including:

- we may not be able to attract and build an effective marketing or sales force;

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- 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 applicable legal and regulatory requirements for sales, marketing and distribution could result in an enforcement action by the FDA, European regulators or other authorities that could jeopardize our ability to market the system or could subject us to substantial liability.

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

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

- costs of complying with varying regulatory requirements and potential, unexpected changes to those requirements;
- fluctuations in and management of 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 system;
- longer payment cycles and difficulties in collecting accounts receivable;
- difficulties in managing and staffing international operations;
- the burdens of complying with a wide variety of non-U.S. laws and legal standards;
- 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 system. If one or more of the suppliers of the components used in our system were unable or unwilling to meet our demand for such components or faced financial or business difficulties in general, 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 system could be delayed and our expenses could increase. Moreover, if any of the suppliers were unable or unwilling to perform, we would be required to find alternative sources for the components provided by such supplier, and there can be no assurance that we would be able to find a replacement supplier on a timely basis, or at all. In particular, the balloon used in our system is highly specialized and is currently solely available from a single supplier. If the manufacturer of the balloon were unable or unwilling to supply this component for any reason, we would have to locate and qualify another supplier and such supplier and its balloon product would have to be qualified with the FDA. Since there is currently no other supplier in the industry, locating and qualifying another supplier could cause significant production delays, causing us to lose revenues and market share and to potentially suffer increased costs and damage to our reputation. Additionally, even if we are able to find a replacement supplier of any of the components used in our system, 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. This 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 system 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 system 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 system and are unable to obtain a sufficient supply of our system, 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 system.

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 system, 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.

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We may not be able to correctly estimate or control our future operating expenses, which could lead to cash shortfalls.

Our operating expenses may fluctuate significantly in the future as a result of a variety of factors, many of which are outside of our control. These factors include:

- the time and resources required to develop, conduct clinical studies and obtain regulatory approvals for the products we develop;
- the expenses we incur for the research and development required to maintain and improve our system;
- the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation;
- the expenses we incur in connection with commercialization activities, including marketing, sales and distribution;
- our sales strategy and whether the revenues from sales of our system will be sufficient to offset our expenses;

- the costs to attract and retain personnel with the skills required for effective operations; and

- the costs associated with being a public company.

Our budgeted expense levels are based in part on our expectations concerning future revenues from sales of our C-Pulse System. We may be unable to reduce our expenditures in a timely manner to compensate for any unexpected shortfall in revenue. Accordingly, a significant shortfall in demand for our system could have an immediate and material impact on our business and financial condition.

We compete against many companies, some of which 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 from medical device companies and medical device divisions of health care companies, as well as pharmaceutical companies and gene- and cell-based therapies is intense and is expected to increase. Our system will compete against therapies, including pharmacological therapies, as well as other medical device competitors that treat or may treat in the future Class III or ambulatory Class IV heart failure patients, including AbioMed, Inc., Berlin Heart GmbH, CardioKinetix, Inc., CircuLite, Inc., HeartWare International Inc., Jarvik Heart, Inc., MicroMed Technology, Inc., SynCardia Systems, Inc., Terumo Heart, Inc. and Thoratec Corporation, as well as a range of other specialized medical device companies with devices at varying stages of development. 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 harm our business. In addition, because our system has been implanted in a limited number of patients to date, all of the material risks and potential competitive disadvantages of our system are not necessarily known at this time.

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

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- financial resources;

- product performance and design;

- product safety;

- acceptance of our system in the marketplace;

- sales, marketing and distribution capabilities;

- manufacturing and assembly costs;

- pricing of our system and of our competitors' products;

- the availability of reimbursement from government and private health insurers;

- success and timing of new product development and introductions;

- regulatory approvals in the United States; 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 harm our results of operations.

The design, manufacture and marketing of medical devices involve certain inherent risks. Manufacturing or design defects, unanticipated use of a product 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 a product (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 of our system could result in significant costs, as well as negative publicity and damage to our reputation that could reduce demand for our system. Personal injuries relating to the use of our system could also result in product liability claims being brought against us. In some circumstances, such adverse events could also cause delays in new product approvals. Any one of these factors could substantially harm our business and results of operations.

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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 system treats 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 system have a high risk of suffering adverse outcomes, regardless of the safety or efficacy of our system. In addition, because our system has been implanted in a limited number of patients to date, we cannot assure you that we are currently aware of all material risks related to use of our system or that could lead to product liability claims against us.

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 system will not protect us from any such liability. We carry product liability insurance with a $10 million aggregate limit. However, if there are 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 be harmed. 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 system, injury to our reputation, diversion of management' s attention from operating our business, withdrawal of clinical trial participants, significant costs of related litigation, loss of revenue or the inability to commercialize the C-Pulse System.

Risks Relating to Regulation

We do not have FDA approval for our system and our success will depend heavily on the success of our pivotal trial for our C-Pulse System. Any failure or significant delay in successfully completing our pivotal trial or obtaining regulatory approvals could harm our financial results and our prospects and require us to seek additional funding.

Upon completion of the six-month follow-up period for our feasibility trial, we submitted the trial' s clinical data to the FDA in November 2011. In November 2012, the FDA provided us with unconditional approval to initiate a pivotal trial. We currently anticipate that enrollment of our pivotal trial will begin during the first half of 2013. Completion of the pivotal trial could be delayed, and adverse events during the trial could cause us to modify the existing design, repeat or terminate the trial. If the trial is delayed, if it must be repeated or if it is terminated, our costs associated with the trial will increase, and it will take us longer to obtain regulatory approvals and commercialize the C-Pulse System, if we are able to do so at all. Our pivotal trial also may be suspended or terminated at any time by regulatory authorities or by us. FDA scrutiny of IDE applications has intensified in recent years, increasing the risk of delay or failure.

If we commence and complete our pivotal clinical trial, we must demonstrate the safety and efficacy of the C-Pulse System by meeting the trial' s endpoints before we can commercialize the C-Pulse System in the United States. Our inability to achieve the safety or efficacy endpoints in the pivotal trial could delay our timeline for obtaining regulatory approval to commercialize our system or prevent us from obtaining such regulatory approval altogether.

In addition to successfully completing our U.S. pivotal trial, we will need to receive approval from regulatory agencies in each country outside of the EU in which we seek to sell our system. 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.

If we are unable to complete our pivotal trial, or experience significant delays in the trial, or if the results of the trial do not meet its safety and efficacy endpoints, our ability to obtain regulatory approval to commercialize our system and to generate revenues will be harmed.

Even if we obtain foreign regulatory approvals, we will need to obtain FDA approval to commercialize our system in the United States.

Even if we obtain foreign regulatory approvals, we will need to obtain FDA approval to commercialize our system 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 system in the United States. We do not currently have the necessary regulatory approvals to commercialize our C-Pulse System in the United States, which we believe is the largest potential market for our C-Pulse System. We can offer no assurance that our IDE application will be approved, that our clinical trials will be successful 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 Premarket Approval, or PMA, from the FDA. A PMA must be supported by pre-clinical and clinical trials to demonstrate safety and efficacy. A clinical trial will be required to support an application for a PMA, and we will be seeking FDA approval of our IDE application that will allow us to commence a clinical trial in the United States. We intend to commence our U.S. pivotal trial in the first half of 2013, 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 meet its objectives or end-points to show the safety and efficacy of our system 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 the product; and
- result in failure to support approval of the product or limitations on the indicated uses of the product.

Increased attention to safety and oversight issues in light of recent, widely publicized events concerning the safety of certain food, drug and medical device products could cause the FDA to take a more cautious approach in connection with 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 would significantly harm 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 2013. The trial will be designed to be a randomized trial that includes approximately 388 patients and is expected to involve approximately 40 sites. Conducting a clinical trial of this size is a complex and uncertain process.

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

- reaching agreement on acceptable terms with prospective clinical trial sites;
- manufacturing sufficient quantities of our C-Pulse System;
- obtaining institutional review board approval to conduct the trial at a prospective site; and

- obtaining sufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the trial.

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

- ongoing discussions with regulatory authorities regarding the scope or design of our preclinical results or clinical trial or requests for supplemental information with respect to our preclinical results or clinical trial results;

- our failure or inability to conduct the clinical trials in accordance with regulatory requirements;

- sites currently participating in the trial may drop out of the trial, which may require us to engage new sites or petition the FDA for an expansion of the number of sites that are permitted to be involved in the trial;

- patients may not achieve the required clinical end-points of 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 system, could cause the FDA or other regulatory authorities to place the clinical trial on hold; and

- clinical investigators may not perform clinical trials on our anticipated schedule or consistent with the clinical trial protocol and good clinical practice requirements.

If our pivotal trial is delayed, it will take us longer to ultimately commercialize a product or the delay could result in our being unable to do so. Our development costs will also increase if we have material delays in our pivotal trial or if we need to perform more or larger clinical trials than planned. Moreover, there can be no assurance that we will be able to successfully complete, or achieve the desired clinical end-points from, our pivotal trial at all, which could prevent us from receiving regulatory approval for the

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C-Pulse System altogether. 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 have limited oversight over these entities and cannot 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 system. 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 system.

Our manufacturers and suppliers might not meet regulatory quality standards applicable to manufacturing and quality processes, which could harm our financial results and prospects.

Even if our system receives marketing approval, product approvals 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 system. 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 system manufactured and to complete our clinical trials and could significantly increase our costs, which would harm our financial results and our prospects. In addition, suppliers of components of, and products used to manufacture, our system 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 system 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 system 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 or administrative interpretations and policies of regulatory agencies, we could be precluded from commercializing our system in those countries and could become 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, third-party health care payors 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 and price 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, third-party health care payors 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 system by third-party payors, there may be no commercially viable markets for our system or the markets may be much smaller than expected.

The availability and levels of reimbursement by governmental and other third-party payors significantly affect the market for our system. Reimbursement by third-party payors in the United States typically is based on the device' s perceived benefit and whether it is deemed medically reasonable and necessary. Reimbursement levels of third-party payors in the United States are also based on established payment formulas that take into account part or all of the cost associated with these devices and the related procedures performed. We cannot assure you the level of reimbursement we might obtain in the United States, if any, for our system. If we do not obtain adequate levels of reimbursement for our system by third-party payors in the United States, which we believe is largest potential market for our system, our financial condition, results of operations and prospects would be harmed.

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 additional clinical data, which may involve one or more additional clinical trials, that compares the cost-effectiveness of our system 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 system in the international markets in which those approvals are sought.

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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 payors may adversely affect the demand for the C-Pulse System and limit our ability to sell the C-Pulse System or any future products on a profitable basis. In addition, third-party payors 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 system is unavailable in any market or limited in scope or amount, or if pricing is set at unsatisfactory levels, market acceptance of our system would be significantly impaired and our future revenues, if any, would be significantly harmed.

We may be subject, directly or indirectly, to U.S. federal and state health care 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 and health care professionals, subject to various U.S. federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, federal False Claims Act, and federal Foreign Corrupt Practices Act, or the FCPA. These laws may impact, among other things, our proposed sales, and 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 health care 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 health care 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 health care industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil and administrative sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal health care programs. An alleged violation of the Anti-Kickback Statute may be used as a predicate offense to establish liability pursuant to other federal laws and regulations such as the federal False Claims Act. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for health care 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 "relators" or "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 health care companies to have to defend a False Claim Act action. The federal Patient Protection and Affordable Care Act includes provisions expanding the ability of certain relators to bring actions that would have been previously dismissed under prior law. 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. The Deficit Reduction Act of 2005 encouraged states to enact or modify their state false claims act to be at least as effective as the federal False Claims Act by granting states a portion of any federal Medicaid funds recovered through Medicaid-related actions. Most states have enacted state false claims laws, and many of those states included laws including

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qui tam provisions. States have until March 31, 2013 to enact or amend their false claims laws modeled after the federal False Claims Act for review and approval to receive a greater portion of any recovery.

The federal Patient Protection and Affordable Care Act includes provisions known as the Physician Payments Sunshine Act, which requires manufacturers of drugs, biologics, devices and medical supplies covered under Medicare and Medicaid starting in 2012 to record any transfers of value to physicians and teaching hospitals and to report this data beginning in 2013 to the Centers for Medicare and Medicaid Services for subsequent public disclosure. Manufacturers must also disclose investment interests held by physicians and their family members. Failure to submit the required information may result in civil monetary penalties of up to $1 million per year for knowing violations and may result in liability under other federal laws or regulations. Similar reporting requirements have also been enacted on the state level in the United States, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with health care professionals. In addition, some states such as Massachusetts and Vermont impose an outright ban on certain gifts to physicians. If we receive FDA clearance to market our system in the United States, these laws could affect our promotional activities by limiting the kinds of interactions we could have with hospitals, physicians or other potential purchasers or users of our system. Both the disclosure laws and gift bans will impose administrative, cost and compliance burdens on us.

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

In addition, to the extent we commence commercial operations overseas, we will be subject to the FCPA and other countries' anti-corruption/anti-bribery regimes, such as the U.K. Bribery Act. The FCPA prohibits improper payments or offers of payments to foreign governments and their officials for the purpose of obtaining or retaining business. Safeguards we implement to discourage improper payments or offers of payments by our employees, consultants, sales agents or distributors may be ineffective, and violations of the FCPA and similar laws may result in severe criminal or civil sanctions, or other liabilities or proceedings against us, any of which would likely harm our reputation, business, financial condition and result of operations.

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 system. As of January 22, 2013, we owned 12 issued patents in the United States and 9 patent applications in the United States, as well as 37 issued patents and 21 patent applications in foreign jurisdictions. We estimate that most of the currently issued U.S. patents will expire between approximately 2020 and 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 system. 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 system.

Intellectual property litigation could be costly and disruptive to us.

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

- stop clinical trials or delay or abandon commercialization of our system;
- 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 our system.

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 system 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 system 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.

Our system could infringe patent rights of others, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages or limit our ability to commercialize our system.

Our commercial success depends on our ability to develop, manufacture and market our system and technology without infringing the patents and other proprietary rights of third parties. As our industry expands and more patents are issued, the risk increases that there may be patents issued to third parties that relate to our system and technologies of which we are not aware or that we must challenge to continue our operations as currently contemplated. Our system may infringe or may be alleged to infringe these patents.

In addition, some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications or that we were the first to invent the

technology. Another party may have filed, and may in the future file, patent applications covering our system or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in our industry, we employ individuals who were previously employed at other medical device companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees, or we, have used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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.

Our common stock has been listed for trading on the Nasdaq Capital Market only since February 16, 2012 and has experienced limited trading volume. Our common stock has been listed on the ASX in the form of CDIs since 2004 and has also experienced limited trading volume on that exchange. The average daily trading volume in our common stock on the Nasdaq Capital Market for the three-month period ended December 31, 2012 was approximately 92,000 shares. The reported average daily trading volume in our common stock on the ASX for the three-month period ended December 31, 2012, was approximately 803,000 CDIs (equivalent to approximately 4,000 shares). There can be no assurance that an active public market for our shares will continue to develop in the United States. If an active trading market does not continue to develop in the United States, the market price and liquidity of shares purchased in this offering would be adversely affected.

The price of our common stock may fluctuate significantly.

Our common stock has been traded on the Nasdaq Capital Market since February 16, 2012 and on the ASX in the form of CDIs since 2004. The price of our common stock has been, and is likely to continue to be, volatile, which means that it could decline substantially within a short period of time. For example, the per share price of our common stock traded on the Nasdaq Capital Market ranged from $2.50 to $22.90 from February 16, 2012 to June 30, 2012, and from $3.01 to $13.30 for the period from July 1, 2012 to December 31, 2012. Our CDI closing price on the ASX ranged from A$0.020 (equivalent to approximately $4.09 per share using a conversion rate of A$1 to $1.0231) to A$0.055 (equivalent to approximately $11.25 per share using a conversion rate of A$1 to $1.0231) for the 6 months ended June 30, 2012, and from A$0.021 (equivalent to approximately $4.36 per share using a conversion rate of A$1 to $1.0386) to A$0.058 (equivalent to approximately $12.05 per share using a conversion rate of A$1 to $1.0386) for the period from July 1, 2012 to December 31, 2012. The price of our common stock could fluctuate significantly for many reasons, including the following:

- future announcements concerning us or our competitors;

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- regulatory developments, disclosure regarding completed, ongoing or future clinical trials and enforcement actions bearing on advertising, marketing or sales;
- reports and recommendations of analysts and whether or not we meet the milestones and metrics set forth in such reports;
- introduction of new products;
- acquisition or loss of significant manufacturers, distributors or suppliers or an inability to obtain sufficient quantities of materials needed to manufacture our system;
- quarterly variations in operating results, which we have experienced in the past and expect to experience in the future;
- business acquisitions or divestitures;
- changes in governmental or third-party reimbursement practices;
- purchases at below prevailing market prices by investors under our February 2012 securities purchase agreement pursuant to their 60-day purchase right;

- fluctuations of investor interest in the medical device sector; and

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

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

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

As of December 31, 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 December 31, 2012), approximately 37.5% of our outstanding common stock. Our executive officers, directors and affiliated entities, if acting together, would be able to control all matters requiring approval by our stockholders, including the election of directors and the approval of mergers, financings 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.

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Our ability to use U.S. net operating loss carryforwards or Australian tax losses might be limited.

As of December 31, 2011, we had U.S. net operating loss carryforwards of approximately $14.6 million for U.S. income tax purposes, which expire in 2023 through 2031. To the extent these net operating loss carryforwards are available, we intend to use them to reduce any corporate income tax liability associated with our operations we might have in the future. Section 382 of the U.S. Internal Revenue Code generally imposes an annual limitation on the amount of net operating loss carryforwards that might be used to offset taxable income when a corporation has undergone significant changes in stock ownership. As a result, prior or future changes in ownership could put limitations on the availability of our U.S. net operating loss carryforwards. In addition, our ability to utilize the current net operating loss carryforwards might be further limited by the issuance of common stock in this offering or future offerings.

As of December 31, 2011, we had tax losses in the Commonwealth of Australia of approximately $54.1 million. Continuing utilization of carry forward tax losses in Australia may also be affected by the issuance of our common stock in this offering and in the future. This is because one test for carrying forward tax losses in Australia from year to year requires continuity of ultimate ownership (subject to the relevant tests in the Australian tax law) of more than 50% between the loss year and the income year in which the loss is claimed.

To the extent our use of our net operating loss carryforwards or tax losses is limited, our income could be subject to corporate income tax earlier than it would if we were able to use net operating loss carryforwards, which could result in lower profits.

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 shares of our common stock on the Nasdaq Capital Market. 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 and could also lead to significant volatility in the price of our common stock.

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 will continue to incur increased costs as a result of being a U.S. reporting company and we have limited experience as a U.S. reporting company.

In connection with the effectiveness of our registration statement on Form 10, as of February 14, 2012, we became subject to the periodic reporting requirements of the Exchange Act. Although we have been listed on the ASX for several years and have been required to file financial information and make certain other filings with the ASX, our status as a U.S. reporting company under the Exchange Act has caused us to incur additional legal, accounting and other expenses that we did not previously incur, including costs related to compliance with the requirements of the Sarbanes-Oxley Act of 2002 and the listing requirements of the Nasdaq Capital Market. We expect these rules and regulations will continue to increase our legal and financial compliance costs and to make some activities more time-consuming and costly, and these activities may increase general and administrative expenses and divert management' s time and attention away from revenue-generating activities. 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.

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 material weaknesses in those controls.

In connection with becoming a company required to file reports with the SEC, we are required to comply with the internal control evaluation and certification requirements of Section 404 of the Sarbanes-Oxley Act of 2002. Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until the later of the year following our first annual report required to be filed with the SEC, or the date we are no longer an "emerging growth company" as defined in the JOBS Act or a "smaller reporting company" as defined by applicable SEC rules.

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 harmed, 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 material weaknesses in those controls.

Failure to maintain effective disclosure controls and procedures could result in the loss of investor confidence and an adverse impact on the price of our common stock.

In connection with preparing this prospectus, we discovered that compensation expenses arising from certain stock option grants were inadvertently omitted from the summary compensation table in amendment no. 1 to our Form 10-K for the fiscal year ended December 31, 2011, which we previously filed with the SEC. We corrected this omission promptly after discovering it by filing a second amendment to our Form 10-K. If we do not, or if investors perceive that we do not, establish and maintain adequate disclosure controls and procedures, investors could lose confidence in our reports filed with the SEC, which would harm the trading price of our common stock.

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 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. This could make it more difficult or impossible for investors to litigate or recover damages from our directors in securities litigation or other claims.

If we are not able to maintain sufficient cash funds, we may cease trading on the ASX.

If we are not able to maintain sufficient funds to fund our activities or if ASX considers that our financial position is not adequate to warrant the continued quotation of our CDIs on ASX, ASX may suspend our CDIs from quotation. This would limit our liquidity and, in particular, could harm the ability of CDI holders to liquidate their position in our company. In addition, the value of our company could decline if we are not able to maintain our listing on ASX.

We are an "emerging growth company," under federal securities laws and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the

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Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. The JOBS Act also permits emerging growth companies to take advantage of an extended transition period to comply with new or revised accounting standards applicable to U.S. public companies. We could be an emerging growth company for up to five years, although we could lose that status sooner if our revenues exceed $1 billion, if we issue more than $1 billion in non-convertible debt in a three-year period, or if the market value of our common stock held by non-affiliates exceeds $700 million as of any June 30 before that time, in which case we would no longer be an emerging growth company as of the following December 31. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and CDIs and our stock price may decline or be more volatile.

As explained above, Section 102(b)(1) of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. An "emerging growth company" can delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period, and as a result of this election, our financial statements may not be comparable to those of companies that comply with public company effective dates for new or revised accounting standards for U.S. public companies.

Our CDIs are traded on the ASX and we are subject to the Listing Rules of the ASX, which increase our operating costs and subject us to regulations not applicable to most other companies listed on the Nasdaq Capital Market.

Since 2004, CDIs representing beneficial ownership of our common stock have been traded on the ASX. We therefore are subject to the Listing Rules of the ASX, which regulate certain actions we can take, such as limiting the circumstances under which we may issue shares of our common stock or CDIs without stockholder approval and require us to disregard votes cast by certain stockholders potentially interested in matters to be voted on at annual or special meetings of stockholders when such stockholders are permitted to vote at the meeting in accordance with the General Corporation Law of Delaware and Nasdaq Listing Rules. Most other companies listed on the Nasdaq Capital Market are not subject to the additional regulatory requirements imposed by the ASX Listing Rules, which increase our operating costs relative to other Nasdaq-listed companies, may make it more difficult to effect certain corporate actions, and might make an investment in our common stock less attractive to potential purchasers.

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The number of shares of common stock which are registered, including the shares to be issued upon exercise of our outstanding warrants, is significant in relation to our currently outstanding common stock and could cause downward pressure on the market price for our common stock.

The number of shares of common stock registered for resale, including those shares which are to be issued upon exercise of our outstanding warrants, is significant in relation to the number of shares of common stock currently outstanding. If the security holder determines to sell a substantial number of shares into the market at any given time, there may not be sufficient demand in the market to purchase the shares without a decline in the market price for our common stock. Moreover, continuous sales into the market of a number of shares in excess of the typical trading volume for our common stock, or even the availability of such a large number of shares, could depress the trading market for our common stock over an extended period of time.

Risks Related to this Offering

Our management team will have broad discretion over the use of the net proceeds from sales made to Aspire Capital.

Our management will use its discretion to direct the net proceeds from sales made to Aspire Capital under the Purchase Agreement. We intend to use all of the net proceeds, together with cash on hand, for general corporate purposes. General corporate purposes may include working capital, capital expenditures, development costs, strategic investments or possible acquisitions. Our management' s judgments may not result in positive returns on your investment and you will not have an opportunity to evaluate the economic, financial or other information upon which our management bases its decisions.

The sale of our common stock to Aspire Capital may cause substantial dilution to our existing stockholders and the sale of the shares of common stock acquired by Aspire Capital could cause the price of our common stock to decline.

We are registering for sale the Commitment Shares that we have issued and an additional $25.0 million in shares that we may sell to Aspire Capital under the Purchase Agreement. It is anticipated that shares registered in this offering will be sold by Aspire Capital over a period of up to approximately 24 months from the date of this prospectus. Under the Purchase Agreement, we have the right, but not the obligation, to sell more than the 3,000,000 shares of common stock offered in this prospectus, if we obtain shareholder approval or an exception pursuant to the rules of the ASX is obtained to issue more than 13.99% (or, in the event we delist from ASX, 19.99%) to be in compliance with the applicable listing maintenance rules of the ASX or the Nasdaq Capital Market, as applicable. The limitation with respect to the Nasdaq Capital Market shall not apply if, at any time the Exchange Cap is reached and at all times thereafter, the average price paid for all shares issued and sold under the Purchase Agreement is equal to or greater than $6.10, the closing sale price of our common stock on January 14, 2013. We are not required or permitted to issue any shares of common stock under the Purchase Agreement if such issuance would breach our obligations under the rules or regulations of the Nasdaq Capital Market. In addition, we must register under the Securities Act the sale by Aspire Capital of any additional shares we may elect to sell to

Aspire Capital before we can put such additional shares to Aspire Capital under the Purchase Agreement. Further, the number of shares ultimately offered for sale by Aspire Capital under this prospectus is dependent upon the number of shares we elect to sell to Aspire Capital under the Purchase Agreement. Depending upon market liquidity at the time, sales of shares of our common stock under the Purchase Agreement may cause the trading price of our common stock to decline.

Aspire Capital may ultimately purchase all, some or none of the $25.0 million of common stock that, together with the Commitment Shares, is the subject of this prospectus. Aspire Capital may sell all, some or none of our shares that it holds or comes to hold under the Purchase Agreement. Sales by Aspire

Capital of shares acquired pursuant to the Purchase Agreement under the registration statement, of which this prospectus is a part, may result in dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock by Aspire Capital in this offering, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of sales of our shares to Aspire Capital, and the Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

The Securities and Exchange Commission encourages companies to disclose forward-looking information so that investors can better understand a company' s future prospects and make informed investment decisions. This prospectus contains such "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be made directly in this prospectus, and they may also be made a part of this prospectus by reference to other documents filed with the Securities and Exchange Commission, which is known as "incorporation by reference."

Words such as "may," "anticipate," "estimate," "expects," "projects," "intends," "plans," "believes" and words and terms of similar substance used in connection with any discussion of future operating or financial performance identify forward-looking statements. All forward-looking statements are management' s present expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Forward-looking statements might include one or more of the following:

- anticipated results of financing activities;
- anticipated agreements with marketing partners;
- anticipated clinical trial timelines or results;
- anticipated research and product development results;
- projected regulatory timelines;
- descriptions of plans or objectives of management for future operations, products or services;
- forecasts of future economic performance; and
- descriptions or assumptions underlying or relating to any of the above items.

Please also see the discussion of risks and uncertainties under the heading "Risk Factors" beginning on page 8.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this prospectus or in any document incorporated by reference might not occur. Investors are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this prospectus or the date of the document incorporated by reference in this prospectus. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise. All subsequent forward-looking statements attributable to Sunshine Heart or to any person acting on its

behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

USE OF PROCEEDS

The selling stockholder will receive all of the proceeds from the sale of the shares offered for sale by it under this prospectus. We will not receive proceeds from the sale of the shares by the selling stockholder. However, we may receive up to an aggregate of $25.0 million in proceeds from the sale of our common stock to the selling stockholder under the Purchase Agreement. We will bear all reasonable expenses incident to the registration of the shares of our common stock under federal and state securities laws other than expenses incident to the delivery of the shares to be sold by Aspire Capital. Any transfer taxes payable on these shares and any commissions and discounts payable to underwriters, agents, brokers or dealers will be paid by Aspire Capital.

Assuming the sale by us of all $25.0 million of shares of our common stock to Aspire Capital and estimated expenses of $1.0 million, the total net proceeds to us, would be $24.0 million, which we currently intend to use for general corporate purposes, including capital expenditures, the advancement of our drug candidates in clinical trials, and to meet working capital needs. The amounts and timing of the expenditures will depend on numerous factors, such as the timing and progress of our clinical trials and research and development efforts, technological advances and the competitive environment for our drug candidates. We expect from time to time to evaluate the acquisition of businesses, products and technologies for which a portion of the net proceeds may be used, although we currently are not planning or negotiating any such transactions. As of the date of this Prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to us from the sale of common stock to Aspire Capital. Accordingly, we will retain broad discretion over the use of these proceeds, if any.

MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

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

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

Period	High (A$)	Low (A$)	High (US$)	Low (US$)
ASX				

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
Nasdaq Capital Market				
First Quarter (from February 16, 2012)	n/a	n/a	22.90	8.50
Second Quarter	n/a	n/a	8.85	2.50
Third Quarter	n/a	n/a	13.30	3.01
Fourth Quarter	n/a	n/a	8.54	6.08

On January 25, 2013, we had approximately 24 registered holders of record of our common stock. On January 25, 2013, the closing sale price of our common stock as reported by NASDAQ was $5.89 per share.

DIVIDEND POLICY

We have never declared any cash dividends with respect to our common stock. Future payment of dividends is within the discretion of our board of directors and will depend on our earnings, capital requirements, financial condition and other relevant factors. Although there are no material restrictions limiting, or that are likely to limit, our ability to pay dividends on our common stock, we presently intend to retain future earnings, if any, for use in our business and have no present intention to pay cash dividends on our common stock.

DILUTION

If you acquire shares of our common stock from the selling stockholder in this offering, your ownership interest will be diluted to the extent of the difference between the public offering price per share of our common stock and the pro forma net tangible book value per share of our common stock after this offering. Our historical net tangible book value of common stock as of September 30, 2012 was $16.3 million, or $1.77 per share of common stock. Historical net tangible book value per share represents the amount of our total tangible assets less total liabilities, divided by the total number of shares of common stock outstanding.

After giving effect to (i) the issuance of the 80,257 Commitment Shares and (ii) the sale of an additional 2,919,743 shares of common stock at $1.00 per share, and after deducting estimated offering expenses payable by us, our pro forma net tangible book value as of September 30, 2012 would have been $19.1 million, or $1.56 per share of common stock. This represents an immediate decrease in pro forma net tangible book value of $(0.21) per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of $(0.56) per share to investors participating in this offering. The following table illustrates this per share dilution:

Assumed public offering price per share	$	1.00
Historical net tangible book value per share as of September 30, 2012	$	1.77
Decrease in net tangible book value per share attributable to this offering		(0.21)
Pro forma net tangible book value per share after this offering		1.56

Dilution per share to investors participating in this offering	$	(0.56)

The shares sold in this offering, if any, in addition to the Commitment Shares and the Initial Purchase Shares may be sold from time to time at various prices.

Each $0.25 increase in the per share price at which we sell shares to Aspire Capital under the Purchase Agreement from the assumed offering price of $1.00 per share would increase our pro forma net tangible book value by $0.73 million, our pro forma net tangible book value per share by $0.06 and dilution per share to new investors purchasing shares of common stock in this offering by $0.50, assuming that the number of shares of common stock offered, as set forth on the cover page of this

prospectus, remains the same and after deducting estimated aggregate offering expenses payable by us. This information is supplied for illustrative purposes only.

The table and calculations set forth above are based on the number of shares of common stock outstanding as of September 30, 2012 and assumes no exercise of any outstanding options or warrants. To the extent that options or warrants are exercised, there will be further dilution to new investors.

The above information excludes the following shares as of January 25, 2013:

- 792,475 shares of common stock authorized and reserved for future issuance under our equity incentive plans;
- 1,123,134 shares of common stock issuable upon exercise of outstanding stock options; and
- 1,663,253 shares of common stock issuable upon exercise of outstanding warrants.

MANAGEMENT' S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Cautionary Statement Regarding Forward-Looking Statements

This report contains certain statements that may be deemed 'forward-looking statements' within the meaning of United States securities laws. All statements, other than statements of historical fact, that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future are forward-looking statements. Such statements are based upon certain assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate. Certain factors that could cause results to differ materially from those projected or implied in the forward looking statements are set forth herein under the caption "Risk factors" section and elsewhere in this prospectus.

We encourage you to read those descriptions carefully. We caution you not to place undue reliance on the forward-looking statements contained in this report. These statements, like all statements in this report, speak only as of the date of this report (unless an earlier date is indicated) and we undertake no obligation to update or revise the statements except as required by law. Such forward-looking statements are not guarantees of future performance and actual results will likely differ, perhaps materially, from those suggested by such forward-looking statements.

Overview

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, or C-Pulse Heart 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. The C-Pulse Heart System 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.

We are in the process of pursuing regulatory approvals necessary to sell our system in the United States. We completed enrollment of our North American feasibility clinical trial in the first half of 2011. In November 2011, we announced the preliminary results of the six-month follow-up period for the feasibility

study and we submitted the clinical data to the United States Food and Drug Administration, or FDA. In March 2012, the FDA notified us that it completed its review of the C-Pulse System feasibility trial data, concluded we met the applicable agency requirements, and indicated that we can move forward with an investigational device exemption, or IDE, application. In November 2012, the FDA provided us with unconditional approval to initiate a pivotal trial. We currently anticipate that enrollment of our pivotal trial will begin during the first half of 2013.

We obtained CE Mark approval for the C-Pulse System in July 2012 and have taken initial steps to evaluate the market potential for our system in targeted countries that accept the CE Mark in anticipation of commencing commercial sales. In order to gain additional clinical data and support reimbursement in Europe, we also expect to initiate a post-market trial in Europe that will evaluate endpoints similar to those for our U.S. pivotal trial.

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 System is not approved for commercial sale in the United States. We currently have no revenue, but we anticipate that any revenue we generate will consist solely of sales of the C-Pulse System to hospitals and clinics pursuant to research arrangements and with appropriate regulatory approvals for sales in conjunction with our clinical trials. For clinical trial implant revenue, the product title generally transfers on the date the system is implanted. We do not charge hospitals and clinics for shipping. We expect to expense shipping costs at the time we report the related revenue and record these costs in cost of sales.

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

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

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

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

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

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

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

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

During the years ended December 31, 2011 and 2010 and through September 30, 2012, 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 our future efforts to raise capital 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 our C-Pulse System being developed. If we are unable to obtain such funding of an amount and on a timeline 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.

Accounting Standards Applicable to Emerging Growth Companies: We qualify as an "emerging growth company" pursuant to the provisions of the JOBS Act, enacted on April 5, 2012. Section 102(b)(1) of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. An "emerging growth company" can delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period, and as a result of this election, our financial statements may not be comparable to those of companies that comply with public company effective dates for new or revised accounting standards for U.S. public companies.

Internal Controls and Procedures

Our independent registered public accounting firm is not yet required to formally attest to the effectiveness of our internal control over financial reporting, and will not be required to do so for as long as we are an "emerging growth company" pursuant to the provisions of the JOBS Act.

Recent Accounting Pronouncements

In May 2011, the FASB issued an update to accounting guidance for improved fair value measurement and disclosures. The update represents converged guidance between U.S. GAAP and IFRS, resulting in common requirements for measuring fair value and for disclosing information about fair value measurements. This new guidance was effective for our fiscal year beginning January 1, 2012 and the

adoption of this guidance did not have an impact on our financial position, results of operations or cash flows.

In June 2011, the FASB issued amended disclosure requirements for the presentation of comprehensive income. The amended guidance eliminates the option to present components of other comprehensive income (***"OCI"***) as part of the statement of changes in equity. Under the amended guidance, all changes in OCI are to be presented either in a single continuous statement of comprehensive income or in two separate but consecutive financial statements. We adopted these changes effective January 1, 2012 and applied retrospectively for all periods. There was no impact to the consolidated results as the amendments related only to changes in financial statement presentation.

Recent Events

Stock Purchase Agreement

On January 15, 2013, we entered into a common stock purchase agreement with Aspire Capital Fund, LLC (***"Aspire"***). Under the terms of the Purchase Agreement, Aspire has committed to purchase up to $25.0 million of share purchases. In consideration for entering into the Purchase Agreement, concurrent with the execution of the Purchase Agreement, we issued to 80,257 shares of our common stock to Aspire for no consideration.

Financial Overview

We are an early-stage medical device company focused on developing, manufacturing and commercializing our C-Pulse 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, 2012, we had an accumulated deficit of $75.2 million and we expect to incur losses for the foreseeable future. To date, we have been funded by private and public equity financings. Although we believe that we will be able to successfully fund our operations, there can be no assurance that we will be able to do so or that we will ever operate profitably.

Results of Operations

Comparison of Three Months Ended September 30, 2012 to Three Months Ended September 30, 2011

Revenue

Three Months Ended September 30, 2012	Three Months Ended September 30, 2011	Increase (Decrease)	% Change
$ –	$ –	$ –	N/A

Sales of the C-Pulse Heart System to hospitals and clinics under contract in conjunction with our North American FDA clinical trials historically have generated all of our revenue. We did not have any sales of our C-Pulse Heart System device in the three month periods ended September 30, 2012 or 2011, as we completed enrollment in our feasibility trial in early 2011 and have not yet commenced enrollment in our pivotal clinical trial. We expect our revenue will be minimal until we begin enrolling patients in our North American pivotal clinical trial and initiate trials in select countries in Europe under our CE Mark, both expected to commence in the first half of 2013.

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Research and Development Expense

Three Months Ended September 30, 2012	Three Months Ended September 30, 2011	Increase (Decrease)	% Change
$ 1,802,000	$ 3,273,000	$ (1,471,000)	(44.9)%

Our decrease in research and development expense for the three months ended September 30, 2012 compared to the prior year' s period was primarily caused by the timing of certain outsourced development activities related to our C-Pulse Heart System period to period. We expect our research and development expense will sequentially increase as we add personnel to support our pivotal clinical trial and pursue our development efforts in the fourth quarter of 2012 and into 2013.

Selling, General and Administrative Expense

Three Months Ended September 30, 2012	Three Months Ended September 30, 2011	Increase (Decrease)	% Change
$ 1,495,000	$ 1,430,000	$ 65,000	4.5%

Our increase in selling, general and administrative expense for the three months ended September 30, 2012 compared to the prior year was primarily caused by increased professional fees and personnel additions in 2011 as we developed our infrastructure, and in preparation for European trials expected to commence in the first half of 2013. We expect our selling, general and administrative expense will continue to be above comparable prior year period levels in future periods as a result of the infrastructure recently put in place to support our growth.

Interest Income

Three Months Ended September 30, 2012	Three Months Ended September 30, 2011	Increase (Decrease)	% Change
$ 1,000	$ 31,000	$ (30,000)	(96.8)%

Our decrease in interest income for the three months ended September 30, 2012 compared to the prior year was primarily caused by the lower interest rates earned on cash balances maintained in the United States, where the majority of our cash was held in the current year period, compared to rates earned on cash balances maintained in Australia, where a large portion of our cash was held during the three months ended September 30, 2011.

Income Tax Benefit

Three Months Ended September 30, 2012	Three Months Ended September 30, 2011	Increase (Decrease)	% Change

$ –	$ –	$ –	N/A

Historically, our income tax benefits have resulted from research and development tax credit refunds in Australia and the state of Minnesota and are recognized upon receipt of the refund or determination that receipt of the refund is reasonably assured. Assuming no further changes to the applicable Australian or Minnesota law for research and development tax credits, we expect to receive tax refunds in the future in amounts that vary based on research and development expenditures in those jurisdictions. At this time, we are working to complete our analysis of the potential Australian research and development tax credit refund that may be available for the period ended June 30, 2012.

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Comparison of Nine Months Ended September 30, 2012 to Nine Months Ended September 30, 2011

Revenue

Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011	Increase (Decrease)	% Change
$ –	$ –	$ –	N/A

Sales of the C-Pulse Heart System to hospitals and clinics under contract in conjunction with our North American FDA clinical trials historically have generated all of our revenue. We did not have any sales of our C-Pulse Heart System device in the nine month periods ended September 30, 2012 or 2011, as we completed enrollment in our feasibility trial in early 2011 and have not yet commenced enrollment in our pivotal clinical trial.

Research and Development Expense

Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011	Increase (Decrease)	% Change
$ 5,755,000	$ 7,939,000	$ (2,184,000)	(27.5)%

Our decrease in research and development expense for the nine months ended September 30, 2012 compared to the prior year' s period was primarily caused by the timing of certain outsourced development activities related to our C-Pulse Heart System period to period.

Selling, General and Administrative Expense

Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011	Increase (Decrease)	% Change
$ 5,004,000	$ 3,250,000	$ 1,754,000	54.0%

Our increase in selling, general and administrative expense for the nine months ended September 30, 2012 compared to the prior year was primarily caused by increased stock-based compensation expense resulting from stock option grants in the second half of the prior year, and increased professional fees and personnel additions in 2011 as we developed our infrastructure and prepared for our Nasdaq listing, which was completed in February 2012, and in preparation for European trials expected to commence in the first half of 2013.

Interest Income

Nine Months Ended September 30, 2012		Nine Months Ended September 30, 2011		Increase (Decrease)		% Change
$	30,000	$	228,000	$	(198,000)	(86.8)%

Our decrease in interest income for the nine months ended September 30, 2012 compared to the prior year was primarily caused by lower average cash balances during the nine months ended September 30, 2012 as compared to the nine months ended September 30, 2011 and the lower interest rates earned on cash balances maintained in the United States, where the majority of our cash was held in the current year period, compared to rates earned on cash balances maintained in Australia, where a large portion of our cash was held during the nine months ended September 30, 2011.

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Income Tax Benefit

Nine Months Ended September 30, 2012		Nine Months Ended September 30, 2011		Increase (Decrease)		% Change
$	(730,000)	$	–	$	(730,000)	N/A

Our income tax benefit for nine months ended September 30, 2012 resulted from a research and development tax credit in Australia. We completed our Australian tax return for the twelve-month period ended June 30, 2011 in the second quarter of 2012 and received a $730,000 research and development tax credit refund during the second quarter of 2012.

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

Revenue

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

Our decrease in revenue for the year ended December 31, 2011 compared to the prior year was primarily caused by completion of enrollment in our feasibility clinical trial in March 2011, after which we had no reimbursable implants. Our revenue during the year ended December 31, 2010 consisted solely of sales of the C-Pulse System to hospitals and clinics pursuant to research arrangements and with appropriate regulatory approvals for sales in conjunction with our feasibility clinical trial.

Research and Development Expense

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

Our increase in research and development expense for the year ended December 31, 2011 compared to the prior year was primarily caused by increased development activities related to our C-Pulse System 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.

Selling, General and Administrative Expense

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

Our increase in selling, general and administrative expense for the year ended December 31, 2011 compared to the prior year was primarily caused by increased stock-based compensation expense resulting from 2011 stock option grants, and increased professional fees and personnel costs as we developed our infrastructure and prepared for our pivotal clinical and Nasdaq listing.

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Interest Income

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

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

Income Tax Benefit

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

Our tax income benefit for the year ended December 31, 2011 resulted from a research and development credit in the state of Minnesota for our tax year ended June 30, 2011. Our income tax benefit for the year ended December 31, 2010 resulted from a research and development tax credit in Australia. We completed our Australian tax return for the period ended June 30, 2011 in the second quarter of 2012 and received a $730,000 research and development tax credit refund during the quarter, which will be reported in our 2012 second quarter operating results. Assuming no further changes to the applicable Australian law for research and development tax credits, we expect to receive tax refunds in the future in amounts that vary based on research and development expenditures in Australia.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations primarily through a series of equity issuances, including the issuance of common shares for net proceeds of $20.6 million and $7.7 million in the nine months ended September 30, 2012 and 2011, respectively. As of September 30, 2012 and December 31, 2011, cash and cash equivalents were $17.4 million and $6.6 million, respectively.

We believe, based on our current operating plan, that the net proceeds from the sale of stock to Aspire Capital, if completed in its entirety, and our cash balances and cash generated from our clinical trials will be sufficient to meet our anticipated cash requirements for at least the next twelve months, but that we will require additional funding to complete our pivotal trial. From time to time we may seek to sell additional equity or convertible debt securities or enter into credit facilities. The sale of additional equity, debt, or convertible debt securities may result in dilution to our stockholders. If we raise additional funds through the issuance of debt, convertible debt or enter into credit facilities, these securities and debt holders could have rights senior to those of our common stock, and this debt could contain covenants that would restrict our operations and would require us to use cash for debt service rather than our operations. We may require additional capital beyond our currently forecasted amounts. Although we have successfully financed our operations through the issuance of common stock and warrants to date, any such required additional capital may not be available to us on acceptable terms, or at all.

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Cash Flows from Operating Activities

Net cash used in operating activities was $9.7 million in each of the nine months ended September 30, 2012 and 2011. The net cash used in each of these periods primarily reflects the net loss for those periods, offset in part by depreciation, amortization of warrants issued for services, 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 $132,000 and $34,000 in the nine months ended September 30, 2012 and 2011, respectively. The majority of cash used in investing activities in first nine months of 2012 and in 2011 was for leasehold improvements, furniture and equipment associated with the relocation of our headquarters.

Cash Flows from Financing Activities

Net cash provided by financing activities was $20.6 million and $7.7 million in the nine months ended September 30, 2012 and 2011, respectively. Net cash provided by financing activities was attributable to proceeds from sales of our common stock and warrants.

Capital Resource Requirements

As of September 30, 2012, we did not have any material commitments for capital expenditures.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

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BUSINESS

Overview

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

We are in the process of pursuing regulatory approvals necessary to sell our system in the United States. We completed enrollment of our North American feasibility clinical trial in the first half of 2011. In November 2011, we announced the preliminary results of the six-month follow-up period for the feasibility study and we submitted the clinical data to the FDA. In March 2012, the FDA notified us that it completed its review of the C-Pulse System feasibility trial data, concluded we met the applicable agency requirements, and indicated that we can move forward with an IDE application. In November 2012, the FDA provided us with unconditional approval to initiate a pivotal trial. We currently anticipate that enrollment of our pivotal trial will begin during the first half of 2013. We expect to complete enrollment of our pivotal trial by the end of 2015 and do not anticipate marketing our system in the United States before 2017.

We obtained CE Mark approval for the C-Pulse System in July 2012 and have taken initial steps to evaluate the market potential for our system in targeted countries that accept the CE Mark in anticipation of commencing commercial sales. In order to gain additional clinical data and support reimbursement in Europe, we also expect to initiate a post-market trial in Europe that will evaluate endpoints similar to those for our U.S. pivotal trial.

We incurred net losses of $16.2 million and $7.6 million in the years ended December 31, 2011 and 2010, respectively and $10.0 million in the nine months ended September 30, 2012. Historically, we have generated our revenue solely from sales of the C-Pulse System to hospitals and clinics pursuant to research arrangements and with appropriate regulatory approvals for sales in conjunction with our feasibility clinical trial. We expect to continue to incur significant net losses as we continue to conduct clinical trials, pursue commercialization and as we ramp up sales of our system.

Our Market Opportunity

Heart failure is a progressive disease caused by impairment of 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 United States and other developed countries. The American Heart Association estimates that 5.7 million people in the United States 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 health care 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 re-hospitalization in the United States. In 2013, as part of the Patient Protection and Affordable

Care Act enacted in 2010, hospitals will have to maintain less than 24.7% patient re-hospitalization rates at 30 days due to worsening heart failure or relinquish part of the reimbursements paid by CMS. We believe this law will encourage hospitals to look more closely at therapies like ours that could enable them to meet these initiatives.

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

- *Class I (Mild)*−Patients have no limits to daily activities; they are able to perform all normal daily activities without becoming tired, short of breath or having heart palpitations.

- *Class II (Mild)*−Patients have some limits to daily activities; they 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; they 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; they 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 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 United States fall into this classification range, and we believe approximately 3.7 million patients in Europe 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 United States consist primarily of pharmacological therapies and pacing devices that are designed to address heart rhythm issues. Although these treatments may provide symptomatic relief and prolong the life of patients, they do not often 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 United States, and one product received FDA approval in the United States for Class IIIb patients although the device is not reimbursed by CMS 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 products 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. The FDA recently rejected a proposed clinical trial that would evaluate the safety and performance of an LVAD technology for Class III heart failure patients because they did not believe the technology risks outweighed the potential rewards for these patients.

Our Strategy

Our goal is to become a market leader in the treatment of heart failure patients through the commercialization of our C-Pulse System, and to continue the development of the system to make it safer and more convenient for patients and physicians. We believe that our technology will provide us with a competitive advantage in the market for treating specific segments of heart failure patients. To achieve our objectives, we intend to:

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- **Conduct a Pivotal Trial in the United States**− We completed enrollment of the North American feasibility clinical trial in the first half of 2011. In November 2011, we obtained the preliminary results of the six-month follow-up period for our North American feasibility clinical trial. In March 2012, the FDA notified us that it completed its review of the C-Pulse System feasibility trial data, concluded we met the applicable agency requirements, and indicated that we can move forward with an IDE application. In November 2012, the FDA provided us with unconditional approval to initiate a pivotal trial. We currently anticipate that enrollment of our pivotal trial will begin during the first half of 2013. We expect to complete enrollment of our pivotal trial by the end of 2015.

- **Conduct Post-Market Trial in Europe to Support Reimbursement of the C-Pulse System** −We have retained consultants to analyze the conditions in various European countries for potential reimbursement for our system and the capabilities of existing hospitals and clinics to implant the C-Pulse System properly and understand the potential benefits of our system. We are targeting the leading LVAD/transplant centers to gain support, promote our technology, and conduct a non-randomized post-market trial that will evaluate endpoints similar to those for our U.S. pivotal trial to aid our reimbursement efforts and gain additional clinical data. We expect to be able to complete this trial in 2014 in our initial target markets.

- **Prepare for the Commercial Launch of the C-Pulse System in Europe**−We obtained CE Mark approval for the C-Pulse System in July 2012 and have taken initial steps to evaluate the market potential for our system in targeted countries in Europe in anticipation of commencing commercial sales. We initially plan to sell the C-Pulse System in Europe through experienced distributors in countries where our system is approved for reimbursement or where we otherwise believe there might be a potentially profitable market for our system. We expect our initial sales efforts in Europe will focus on Germany and Italy, which we believe are the largest potential markets for the C-Pulse System in Europe and have supported reimbursement for heart failure technologies in the past.

- **Continue to Enhance the C-Pulse System**−We believe it will be important to continue refining the C-Pulse System to make it more appealing for both patients and physicians. Since completing our 20 patient North American feasibility trial, we have made several improvements to the C-Pulse System based on the feasibility trial outcomes and feedback we received from surgeons and patients during the trial. These changes include enhancements to our driver, cuff, Percutaneous Interface Leads, or PIL, and our C-Patch, among others. We have also completed an initial animal study of a next-generation, fully-implantable C-Pulse System, which would eliminate the risk of exit-site infections.

Our System

The C-Pulse 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 sustain the patient’ s current condition, or, in some cases, reverse the heart failure process, thereby potentially preventing the need for later-stage heart failure devices, such as LVADs, artificial hearts or transplants. It may also provide relief from the symptoms of Class III and ambulatory Class IV heart failure and improve quality of life and cardiac function. Based on the patient results from our feasibility trial, we also believe that some patients treated with our C-Pulse System will be able to stop using the device due to sustained improvement in their conditions as a result of the therapy.

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 via the coronary arteries. Just before the heart pumps, the C-Pulse cuff deflates to reduce the heart’ s workload through pressure changes, 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 abdominal wall to connect to a power driver outside the body. The system’ s driver and battery source are contained inside a carrying bag.

Surgeons in the feasibility phase of our clinical trial initially implanted the C-Pulse System in patients via a full sternotomy. We have developed a procedure to allow the C-Pulse System to be implanted via a small pacemaker-like incision between the patient’ s ribs and sternum, rather than through a full sternotomy, and the first implant using this less invasive procedure was completed in 2010. Patients implanted via our minimally invasive procedure typically require a hospital stay of four to seven days in connection with implantation of the C-Pulse System, after which they return home. This compares to an average hospital stay of 14 days for patients implanted with the C-Pulse System via a full sternotomy. Further, final clinical data from two LVAD studies indicate median hospital stays of 19 and 25 days for patients implanted via a full sternotomy. Therefore, we believe this less invasive approach can reduce procedural time, hospital stays, overall cost and patient risk as compared to treatment options that require a full sternotomy.

The C-Pulse System distinguishes itself from other mechanical heart failure therapies in two important respects, which we believe differentiate our system from other products addressing moderate to severe heart failure patients:

- **The C-Pulse System is Placed Outside 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. Because it rests outside the vasculature, it also does not require blood thinning agents that are necessary for patients with devices that are in contact with the bloodstream. As with any implanted device, patients using our system have a risk of infection from the implantation procedure, and any untreated sternal infection arising from the implantation procedure or otherwise could result in erosion of the aortic wall or an aortic rupture in connection with using our system. Because our system has been implanted in a limited number of patients to date, the potential competitive disadvantages and risks associated with the use of our system are not fully known at this time.

- **The C-Pulse System Can be Safely Turned On or Off at Any Time.** The C-Pulse System does not need to be in constant operation for patients once implanted, and the device can be safely turned on or off at any time. This feature allows patients intervals of freedom to perform certain activities such as showering. Patients are not required to visit a medical facility when turning our device on or off or using the device. However, patients are advised to turn off the C-Pulse System only for short periods of time and for specified activities to maximize the benefit from the system. If the C-Pulse System is not used as directed, patients might experience a return of their heart failure symptoms, a loss of any improvement in their condition resulting from use of our system or an overall worsening of their heart failure symptoms compared to when they began using our system.

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Clinical Development

Our North American feasibility clinical trial was primarily designed to assess safety and provide indications of performance of the C-Pulse System in moderate to severe heart failure patients who suffer from symptoms such as shortness of breath and reduced mobility. In the first half of 2011, we completed enrollment and implantation of 20 patients in the trial and received FDA approval of an expansion protocol to allow us to implant up to 20 additional patients and add two centers to our feasibility study. We implanted three additional patients with the C-Pulse System since the original 20 patients, one in the U.S. and two in Canada. We currently do not have plans to implant any additional patients in the United States because the FDA has granted us full approval of the IDE pivotal trial.

System feasibility trial data, concluded we met the applicable agency requirements and indicated that we can move forward with an IDE application.

In November 2011, we announced the preliminary results of the six-month follow-up period for the feasibility study and we submitted the clinical data to the FDA. The table below summarizes results from the six-month follow-up data as well as the twelve-month data, which became available in June 2012. We also completed a two-year follow-up for a patient implanted with our system in July 2012.

Summary of Efficacy Measures

	All Patients Mean (Average) ± Standard Deviation (Range) (1)		
Parameter	**Change from Baseline(2) at 6 months Number of Patients=15 (3)**	**Change from Baseline(2) at 12 months Number of Patients=12 (4)**	**Significance**
Quality of Life(MLWHF score)(5)	-23.4 ± 19.0	-24.6 ± 16.5	**A reduction of seven points (-7) demonstrates material improvement in patient quality of life. Average patient results at 6 and 12 months were more than 3 times the reduction needed to show a material improvement in quality of life using the MLWHF standard.**
NYHA Class	-1.1 ± 0.7	-1.2 ± 0.8	**Material reduction to NYHA Class for most patients as indicated in footnote 6 below.**
Six Minute HallWalk (meters)	24.1 ± 62.6	46.8 ± 64.9	**On average, patients were able to walk an additional 24 meters during a 6-minute period 6 months after implantation compared to their pre-implantation ability. This improvement doubled from 6-12 months.**

(1) All event types and relationship to device have been adjudicated by the Clinical Events Committee (CEC). The numbers in the chart reflect the average change in patient results and the range of patient results for the particular parameter after C-Pulse System implant.

(2) Baseline reflects a patient' s result for the particular parameter prior to C-Pulse System implant.

(3) Patients at 6 months exclude 1 patient that received a heart transplant, 1 patient implanted with an LVAD, 1 patient death during surgery to treat a sternal infection, 1 patient death resulting from a non-device related drug allergic reaction, and 1 patient death for which the autopsy report notes "no definite anatomic cause of death" and for which the investigator stated the death was due to a respiratory, non-device related issue.

(4) Patient population at 12 months includes patients from 6-month follow-up, excluding 1 patient that received a heart transplant at day 212, 1 patient removed from the study at day 232 due to issues with the PIL that led physician to implant an LVAD, and 1 patient that was explanted due to a fall that resulted in damage to the PIL.

(5) Minnesota Living with Heart Failure Quality of Life (MLWHF) scores are 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.

(6) The table below summarizes the data from follow-up periods indicated for NYHA Class:

Follow-up Period	No Change	1 Class Reduction	2 Class Reduction	3 Class Reduction
6 months	3	7	5	0
12 months	2	7	2	1

Each decrease in NYHA Class represents an improvement to a patient' s heart failure symptoms or a reduction in the patient' s functional limitations. See page 44 for a summary of the NYHA classification system.

Summary of Safety Device Events at 6 and 12 Months (1)

	All Subjects (N=20)	
	6 months	12 months
Aortic Disruption (e.g., aortic rupture)(2)	1	1
Neurological Dysfunction (e.g., stroke)	0	0
Myocardial Infarction (heart attack)	0	0
Major Infection		
• Localized Non-Device Infection–PICC Line (3)	1	1
• Drive-Line Exit Site Infection	8	8
• Pocket Infection(4)	0	0
• Internal Pump Component, Inflow or Outflow Tract Infection Percutaneous Interface Lead (PIL) (Replaceable Portion of Drive-line)	1	1
• Sepsis(5)	0	0
Any Other Device-related AE Acute Renal Dysfunction (6)	1	1
Patients re-hospitalized due to worsening heart failure	1	3(7)

(1) All event types and relationship to device have been adjudicated by the Clinical Events Committee (CEC).

(2) Device-related adverse event of aortic disruption at time of re-do surgery for mediastinitis, which is swelling and irritation (inflammation) of the area between the lungs (mediastinum), usually caused by infection.

(3) A PICC line is a peripherally inserted central catheter, which is a long, slender, small, flexible tube. The PICC line is inserted into a peripheral vein, typically in the upper arm, and advanced until the catheter tip terminates in a large vein in the chest near the heart to obtain intravenous access. It is similar to other central lines, as it terminates into a large vessel near the heart.

(4) Pocket infection means an infection involving the subcutaneous (under the skin) pocket containing the device.

(5) Sepsis is a condition in which the body is fighting a severe infection that has spread via the bloodstream.

(6) Acute renal dysfunction is a rapid loss of kidney function. Computed tomography (CT) with contrast, which is used for the assessment of possible device infection resulted in acute renal dysfunction.

(7) The 2 patient increase from 6 months to 12 months were noncompliant due to approximately 20% driver usage. Patients participating in our feasibility trial were advised to keep the C-Pulse System on for at least 80% of each day. Our 12 month rehospitalization rate of 15% compares to a recent study control group rehospitalization rate of over 40% at 6 months (n=280), which included NYHA Class III patients who had been previously hospitalized for heart failure. We believe that this population is similar to the majority of patients profiled in our feasibility study and our planned IDE study with the exception of NYHA Class IV ambulatory.

We believe the results of the six-month and 12-month follow-up demonstrate the feasibility of the C-Pulse System implantation procedure and provide indications of safety and efficacy of the C-Pulse System in patients with moderate to severe heart failure necessary to proceed with a pivotal trial. In March 2012, the FDA notified us that it completed its review of the C-Pulse System feasibility trial data, concluded we met the applicable agency requirements, and indicated that we can move forward with an IDE application.

In November 2012, the FDA provided us with unconditional approval to initiate a pivotal trial. We currently anticipate that enrollment of the pivotal trial will begin in the first half of 2013, and we currently expect to complete our pivotal trial enrollment by the end of 2015.

Research and Development

Our research and development expense totaled $5.8 million for the nine months ended September 30, 2012, and $11.2 million and $6.2 million for the years ended December 31, 2011 and 2010, respectively. Research and development costs include activities related to research, development, design, testing and manufacturing of prototypes of our system as well as costs associated with certain clinical and regulatory activities.

Since completing our 20 patient North American feasibility trial, we have made several improvements to the C-Pulse System based on the patient outcomes and feedback we received from surgeons and patients during the trial. Some of these changes and enhancements to our C-Pulse System, all of which have been completed and can be utilized in our planned pivotal trial, include the following:

- Our next generation driver has been modified to be lighter, smaller, and quieter than our previous C-Pulse System driver. We expect the lighter and smaller C-Pulse System driver will be easier for patients to carry with them while they are receiving therapy, and we believe a quieter C-Pulse System will reduce the inconvenience for patients, and will encourage them to utilize the C-Pulse System at higher rates. This modified driver is already being used by three existing patients in Canada, and they have provided positive feedback to date.

- Our C-Pulse cuff has been enhanced so that the cuff is now designed with sutures already in place. We believe this pre-sutured cuff will allow surgeons to implant the C-Pulse System more quickly and easily via a minimally invasive procedure.

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- Our PIL, which connects the internal portion of the C-Pulse System with the external driver, has been redesigned to address some instances of PIL wear experienced in our feasibility trial. After enhanced testing performed on the updated PIL, we believe the more robust design will alleviate wear concerns in future implants, improving the safety and reliability of the C-Pulse System for patients. Three patients in the United States and Canada have been implanted with the modified PIL and we have experienced positive results to date.

- We have introduced a C-Patch mechanism to better secure the PIL at the site from which it exits the patient. Because the C-Pulse System allows patients to disconnect for certain activities, we believe the PIL exit site is more likely to become infected because of the PIL movement caused by patients disconnecting. The C-Patch was developed to reduce the PIL movement during the process of disconnecting the C-Pulse System, which we anticipate will help minimize future patient infections at the PIL exit site.

We also completed an initial animal study of a next-generation, fully implantable C-Pulse System in June 2011. 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 developments to our C-Pulse System, such as the development of a fully implantable system.

Sales and Marketing

To date, all of our sales of the C-Pulse System have been to U.S. hospitals and clinics pursuant to research arrangements and with appropriate regulatory approvals for sales in conjunction with our feasibility clinical trial. 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 system. Enrollment in our North American feasibility clinical trial was completed in the first half of 2011 and we did not generate any revenue from sales of our system during 2011. We expect to commence our U.S. pivotal clinical trial in the first half of 2013, which is projected to extend to the end of 2015. We do not expect to market our system in the United States before 2017.

We obtained CE Mark approval in July 2012 and intend to market our system in Europe in the second half of 2012. The degree and timing of any commencement or expansion of sales in Europe, however, cannot be predicted with certainty. We have retained consultants to analyze the conditions in various European countries for potential reimbursement for our system and the capabilities of existing hospitals and clinics to implant the C-Pulse System properly and understand the potential benefits of our system. We initially plan to sell our system in Germany and Italy, which we believe are currently the largest potential European markets for our system and have supported reimbursement for heart failure technologies in the past. We have not obtained approval for reimbursement in any European country. We initially plan to sell the C-Pulse System in Europe through experienced distributors. 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 regulatory approval and funding, the results of our pivotal clinical trials and the other factors described under "Risk Factors" and elsewhere in this prospectus.

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Manufacturers and Suppliers

The C-Pulse System is currently implanted only in connection with clinical trials. We outsource the manufacture of our system to suppliers with our activities directed toward supply chain management and distribution of our system 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 system do not require significant customization for use in our system 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 system, although we believe we could find alternative suppliers for each component of our system, other than the balloon, without materially interrupting production of our system at current levels. If the manufacturer of the balloon used in our system 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 System, all of our outsourced manufacturers will need to increase their production of our system or we will need to develop capabilities to manufacture the system ourselves.

Intellectual Property

We have established an intellectual property portfolio through which we seek to protect our system and technology. As of January 22, 2013, our portfolio consisted of 49 issued patents, of which 12 were issued in the United States and 37 were issued in other countries. We also had 30 patent applications pending, including 9 in the United States as of that date. Our patents and patent applications cover various aspects of both the methodology as well as the design of the C-Pulse 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 system infringes 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 "Risk Factors" section of this prospectus.

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 companies and medical device divisions of health care 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 ambulatory Class IV heart failure, and therefore we continue to expect new competitors both from the pharmacological and the medical device space. Among the other medical device competitors that treat or

may treat in the future Class III or ambulatory Class IV heart failure patients are AbioMed, Inc., Berlin Heart GmbH, CardioKinetix, Inc., CircuLite, Inc., HeartWare International Inc., Jarvik Heart, Inc., MicroMed Technology, Inc., SynCardia Systems, Inc., Terumo Heart, Inc. and Thoratec Corporation, as well as a range of other specialized medical device companies with devices at varying stages of development. Some of these competitors are larger than we are and have significantly greater financial resources and name recognition than we do. Our system has been implanted in a limited number of individuals to date and the efficacy and potential competitive disadvantages of the C-Pulse System are not fully known at this time.

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

- financial resources;
- product performance and design;
- product safety;
- acceptance of our system in the marketplace;
- sales, marketing and distribution capabilities;
- manufacturing and assembly costs;
- pricing of our system and of our competitors' products;
- the availability of reimbursement from government and private health insurers;
- success and timing of new product development and introductions;
- regulatory approvals in the United States; and
- intellectual property protection.

We believe the C-Pulse System' s lower risk profile resulting from its position outside a patient' s vascular system, the ability to temporarily disconnect the C-Pulse System without harm to the patient, and the minimally invasive manner in which the C-Pulse System can be implanted would help our system effectively compete in the markets where it is approved for sale.

Third-Party Reimbursement

If approved in the United States, the C-Pulse System is expected to be purchased primarily by customers, such as hospitals, who then would bill various third-party payors for the services provided to the patients. These payors, which include federal health care programs (*e.g.,* Medicare and Medicaid), state health care programs, 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 System 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. There can be no assurance, however, that fiscal intermediaries or Medicare Administrative Contractors will make payment.

We are analyzing the potential for third-party reimbursement in various European countries. Third-party reimbursement requirements vary from country to country in Europe and we are not approved for reimbursement in any European country at this time. Health care laws in the United States 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 health care is financed by both governmental and private insurers and may negatively impact payment rates for our system. 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 United States and international markets, we expect that both government and third-party payors will continue to attempt to contain or reduce the costs of health care by challenging the prices charged, or deny coverage, for health care products and services.

Government Regulations

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

Products must be manufactured in registered establishments and must be manufactured in accordance with Quality System Regulations, or QSR. Furthermore, the FDA may at any time inspect our facilities or the facilities of our suppliers to determine whether we or our suppliers comply with FDA regulations, including the QSR, which requires manufacturers to follow stringent design, testing, control,

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documentation and other quality assurance procedures during all aspects of the design and manufacturing process.

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

Health Care Regulation

Our business is subject to extensive federal and state government regulation. This includes the federal Anti-Kickback Statute and similar state anti-kickback laws, the federal False Claims Act and similar state false claims laws, and the Health Insurance Portability and Accountability Act of 1996, or HIPAA, the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, and similar state laws addressing privacy and security. Although we believe that our operations materially comply with the laws governing our industry, it is possible that non-compliance with existing laws or the adoption of new laws or interpretations of existing laws could adversely affect our financial performance.

Fraud and Abuse Laws

The health care industry is subject to extensive federal and state regulation. In particular, the federal Anti-Kickback Statute 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 health care 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. The Patient Protection and Affordable Care Act revises the evidentiary standard under the Anti-Kickback Statute and eliminates the requirement of actual knowledge, or specific intent, to commit a violation of the statute. This amendment to the Anti-Kickback Statute may improve the government' s ability to meet its evidentiary burden for establishing liability. The penalties for violating the Anti-Kickback Statute can be severe. These sanctions include criminal penalties and civil and administrative sanctions, including fines, imprisonment and possible administrative action for suspension or exclusion from the Medicare and Medicaid programs.

The Anti-Kickback Statute is broad, and it prohibits many arrangements and practices that are lawful in businesses outside of the health care industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the health care 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 health care providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. 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. Conduct and business arrangements that do not fully satisfy one of these safe harbor provisions may result in increased scrutiny or enforcement actions 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 Statute. Some of these state prohibitions apply to referral of patients for health care services reimbursed by any source, not only federal

health care 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 and administrative penalties or possible administrative action for suspension or exclusion from federal or state health care programs. Such penalties would adversely affect our financial performance and our ability to operate our business.

HIPAA created new federal statutes to prevent health care fraud and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care 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 health care benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment or administrative action for suspension 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 health care services. The federal government also has increased funding to fight health care 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 health care industry will continue to be subject to increased government scrutiny and investigations.

Federal False Claims Act

Another trend affecting the health care industry is the increased use of the federal False Claims Act and, in particular, actions under the False Claims Act' s "relator" or "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 health care providers by private individuals has increased dramatically. In addition, most states have enacted or are considering enacting laws modeled after the federal False Claims Act. Under the Deficit Reduction Act of 2005, states are being encouraged to adopt false claims acts similar to the federal False Claims Act, which establish liability for submission of fraudulent claims to the State Medicaid program and contain whistleblower provisions. Even in instances when a whistleblower action is dismissed with no judgment or settlement, we may incur substantial legal fees and other costs relating to an investigation. Future actions under the False Claims Act may result in significant fines and legal fees, which would adversely affect our financial performance and our ability to operate our business.

Further, the Fraud Enforcement and Recovery Act of 2009 expands the types of entities and conduct subject to the False Claims Act. We strive to ensure that we meet applicable regulatory requirements and guidance. 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 health care transactions and protecting the security and privacy of individually identifiable health information maintained or transmitted by health care providers, health plans and health care clearinghouses.

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

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

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

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

International Regulations

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

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

Anti-Corruption/Anti-Bribery Laws

To the extent we commence commercial operations overseas, we will be subject to the FCPA and other countries' anti-corruption/anti-bribery regimes, such as the U.K. Bribery Act. The FCPA prohibits improper payments or offers of payments to foreign governments and their officials for the purpose of obtaining or retaining business. Safeguards we implement to discourage improper payments or offers of payments by our employees, consultants, sales agents or distributors may be ineffective, and violations of the FCPA and similar laws may result in severe criminal or civil sanctions, or other liabilities or proceedings against us, any of which would likely harm our reputation, business, financial condition and result of operations.

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, 2012 we had 30 employees, consisting of 29 full-time and one part-time employee(s). None of our employees are covered by a collective bargaining agreement. We consider relations with our employees to be good.

Properties

We lease a 23,000 square foot facility located in Eden Prairie, Minnesota. The lease period commenced December 1, 2011 and extends through March 31, 2016. This facility serves as our corporate headquarters and houses substantially all of our functional areas. Monthly rent and electricity for our new headquarters total approximately $21,000.

Legal Proceedings

We are not currently involved in any material legal proceedings.

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Corporate information

Our corporate headquarters are located at 12988 Valley View Road, Eden Prairie, Minnesota 55344, and our telephone number is 952-345-4200.

MANAGEMENT AND CORPORATE GOVERNANCE

The Board of Directors

The following table sets forth certain information regarding our executive officers and directors as of December 31, 2012:

Name	Age	Position
David Rosa	48	Director; Chief Executive Officer
Kevin Bassett	45	Senior Vice President, Technology & Operations
Debra Kridner	60	Executive Vice President Clinical Research & Regulatory Affairs
Jim Yearick	50	Vice President Marketing & Sales

Jeffrey Mathiesen	52	Chief Financial Officer and Secretary
John Erb	63	Chairman of the Board, Director
Paul Buckman	57	Director
Dr. Geoffrey Brooke	57	Director
Donal O' Dwyer	59	Director
Dr. William Peters	47	Director; Chief Technical Officer & Medical Director
Gregory Waller	63	Director

Executive Officers

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

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

Debra Kridner: Ms. Kridner is our Executive Vice President of Clinical Research and Regulatory Affairs, a position she has held since October 2012. Prior to that time, Ms. Kridner was Vice President of Clinical Research and Regulatory Affairs from 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, Quality and Regulatory Affairs for St. Jude Medical' s Cardiac Surgery and Interventional Cardiology for the Cardiovascular Division.

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

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

Jim Yearick: Mr. Yearick has served as our Vice President of Marketing and Sales since September 2011. 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.

Board of Directors

Geoff Brooke: Director since September 2003. Dr. Brooke is managing director of GBS Venture Partners, an Australian venture capital firm that seeks out investments in life sciences companies. Dr. Brooke 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 the President and Chief Executive Officer of Sentreheart, Inc., a medical technology company focused on closure of various anatomic structures, since February 2012. Mr. Buckman served as Chief Executive Officer and Director of Pathway Medical Technologies, Inc., a medical device company focused on treatment of peripheral arterial disease from September 2008 to February 2012. From December 2006 until September 2008, Mr. Buckman served as Chief Executive Officer of Devax, Inc., a developer and manufacturer of drug eluting stents, while also serving as Chairman of the Board of Directors for Pathway Medical Technologies, Inc. From August 2004 to December 2006, Mr. Buckman served as President of the Cardiology Division of St. Jude Medical, Inc., a diversified medical products company. Prior to joining St. Jude Medical, Mr. Buckman served as Chairman of the Board of Directors and Chief Executive Officer of ev3, LLC, a Minnesota-based medical device company focused on endovascular therapies that Mr. Buckman founded and developed into an $80 million business, from January 2001 to January 2004. Mr. Buckman has worked in the medical device industry for over 30 years, including 10 years at Scimed Life Systems, Inc. and Boston Scientific Corporation, where he held several executive positions before becoming President of the Cardiology Division of Boston Scientific in January 2000. In addition to Pathway Medical Technologies, Inc., Mr. Buckman also currently serves as a Director for SentreHeart, Inc., Conventus Orthopaedics, Inc., 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.

John Erb: Mr. Erb, is currently chief executive officer of Cardia Access, Inc., a medical device company involved in developing new devices for the treatment of heart disease, a position he has held since

February 2007. During 2007, Mr. Erb served as executive chairman of the board of CHF Solutions, Inc., a medical device company involved in the development, manufacturing and distribution of devices to treat congestive heart failure. From 2001 through 2006, Mr. Erb was chief executive officer of CHF Solutions, Inc. Mr. Erb was president and chief executive officer of IntraTherapeutics, Inc., a medical device company involved in the development, manufacturing and distribution of peripheral vascular stents from 1997 through 2001. Previously, Mr. Erb was vice president of worldwide operations for Schneider Worldwide, a division of Pfizer, Inc. Mr. Erb served as a director of SenoRx, Inc., a publicly-traded company, from December 2001 until July 2010, and also served as a director of CryoCath Technologies Inc., a publicly-traded Canadian company, from October 2000 through December 2008. Mr. Erb currently serves as a director of several private companies, as well as Osprey Medical, Inc., which is listed on the Australian Securities Exchange, and Vascular Solutions, Inc., a Nasdaq listed company, for which he has served on the board since 2002. Mr. Erb serves as a director of VivoMetrics, Inc., a privately held company, which filed a petition under Chapter 11 of the bankruptcy code in 2010.

With over 30 years of experience in the medical device industry, including 14 years of experience serving as chief executive officer of medical device companies, Mr. Erb brings to our board valuable business, management and leadership experience and a deep understanding of the challenges presented in growing a medical device company. In addition, his role on the boards of Vascular Solutions, SenoRx and CryoCath Technologies has provided him with other public company board experience. Through his position managing significant operations of a multi-national medical device company, Mr. Erb also brings to the board valuable private company operational experience.

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 health care 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.

William Peters: Director since August 2002. Dr. Peters has served as our Chief Technical Officer and Medical Director since 2002. 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.

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

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

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

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.

Board Composition

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 III directors are Messrs. O' Dwyer, Erb and Waller and their terms expire at this year' s annual meeting of stockholders;

- The Class I directors are Dr. Peters and Mr. Buckman and their terms expire at the annual meeting of stockholders to be held in 2014, and

- The Class II directors are Dr. Brooke and Mr. Rosa and their terms expire at the annual meeting of stockholders to be held in 2015.

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.

Director Independence

Our board of directors currently consists of eight directors. Our board of directors has determined that five of our seven directors are independent directors, as defined under the applicable rules of the Nasdaq Stock Market. The independent directors are Messrs. Buckman, Brooke, O' Dwyer, Erb, and Waller.

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

Board Committees

The board of directors has established an audit committee, a compensation committee and a governance and nominating committee. Each of our committees has a charter and each charter is posted on our website. The following sets forth the membership of each of our committees.

Director	Audit Committee	Compensation Committee	Governance and Nominating Committee
Geoffrey Brooke		X	
Paul Buckman		Chair	X
John Erb	X	X	X
Donal O' Dwyer	X		
Gregory Waller	Chair		Chair

Audit Committee

Among other matters, our audit committee:

- evaluates the qualifications, performance and independence of our independent auditor and reviews and approves both audit and nonaudit services to be provided by the independent auditor;
- discusses with management and our independent auditors any major issues as to the adequacy of our internal controls, any actions to be taken in light of significant or material control deficiencies and the adequacy of disclosures about changes in internal control over financial reporting;
- establishes procedures for the receipt, retention and treatment of complaints regarding accounting, internal accounting controls or auditing matters, including the confidential, anonymous submission by employees of concerns regarding accounting or auditing matters;
- administers our investment and cash management policies; and
- prepares the audit committee report that SEC rules require to be included in our annual proxy statement and annual report on Form 10-K.

Each of the members of our audit committee meets the requirements for financial literacy under the applicable rules and regulations of the SEC and the Nasdaq Stock Market. Our board of directors has determined that Mr. Waller is our audit committee financial expert, as defined under the applicable rules of the SEC. Each member of our audit committee satisfies the Nasdaq Stock Market independence standards and the independence standards of Rule 10A-3(b)(1) of the Exchange Act.

Compensation Committee

Our compensation committee reviews and approves on an annual basis the goals and objectives relevant to our Chief Executive Officer' s compensation and annually reviews the evaluation of the performance of our executive officers and approves our executive officers' annual compensation.

Governance and Nominating Committee

Our governance and nominating committee identifies individuals qualified to become members of the board of directors, recommends individuals to the board for nomination as members of the board and board committees, and oversees the evaluation of our board of directors.

Code of Conduct

We have adopted a Code of Business Conduct and Ethics relating to the conduct of our business by our directors, officers and employees, which is posted on our website at *www.sunshineheart.com/corporate-governance.*

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. Historically, our fiscal years 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 to 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.

Name	Fiscal Year Ended	Fees Earned or Paid in Cash ($)	Option Awards ($) (1)	Total ($)
Geoffrey Brooke (2)	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(3)	12/31/11	51,375	125,939	177,314
	6/30/11	103,234	–	103,234
Dr. Mark Harvey (4)	12/31/11	12,649	76,887	89,536
	6/30/11	–	–	–
Crispin Marsh (5)	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 (6)	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 included in this prospectus.

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(2) Dr. Brooke is required to transfer the compensation he receives for service on our board of directors to venture capital funds affiliated with GBS Venture Partners.

(3) Mr. Callinan resigned from the Board on December 31, 2012.

(4) Dr. Harvey became a director of our company in September 2011 and resigned from the Board on November 12, 2012.

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

(5) 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 ($255,775 based on a conversion rate of A$1 to $1.0231) 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 equal 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 Australian 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.

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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, 9,100 of which were unvested;
- Mr. Buckman−11,685 shares, 9,494 of which were unvested;
- Mr. Callinan−29,205 shares, 15,604 of which were unvested;
- Dr. Harvey−11,685 shares, 11,189 of which were unvested;

- Mr. Marsh−16,734 shares, 9,100 of which were unvested;
- Mr. O' Dwyer−11,685 shares, 9,100 of which were unvested; and
- Mr. Waller−11,685 shares, 10,711 of which were unvested.

Executive Compensation

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.

SUMMARY COMPENSATION TABLE

Name and Principal Position	Fiscal Year Ended	Salary ($)	Option Awards ($) (1)	Non-Equity Incentive Plan Compensation ($) (2)	Total ($)
David Rosa	12/31/11	156,550	1,473,358	79,825	1,709,773
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	377,666	44,000	528,333
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 included in this prospectus.

(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. The 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 amount shown for the fiscal year ended June 30, 2011 was 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 system, 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 employees based in Australia and New Zealand, 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 United States 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 and 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 system 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 system, 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 and 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 his 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 approximately $7.16 (using a conversion rate of A$1.00 to $1.0231 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 approximately $13.10 (using a conversion rate of A$1.00 to $1.0231 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 stockholders in November 2011, our stockholders approved a stock option award to Mr. Rosa approved by our board 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 approximately $8.39 (using a conversion rate of A$1.00 to $1.0231 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 below, as of December 31, 2012, Mr. Rosa beneficially owned approximately 1.6% 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 employees based in Australia and New Zealand, 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 employees based in Australia and New Zealand 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 system and meeting our business plan. As of January 1, 2012, salaries

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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 system 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 at Fiscal Year End

The following table sets forth certain information concerning equity awards held by our named executive officers that were outstanding as of December 31, 2011.

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	Option Awards			
Name	**Number of Securities Underlying Unexercised**	**Number of Securities Underlying Unexercised**	**Option Exercise Price ($) (1)**	**Option Expiration Date**

	Options(#) Exercisable	Options(#) Unexercisable		
David Rosa	37,500(2)	12,500	$ 10.23	11/29/20
	28,960(3)	125,490	$ 7.16	8/17/21
	−(5)	29,210	$ 13.10	8/17/21
	−(5)	43,000	$ 8.39	11/28/21
William Peters, MD	3,990(4)	−	$ 3.17	1/30/13
	3,880(4)	−	$ 51.16	7/5/14
	2,200(4)	−	$ 36.83	11/1/16
	280(4)	−	$ 61.39	1/31/17
	3,000(4)	−	$ 61.39	4/18/17
	488(4)	−	$ 40.92	7/9/18
	3,249(5)	1,477	$ 16.37	8/20/18
	15,140(3)	65,605	$ 7.16	8/17/21
Jeffrey Mathiesen	−(5)	52,575	$ 7.16	8/17/21
	−(5)	5,000	$ 8.39	11/1/21

(1) Amount converted from Australian Dollars to U.S. Dollars using a conversion rate of A$1.00 to $1.0231.

(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 health care 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 health care 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.

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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 the "Certain Relationships and Related Party Transactions" section 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.

CERTAIN RELATIONSHIPS AND RELATED-PARTY TRANSACTIONS

We give careful attention to related person transactions because they may present the potential for conflicts of interest. We refer to "related person transactions" as those transactions, arrangements, or relationships in which:

- we were, are or are to be a participant;

- the amount involved exceeds $120,000; and
- any of our Directors, Director nominees, executive officers or greater-than five percent stockholders (or any of their immediate family members) had or will have a direct or indirect material interest.

To identify related person transactions in advance, we rely on information supplied by our executive officers, Directors and certain significant stockholders. We maintain a comprehensive written policy for the review, approval or ratification of related person transactions, and our Audit Committee reviews all related person transactions identified by us. The Audit Committee approves or ratifies only those related person transactions that are determined by it to be, under all of the circumstances, in the best interest of our company and its stockholders.

Since July 1, 2009, we have entered into the following transactions with our directors, executive officers, holders of more than 5% 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 and warrants to purchase shares of our common stock to Jeffrey Mathiesen, our Chief Financial Officer, at the price of A$8.00 per unit as part of a private placement.

In September 2011, we sold 125,000 shares of our common stock and warrants to purchase shares of our common stock to funds affiliated with CM Capital at the price of A$8.00 per unit as part of a private placement. Funds affiliated with CM Capital beneficially own more than 5% of our common stock and Dr. Mark Harvey, one of our directors, is a partner of CM Capital.

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.

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SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT (2)

The following table sets forth certain information with respect to the beneficial ownership of our outstanding common stock as of December 31, 2012 by (i) each of our named executive officers; (ii) each of our directors; (iii) all of our executive officers and directors as a group; and (iv) each of those known by us to be beneficial owners of more than 5% of our common stock. This table lists applicable percentage ownership based on 9,282,724 shares of common stock outstanding as of that date.

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 table below includes the number of shares underlying options which are exercisable within 60 days from the date of this offering. Except as otherwise noted below, the address for each person or entity listed in the table is c/o Sunshine Heart, Inc., 12988 Valley View Road, Eden Prairie, Minnesota 55344.

Name of Beneficial Owner	Number of Shares	Percent(1)
Executive Officers and Directors:		
Dr. Geoffrey Brooke	1,449,523(2)	15.2%
Paul Buckman	5,599(3)	*
Jeffrey Mathiesen	45,443(4)	*
Donal O' Dwyer	64,849(5)	*
Dr. William Peters	99,244(6)	1.1%
David Rosa	151,224(7)	1.6%
Gregory Waller	4,382(8)	*
All directors, director nominees, named executive officers and other executive officers as a group (12 persons)	3,818,632(9)	37.5%
5% Stockholders:		
GBS Venture Partners Pty Ltd	1,443,671(10)	15.1%
Funds affiliated with CM Capital	1,877,498(11)	19.4%
Persons affiliated with Straus & Partners	653,057(12)	6.0%

* Less than 1%.

(1) Based on 9,282,724 shares outstanding as of December 31, 2012.

(2) Includes 1,194,761 shares owned by GBS Bioventures II A/C and GBS Bioventures III A/C, which we collectively refer to as GBS; 5,852 shares subject to outstanding options exercisable within 60 days of December 31, 2012; and 248,910 shares subject to outstanding warrants held by GBS exercisable within 60 days of December 31, 2012. Dr. Brooke is a managing director of GBS Venture Partners Pty Ltd which manages GBS Bioventures II/AC and GBS Bioventures III/AC. Dr. Brooke shares voting and investment power with another partner and may be deemed to be an indirect beneficial owner of the reported securities. Dr. Brooke disclaims beneficial ownership of the reported securities except to the extent of his pecuniary interest. This report shall not be deemed an admission that the reporting person is the beneficial owner of such securities for purposes of Section 16 or for any other purpose.

(3) Includes 5,599 shares subject to outstanding options exercisable within 60 days of December 31, 2012.

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(4) Includes 11,875 shares held by UBS which is Mr. Mathiesen' s IRA account and 2,500 shares owned by Mr. Mathiesen and his wife jointly. Includes 26,755 shares subject to outstanding options exercisable within 60 days of December 31, 2012; and 4,313 shares acquirable on exercise of outstanding warrants exercisable within 60 days of December 31, 2012.

(5) Includes 10,370 shares held by a family trust, for which Mr. O' Dwyer and his wife serve as a trustees, 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 686 shares owned by Mr. O' Dwyer. Includes 5,852 shares subject to outstanding options exercisable within 60 days of December 31, 2012; and 9,150 shares acquirable on exercise of outstanding warrants exercisable within 60 days of December 31, 2012.

(6) Includes 7,250 shares owned by Dr. William Peters and Szigetvary Trustee Services Ltd as trustees to Peters JAM Trust; 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 shares owned by Dr. William Peters for the benefit of James Peters; 33,433 shares owned by Dr. William Peters and Apollo Trustees No. 1 Limited as trustees to Peters Apollo Trust; 3,990 shares owned by Dr. William Peters; 52,407 shares acquirable upon exercise of outstanding warrants exercisable within 60 days of December 31, 2012; and 2,041 shares subject to outstanding options exercisable within 60 days of December 31, 2012.

(7) Includes 1,000 shares owned by Mr. Rosa, and 150,224 shares subject to outstanding options exercisable within 60 days of December 31, 2012.

(8) Includes 4,382 shares subject to outstanding options exercisable within 60 days of December 31, 2012.

(9) Consists of (i) 2,837,877 shares beneficially owned by the current directors and executive officers; and (ii) 980,755 shares issuable upon exercise of outstanding options or warrants that are exercisable within 60 days of December 31, 2012.

(10) Based upon Form 3 filed with the SEC on February 28, 2012. Includes 1,194,761 shares beneficially owned by GBS Venture Partners Pty Ltd affiliates, and includes 248,910 shares acquirable upon exercise of outstanding warrants exercisable within 60 days of December 31, 2012. Dr. Geoffrey 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.

(11) Based upon Form 3/A filed with the SEC on May 10, 2012. Includes 1,500,712 shares beneficially owned by CM Capital Investments Pty Ltd affiliates, and includes 376,786 shares acquirable upon exercise of outstanding warrants exercisable within 60 days of December 31, 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.

(12) Based upon Schedule 13G filed with the SEC on February 23, 2012. The address for the filing person is 767 Third Avenue, 21st Floor, New York, NY 10017. Straus Asset Management, L.L.C. reported shared voting and shared investment power with respect to 653,057 shares of our common stock. Straus Healthcare Partners, L.P. reported shared voting and shared investment power with respect to 367,154 shares of our common stock. Melville Straus reported shared voting and shared investment power with respect to 653,057 shares of our common stock.

SELLING STOCKHOLDER

The following table presents information regarding the selling stockholder as of January 25, 2013. Neither the selling stockholder nor any of its affiliates has held a position or office, or had any other material relationship, with us.

No estimate can be given as to the amount or percentage of our common stock that will be held by the selling stockholder after any sales or other dispositions made pursuant to this Prospectus because the selling stockholder is not required to sell any of the shares being registered under this Prospectus. The table above assumes that the selling stockholder will sell all of the shares listed in this Prospectus.

The information is based in part on information provided by or on behalf of the selling stockholder.

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Selling Stockholder	Shares Beneficially Owned Before Offering(1)	Percentage of Outstanding Shares Beneficially Owned Before Offering(1)	Shares to be Sold in the Offering	Shares Beneficially Owned After Offering	Percentage of Outstanding Shares Beneficially Owned After Offering
Aspire Capital(2)	80,257(3)	*	3,000,000	0	0%

(1) Beneficial ownership is determined in accordance with the rules and regulations of the SEC. In general, a person is deemed to be the beneficial owner of (i) any shares of our common stock over which such person has sole or shared voting power or investment power, plus (ii) any shares which such person has the right to acquire beneficial ownership of within 60 days, whether through the exercise of options, warrants or otherwise.

(2) Steven G. Martin, Erik J. Brown and Christos Komissopoulos, the principals of Aspire Capital, are deemed to be beneficial owners of all of the shares of common stock owned by Aspire Capital. Messrs. Martin, Brown and Komissopoulos have shared voting and investment power over the shares being offered under the prospectus filed with the SEC in connection with the transactions contemplated under the Purchase Agreement. Aspire Capital is not a licensed broker dealer or an affiliate of a licensed broker dealer.

(3) As of the date hereof, 80,257 shares of our common stock have been acquired by Aspire Capital under the Purchase Agreement, consisting of the Commitment Shares. Pursuant to the terms of the Purchase Agreement, Aspire Capital has agreed to an initial purchase of $1.0 million of our shares of common stock upon Commencement. Thereafter, the Company may elect in its sole discretion to sell to Aspire Capital up to an additional number of shares under the Purchase Agreement equal to $24.0 million in value, but Aspire Capital does not presently beneficially own these shares as determined in accordance with the rules of the SEC.

* Less than 1%

THE ASPIRE CAPITAL TRANSACTION

General

On January 15, 2013, we entered into the Purchase Agreement, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $25.0 million of shares of our common stock over the 24-month term of the Purchase Agreement. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital the Commitment Shares. Concurrently with entering into the Purchase Agreement, we also entered into the Registration Rights Agreement, in which we agreed to file one or more registration statements, as permissible and necessary to register under the Securities Act, the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the Purchase Agreement.

As of January 15, 2013, there were 9,362,981 shares of our common stock outstanding (6,525,104 shares held by non-affiliates) excluding the 2,919,743 shares offered that may be issuable to Aspire Capital pursuant to the Purchase Agreement. If all of the 3,000,000 shares of our common stock offered hereby were issued and outstanding as of January 15, 2013, such shares would represent 24% of the total common stock outstanding, or 32% of the non-affiliate shares of common stock outstanding as of January 15, 2013. The number of shares of our common stock ultimately offered for sale by Aspire Capital is dependent upon the number of shares purchased by Aspire Capital under the Purchase Agreement.

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we are registering under the Securities Act 3,000,000 shares of our common stock, which includes the Commitment Shares and an additional 2,919,743 shares of common stock that we may issue to Aspire Capital after the registration statement of which this prospectus is a part is declared effective under the Securities Act. All 3,000,000 shares of common stock are being offered pursuant to this prospectus.

Under the Purchase Agreement, we have the right, but not the obligation, to sell more than the 3,000,000 shares of common stock offered in this prospectus. The Purchase Agreement provides that the number of shares that may be sold pursuant to the Purchase Agreement shall be limited to 1,298,653 (the ***"Exchange Cap"***), which represents 13.99% of our outstanding shares as of December 14, 2012, to be in compliance with the applicable listing maintenance rules of the ASX. If at any time during the term of the Purchase Agreement, our securities cease to be listed on the ASX, the Exchange Cap will be reset to 1,856,616 shares, or 19.99% of our outstanding stock as of the date of the Purchase Agreement, to be in compliance with the applicable maintenance rules of the Nasdaq Capital Market. The Nasdaq limitation shall not apply if, at any time the Exchange Cap is reached and at all times thereafter, the average price paid for all shares issued and sold under the Purchase Agreement is equal to or greater than $6.10, the closing sale price of our common stock on January 14, 2013. We are not required or permitted to issue any shares of common stock under the Purchase Agreement if such issuance would breach our obligations under the rules or regulations of the ASX or the Nasdaq Capital Market.

After the SEC has declared effective the registration statement of which this prospectus is a part, Aspire Capital will make an initial purchase of $1.0 million (the "***Initial Purchase"***) of an amount of our common stock equal to $1.0 million divided by the average closing share price for the five consecutive trading days preceding the Commencement Date (as defined in the Purchase Agreement). Thereafter, we have the right, in our sole discretion, to present Aspire Capital with a Purchase Notice, directing Aspire Capital (as principal) to purchase up to 50,000 shares of our common stock per business day, up to an additional $24.0 million of our common stock in the aggregate at a Purchase Price calculated by reference to the prevailing market price of our common stock over a preceding 12-business day period (as more specifically described below); however, no sale pursuant to a Purchase Notice may exceed $1,000,000 per trading day.

In addition, on any date on which we submit a Purchase Notice to Aspire Capital in an amount equal to 50,000 shares, we also have the right, in our sole discretion, to present Aspire Capital with a VWAP Purchase Notice directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company' s common stock traded on The Nasdaq Capital Market on the next trading day, subject to the VWAP Purchase Share Volume Maximum and the VWAP Minimum Price Threshold. The VWAP Purchase Price is calculated by reference to the prevailing market price of our common stock (as more specifically described below).

The Purchase Agreement provides that in no event will any shares of common stock be sold at a Purchase Price less than $1.00, or the Floor Price, unless and until such time as the stockholders of the Company approve the transaction contemplated by the Purchase Agreement. This Floor Price and the respective prices and share numbers in the preceding paragraphs shall be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction. Additionally, the Purchase Agreement provides that the Company and Aspire Capital shall not effect any sales under the Purchase Agreement if such shares proposed to be issued and sold, when aggregated with all other shares of the Company' s common stock that Aspire Capital and its affiliates beneficially own, would result in Aspire Capital and its affiliates beneficially owning more than the Exchange Cap.

There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Aspire Capital. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as we direct in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us. The rights and obligations of Aspire Capital under the Purchase Agreement are not assignable or transferable.

Purchase of Shares under the Purchase Agreement

Under the Purchase Agreement, on any trading day selected by us on which the closing price of our common stock is not less than $1.00 per share, we may direct Aspire Capital to purchase up to 50,000 shares of our common stock per trading day so long as no sale pursuant to such Purchase Notice may exceed $1,000,000 per trading day. The Purchase Price of such shares is equal to the lesser of:

- the lowest sale price of our common stock on the Nasdaq Capital Market on the purchase date; or
- the arithmetic average of the three lowest closing sale prices for our common stock on the Nasdaq Capital Market during the twelve consecutive trading days ending on the trading day immediately preceding the purchase date.

In addition, on any date on which we submit a Purchase Notice to Aspire Capital in an amount equal to 50,000 shares we also have the right to direct Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company' s common stock traded on the Nasdaq Capital Market on the next trading day, subject to the VWAP Purchase Share Volume Maximum and the VWAP Minimum Price Threshold, which is equal to the greater of (a) 90% of the closing price on the Nasdaq Capital Market on the business day immediately preceding the VWAP Purchase Date or (b) such higher price as set forth by the Company in the VWAP Purchase Notice. The VWAP Purchase Price of such shares is the lower of:

(a) The closing sale price on the VWAP Purchase Date; or

(b) 95% of the volume-weighted average price for our common stock traded on the Nasdaq Capital Market during normal trading hours:

- on the VWAP Purchase Date, if the aggregate shares traded on the Nasdaq Capital Market have not exceeded the VWAP Purchase Share Volume Maximum; or
- the portion of the VWAP Purchase Date until such time as the sooner to occur of (i) the time at which the aggregate shares traded on the Nasdaq Capital Market has exceeded the VWAP Purchase Share Volume Maximum or (ii) the time at which the sale price of the common stock falls below the VWAP Minimum Price Threshold.

The Purchase Price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction occurring during the period(s) used to compute the Purchase Price. We may deliver multiple Purchase Notices and VWAP Purchase Notices to Aspire Capital from time to time during the term of the Purchase Agreement, so long as the most recent purchase has been completed.

Minimum Share Price

Under the Purchase Agreement, the Company and Aspire Capital may not effect any sales of shares of our common stock on any trading day that the closing sale price of our common stock is less than $1.00 per share.

Compliance with ASX Rules and The Nasdaq Capital Market Price

The Purchase Agreement provides that the number of shares that may be sold pursuant to the Purchase Agreement shall be limited to 1,298,653, the Exchange Cap, which represents 13.99% of our outstanding shares as of January 15, 2013, unless shareholder approval or an exception pursuant to the rules of the ASX is obtained to issue more than 13.99%, to be in compliance with the applicable listing maintenance rules of the ASX. If at any time during the term of the Purchase Agreement our securities cease to be listed on the ASX, the Exchange Cap will be reset to 1,856,616 shares, or 19.99% of our outstanding stock as of the date of the Purchase Agreement, to be in compliance with the applicable maintenance rules of the Nasdaq Capital Market. The Nasdaq limitation shall not apply if, at any time the Exchange Cap is reached and at all times thereafter, the average price paid for all shares issued and sold under the Purchase Agreement is equal to or greater than $6.10, the closing sale price of our common stock on December 14, 2012. We are not required or permitted to issue any shares of common stock under the Purchase Agreement if such issuance would breach our obligations under the rules or regulations of the Nasdaq Capital Market. We currently do not intend to seek stockholder approval of the transactions contemplated by the Purchase Agreement.

Beneficial Ownership Limitation

Under the Purchase Agreement, the Company and Aspire Capital may not effect any sales of shares of our common stock if such shares proposed to be issued and sold, when aggregated with all other shares of our common stock beneficially owned by Aspire Capital and its affiliates, would result in the beneficial ownership by Aspire Capital and its affiliates of more than the Exchange Cap.

Events of Default

Generally, Aspire Capital may terminate the Purchase Agreement upon the occurrence of any of the following events of default:

- the effectiveness of any registration statement that is required to be maintained effective pursuant to the terms of the Registration Rights Agreement between us and Aspire Capital lapses for any reason (including, without limitation, the issuance of a stop order) or is unavailable to Aspire Capital for sale of our shares of common stock, and such lapse or unavailability continues for a period of ten consecutive business days or for more than an aggregate of thirty business days in any 365-day period, which is not in connection with a post-effective amendment to any such registration statement; provided, however, that in connection with any post-effective amendment to such registration statement that is required to be declared effective by the SEC, such lapse or unavailability may continue for a period of no more than thirty consecutive business days;

- the suspension from trading or failure of our common stock to be listed on the Principal Market (as defined in the Purchase Agreement) for a period of three (3) consecutive business days;

- the delisting of our common stock from the Nasdaq Capital Market, provided our common stock is not immediately thereafter trading on the New York Stock Exchange, the Nasdaq Global Select Market, the Nasdaq Global Market, the NYSE Amex Equities or the OTCQB or OTCQX market places of the OTC markets;

- our transfer agent' s failure to issue to Aspire Capital shares of our common stock which Aspire Capital is entitled to receive under the Purchase Agreement within five business days after an applicable purchase date;

- any breach by us of the representations, warranties, covenants or other term or condition contained in the Purchase Agreement or any related agreements that would reasonably be expected to have a material adverse effect except, in the case of a breach of a covenant which is reasonably curable, only if such breach continues for a period of at least five business days;

- if at any time the issuance of shares of common stock upon the submission of a Purchase Notice or VWAP Purchase Notice under this Agreement would result in the issuance of an aggregate of number of shares of common stock that would exceed the number of shares of common stock that we may issue under this agreement without breaching our obligations under the rules or regulations of the Nasdaq Capital Market;

- if we become insolvent or are generally unable to pay our debts as they become due; or

- any participation or threatened participation in insolvency or bankruptcy proceedings by or against us.

Our Termination Rights

The Purchase Agreement may be terminated by us at any time, at our discretion, without any cost to us.

No Short-Selling or Hedging by Aspire Capital

Aspire Capital has agreed that neither it nor any of its agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging, which establishes a net short position with respect to our common stock during any time prior to the termination of the Purchase Agreement.

Effect of Performance of the Purchase Agreement on Our Stockholders

The Purchase Agreement does not limit the ability of Aspire Capital to sell any or all of the 3,000,000 shares registered in this offering. It is anticipated that shares registered in this offering will be sold over a period of up to approximately 24 months from the date of this prospectus. The sale by Aspire Capital of a significant amount of shares registered in this offering at any given time could cause the market price of our common stock to decline or to be highly volatile. Sales to Aspire Capital by us pursuant to the Purchase Agreement also may result in dilution to the interests of other holders of our common stock. However, we have the right to control the timing and amount of sales of our shares to Aspire Capital, and the Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

Amount of Potential Proceeds to be Received under the Purchase Agreement

In connection with entering into the Purchase Agreement, we authorized the sale to Aspire Capital of up to $25.0 million of shares of our common stock. However, we estimate that we will sell no more than 2,919,743 shares to Aspire Capital under the Purchase Agreement (exclusive of the Commitment Shares), all of which are included in this offering. Subject to any required approval by our board of directors, we have the right but not the obligation to issue more than the 3,000,000 shares included in this prospectus to Aspire Capital under the Purchase Agreement. In the event we elect to issue more than 3,000,000 shares under the Purchase Agreement, we will be required to file a new registration statement and have it declared effective by the SEC. The number of shares ultimately offered for sale by Aspire Capital in this offering is dependent upon the number of shares purchased by Aspire Capital under the Purchase Agreement. The

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following table sets forth the number and percentage of outstanding shares to be held by Aspire Capital after giving effect to the sale of shares of common stock issued to Aspire Capital at varying purchase prices:

Assumed Average Purchase Price	Number of Shares to be Sold if Full Purchase(1)	Percentage of Outstanding Shares After Giving Effect to the Aspire Capital Transaction(2)	Proceeds from the Sale of Shares to Aspire Capital Under the Common Stock Purchase Agreement
$ 1.00	2,919,743	24.0%	$ 2,919,743
$ 4.00	2,919,743	24.0%	$ 11,678,972
$ 7.00	2,919,743	24.0%	$ 20,438,201
$ 10.00	2,500,000	21.0%	$ 25,000,000
$ 13.00	1,923,077	17.0%	$ 25,000,000

(1) Excludes 80,257 shares issued as Commitment Shares.

(2) The denominator is based on 9,362,981 shares outstanding on January 15, 2013, plus the number of shares set forth in the adjacent column which we would have sold to Aspire Capital. The numerator is based on the number of shares which we would have sold under the Purchase Agreement at the corresponding assumed purchase price set forth in the adjacent column. Calculations disregard the potential application of the Exchange Cap, to the extent applicable.

PLAN OF DISTRIBUTION

The common stock may be sold or distributed from time to time by the selling stockholder directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the common stock offered by this prospectus may be effected in one or more of the following methods:

- ordinary brokers' transactions;
- transactions involving cross or block trades;
- through brokers, dealers, or underwriters who may act solely as agents;
- "at the market" into an existing market for the common stock;
- in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;
- in privately negotiated transactions; or
- any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the registration or qualification requirement is available and complied with.

The selling stockholder may also sell shares of common stock under Rule 144 promulgated under the Securities Act, if available, rather than under this prospectus. In addition, the selling stockholder may transfer the shares of common stock by other means not described in this prospectus.

Brokers, dealers, underwriters, or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts, or concessions from the selling stockholder and/or purchasers of the common stock for whom the broker-dealers may act as agent. Aspire Capital has informed us that each such broker-dealer will receive commissions from Aspire Capital which will not exceed customary brokerage commissions.

The selling stockholder and its affiliates have agreed not to engage in any direct or indirect short selling or hedging of our common stock during the term of the Purchase Agreement.

Aspire Capital is an “underwriter” within the meaning of the Securities Act.

We have advised Aspire Capital that while it is engaged in a distribution of the shares included in this prospectus it is required to comply with Regulation M promulgated under the Securities Exchange Act of 1934, as amended. With certain exceptions, Regulation M precludes the selling stockholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the shares offered hereby this prospectus.

We may suspend the sale of shares by Aspire Capital pursuant to this prospectus for certain periods of time for certain reasons, including if the prospectus is required to be supplemented or amended to include additional material information.

This offering will terminate on the date that all shares offered by this prospectus have been sold by Aspire Capital.

DESCRIPTION OF SECURITIES

Authorized Capital

We are authorized to issue up to 100,000,000 shares of common stock, with a par value of $0.0001 per share and up to 40,000,000 shares of preferred stock, with a par value of $0.0001 per share.

Outstanding Capital Stock

As of December 31, 2012, we had 9,282,724 shares of our common stock issued and outstanding and we had 23 holders of record of our common stock. As of December 31, 2012, we had outstanding options to acquire 1,123,134 shares of common stock held by employees, directors, and consultants granted options to purchase our common stock, as well as outstanding warrants to purchase 1,663,253 shares of common stock held by employees, directors, consultants, and investors.

Common Stock

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

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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 certain 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 "Limitation on Liability of Directors and Officers and Indemnification"; 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.

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The foregoing description of our authorized capital, outstanding common stock and common stock is a summary only and is qualified in its entirety by reference to our certificate of incorporation and bylaws, both of which are exhibits to the registration statement of which this prospectus is a part and have been filed with the SEC and are available at the SEC' s website at *www.sec.gov*

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

Preferred Stock

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 Pty Limited, or ASX Settlement. ASX Settlement 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. No share certificates are issued in respect of shareholdings that are quoted on ASX and settled on CHESS, nor is it a requirement for transfer forms to be executed in relation to transfers that occur on CHESS.

CDIs confer the beneficial ownership in the shares of common stock on the CDI holder, with the legal title to such shares held by CHESS Depositary Nominees Pty Ltd, a wholly-owned subsidiary of ASX, to act as our Australian depositary and issue CDIs. Every 200 CDIs represents beneficial ownership of one share of our common stock.

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 a book entry for the shares of common stock will be made on the records of our transfer agent. If thereafter the holder wishes to sell their investment on ASX, it will be necessary for them to convert their shares of common stock back into CDIs.

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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 our 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:

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- 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 the securities purchase agreement, dated February 6, 2012, by and among us and the purchasers party thereto, the purchasers thereunder have a contractual preemptive right to purchase equity, equity based and related securities, convertible securities, debt, preferred stock or purchase rights we offer, subject to customary exclusions, through the first anniversary of the closing of the transactions contemplated by the securities purchase agreement. Prior to offering any of these securities during this period, or within 30 days after the closing of any sale of these securities, we must offer to issue to the purchasers under the February 2012 securities purchase agreement, 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 that 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 February 2012 securities purchase agreement by all purchasers thereunder. If a purchaser fails to purchase its pro rata share of the securities subject to the preemptive right, then that purchaser will no longer have preemptive rights pursuant to the February 2012 securities purchase agreement for any subsequent placement of our securities. The preemptive right provided by the February 2012 securities purchase agreement is subject to certain customary exceptions, including for securities issued pursuant to convertible securities issued prior to the date of the securities purchase agreement, securities issued pursuant to certain commercial arrangements and securities issued under our 2002 Stock Plan and our 2011 Equity Incentive Plan.

Within 30 days after the closing of this offering, we intend to offer the purchasers under the securities purchase agreement the number of shares we are required to offer them thereunder in connection with this offering. Each purchaser will have 20 days from the date of receipt of our offer to elect to exercise the purchaser' s preemptive right under the February 2012 securities purchase agreement. We cannot determine at this time how many shares, if any, the purchasers under the February 2012 securities purchase agreement will purchase pursuant to their preemptive rights thereunder.

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.

Limitation on Liability of Directors and Indemnification

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

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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 SEC this indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Listing

Our common stock is listed 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 transfers of shares of our common stock is American Stock Transfer & Trust Company, LLC, or AST. AST' s address is 6201 15th Avenue, Brooklyn, New York 11219 and its telephone number is (800) 937-5449. 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.

Options and Warrants

As of December 31, 2012, we had outstanding options to purchase 1,123,134 shares of our common stock, of which options to purchase 416,896 shares were vested, with a weighted average per share exercise price of $13.06 and expiration dates between January 30, 2013 and November 1, 2021. We also had reserved an additional 792,475 shares of common stock for grants pursuant to our 2011 Equity Incentive Plan as of that date. We have filed a registration statement on Form S-8 under the Securities Act to register the sale of shares issued or issuable upon the exercise of all these stock options and options and other awards issuable pursuant to our 2011 Equity Incentive Plan and 2002 Stock Plan. Our board of directors also has adopted, subject to approval of our stockholders, which was granted on August 9, 2012, an amendment to our 2011 Equity Incentive Plan that will increase the number of shares that may be issued thereunder on January 1 of each year beginning January 1, 2013 and ending on and including January 1, 2017 to be an amount equal to the difference between (i) 13% of the fully diluted shares of our common stock deemed outstanding on the immediately preceding December 31 and (ii) the number of our shares of common stock issuable upon the exercise of options then outstanding under our 2002 Stock Plan, unless our board determines that that the increase will involve a lesser number of shares (or no shares). Subject to the exercise of issued and outstanding options and contractual restrictions, shares of our directors and executive officers to which Rule 701 is applicable or which are to be registered under the registration statements on Form S-8 will be available for sale into the public market after the expiration of the 90-day lock-up period as described above, subject to the vesting requirements.

As of December 31, 2012, warrants to purchase a total of 1,663,253 shares of our common stock were outstanding with a weighted average per share exercise price of A$7.75 (or approximately $8.24 based on a conversion rate of A$1.00 to $1.0371) and expiration dates between June 2014 and February 2017. Any shares of common stock issued upon exercise of such warrants will be restricted securities and

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may be sold in the public market only if registered or pursuant to an exemption from registration, such as Rule 144.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

General

The following is a discussion of the material U.S. federal income tax consequences of the acquisition, ownership, and disposition of our common stock by a non-U.S. holder, as defined below, that acquires our common stock pursuant to this offering. This discussion assumes that a non-U.S. holder will hold our common stock issued pursuant to this offering as a capital asset within the meaning of Section 1221 of the Internal Revenue Code of 1986, as amended, or the Code. This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular investor in light of the investor' s individual circumstances. In addition, this discussion does not address (i) U.S. federal non-income tax laws, such as gift or estate tax laws, (ii) state, local or non-U.S. tax consequences, (iii) the special tax rules that may apply to certain investors, including, without limitation, banks, insurance companies, financial institutions, controlled foreign corporations, passive foreign investment companies, broker-dealers, grantor trusts, personal holding companies, taxpayers who have elected mark-to-market accounting, tax-exempt entities, regulated investment companies, real estate investment trusts, a partnership or other entity or arrangement classified as a partnership for United States federal income tax purposes or other pass-through entities, or an investor in such entities or arrangements, or U.S. expatriates or former long-term residents of the United States, (iv) the special tax rules that may apply to an investor that acquires, holds, or disposes of our common stock as part of a straddle, hedge, constructive sale, conversion or other integrated transaction, or (v) the impact, if any, of the alternative minimum tax.

This discussion is based on current provisions of the Code, applicable U.S. Treasury Regulations promulgated thereunder, judicial opinions, and published rulings of the Internal Revenue Service, or the IRS, all as in effect on the date of this prospectus and all of which are subject to differing interpretations or change, possibly with retroactive effect. We have not sought, and will not seek, any ruling from the IRS or any opinion of counsel with respect to the tax consequences discussed herein, and there can be no assurance that the IRS will not take a position contrary to the tax consequences discussed below or that any position taken by the IRS would not be sustained.

As used in this discussion, the term "U.S. person" means a person that is, for U.S. federal income tax purposes, (i) a citizen or individual resident of the United States, (ii) a corporation (or other entity taxed as a corporation) created or organized (or treated as created or organized) in the United States or under the laws of the United States or any state thereof or the District of Columbia, (iii) an estate the income of which is subject to U.S. federal income taxation regardless of its source, or (iv) a trust if (A) a court within the United States is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have the authority to control all substantial decisions of the trust, or (B) it has in effect a valid election under applicable U.S. Treasury Regulations to be treated as a U.S. person. As used in this discussion, the term "non-U.S. holder" means a beneficial owner of our common stock (other than a partnership or other entity treated as a partnership or as a disregarded entity for U.S. federal income tax purposes) that is not a U.S. person.

The tax treatment of a partnership and each partner thereof will generally depend upon the status and activities of the partnership and such partner. A holder that is treated as a partnership for U.S. federal income tax purposes or a partner in such partnership should consult its own tax advisor regarding the U.S. federal income tax consequences applicable to it and its partners of the acquisition, ownership and disposition of our common stock.

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THIS DISCUSSION IS ONLY A SUMMARY OF MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK. IT IS NOT TAX ADVICE. EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR WITH RESPECT TO THE PARTICULAR TAX CONSEQUENCES OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR COMMON

STOCK, INCLUDING THE APPLICABILITY AND EFFECT OF ANY STATE, LOCAL, AND NON-U.S. TAX LAWS, AS WELL AS U.S. FEDERAL ESTATE AND GIFT TAX LAWS, AND ANY APPLICABLE TAX TREATY.

Income Tax Consequences of an Investment in Common Stock

Distributions on Common Stock

As discussed under "Dividend Policy," we do not anticipate paying dividends. If we pay cash or distribute property to holders of shares of common stock, such distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Distributions in excess of current and accumulated earnings and profits will constitute a return of capital that will be applied against and reduce (but not below zero) the holder' s adjusted tax basis in our common stock. Any remaining excess will be treated as gain from the sale or exchange of the common stock and will be treated as described under "− Gain or Loss on Sale, Exchange or Other Taxable Disposition of Common Stock" below.

Dividends paid to a non-U.S. holder that are not effectively connected with the non-U.S. holder' s conduct of a trade or business in the United States generally will be subject to withholding of U.S. federal income tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty. A non-U.S. holder that wishes to claim the benefit of an applicable tax treaty withholding rate generally will be required to (i) complete IRS Form W-8BEN (or other applicable form) and certify under penalties of perjury that such holder is not a U.S. person and is eligible for the benefits of the applicable tax treaty or (ii) if our common stock is held through certain foreign intermediaries, satisfy the relevant certification requirements of applicable U.S. Treasury Regulations. These forms may need to be periodically updated.

A non-U.S. holder eligible for a reduced rate of withholding of U.S. federal income tax pursuant to an income tax treaty may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. holders should consult their own tax advisors regarding their entitlement to benefits under an applicable income tax treaty and the manner of claiming the benefits of such treaty (including, without limitation, the need to obtain a U.S. taxpayer identification number).

Dividends that are effectively connected with a non-U.S. holder' s conduct of a trade or business in the United States, and, if required by an applicable income tax treaty, attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States, are subject to U.S. federal income tax on a net income basis at the U.S. federal income tax rates generally applicable to a U.S. holder and are not subject to withholding of U.S. federal income tax, provided that the non-U.S. holder establishes an exemption from such withholding by complying with certain certification and disclosure requirements. Any such effectively connected dividends (and, if required, dividends attributable to a U.S. permanent establishment or fixed base) received by a non-U.S. holder that is treated as a foreign corporation for U.S. federal income tax purposes may be subject to an additional branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty.

Gain or Loss on Sale, Exchange or Other Taxable Disposition of Common Stock

Any gain recognized by a non-U.S. holder on a sale or other taxable disposition of our common stock generally will not be subject to U.S. federal income tax, unless:

(i) the gain is effectively connected with a trade or business of the non-U.S. holder in the United States (and, if required by an applicable income tax treaty, is attributable to a U.S. permanent establishment or fixed base of the non-U.S. holder),

(ii) the non-U.S. holder is an individual who is present in the United States for 183 days or more in the taxable year of that disposition, and certain other conditions are met, or

(iii) we are or have been a United States real property holding corporation, or a USRPHC, for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition or the period that the non-U.S. holder held the common stock, and, in the case where the shares of our common stock are regularly traded on an established securities market, the non-U.S. holder holds or held (at any time during the shorter of the five-year period ending on the date of disposition or the non-U.S. holder' s holding period) more than 5% of our common stock. A corporation generally is a USRPHC if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. We believe that we currently are a USRPHC, and we expect to remain a USRPHC.

Any gain recognized by a non-U.S. holder that is described in clause (i) or (iii) of the preceding paragraph generally will be subject to tax at the U.S. federal income tax rates generally applicable to a U.S. person and be required to file a U.S. tax return. Such non-U.S. holders are urged to consult their tax advisors regarding the possible application of these rules. Any gain of a corporate non-U.S. holder that is described in clause (i) above may also be subject to an additional branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty. An individual non-U.S. holder that is described in clause (ii) of such paragraph generally will be subject to a flat 30% tax (or a lower applicable tax treaty rate) on the U.S. source capital gain derived from the disposition, which may be offset by U.S. source capital losses during the taxable year of the disposition.

Information Reporting and Backup Withholding

We generally must report annually to the IRS and to each non-U.S. holder of our common stock the amount of dividends paid to such holder on our common stock and the tax, if any, withheld with respect to those dividends. Copies of the information returns reporting those dividends and withholding may also be made available to the tax authorities in the country in which the non-U.S. holder is a resident under the provisions of an applicable income tax treaty or agreement. Information reporting also is generally required with respect to the proceeds from sales and other dispositions of our common stock to or through the U.S. office (and in certain cases, the foreign office) of a broker.

Under some circumstances, U.S. Treasury Regulations require backup withholding of U.S. federal income tax, currently at a rate of 28% (scheduled to increase to 31% in 2011), on reportable payments with respect to our common stock. A non-U.S. holder generally may eliminate the requirement for information reporting (other than in respect to dividends, as described above) and backup withholding by providing certification of its foreign status, under penalties of perjury, on a duly executed applicable IRS Form W-8 or by otherwise establishing an exemption. Notwithstanding the foregoing, backup withholding and information reporting may apply if either we or our paying agent has actual knowledge, or reason to know, that a holder is a U.S. person.

Backup withholding is not a tax. Rather, the amount of any backup withholding will be allowed as a credit against a non-U.S. holder' s U.S. federal income tax liability, if any, and may entitle such non-U.S. holder to a refund, provided that certain required information is timely furnished to the IRS. Non-U.S. holders should consult their own tax advisors regarding the application of backup withholding and the availability of and procedure for obtaining an exemption from backup withholding in their particular circumstances.

LEGAL MATTERS

Certain legal matters in connection with the offering and the validity of the common stock offered by this prospectus will be passed upon for us by Honigman Miller Schwartz and Cohn LLP.

EXPERTS

The consolidated financial statements of Sunshine Heart, Inc. at December 31, 2011 and 2010, and for the years then ended, appearing in this prospectus and registration statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company' s ability to continue as a going concern as described in Note 1 to the consolidated financial statements) appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the informational requirements of the Exchange Act, and file annual, quarterly and current reports, proxy statements, and other information with the SEC. You can read the registration statement and our future filings with the SEC over the Internet at the SEC' s website at *www.sec.gov* . You may request copies of the filing, at no cost, by telephone at (952) 245-4200 or by mail at Sunshine Heart, Inc., 12988 Valley View Road, Eden Prairie, Minnesota 55344. You may also read and copy any document we file with the SEC at its public reference facility at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock being offered by this prospectus. This prospectus is part of that registration statement. This prospectus does not contain all of the information set forth in the registration statement or the exhibits to the registration statement. Further information with respect to us and the share we are offering pursuant to this prospectus, you should refer to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract, agreement or other document referred to are not necessarily complete, and you should refer to the copy of that contract or other documents filed as an exhibit to the registration statement. You may read or obtain a copy of the registration statement at the SEC' s public reference room and website referred to above.

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SUNSHINE HEART, INC. AND SUBSIDIARY

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

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

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

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

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

/s/ Ernst & Young LLP

Minneapolis, Minnesota

March 23, 2012, except for the change in the presentation of comprehensive income, discussed in Note 1 to the consolidated financial statements, as to which the date is July 17, 2012.

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SUNSHINE HEART, INC. AND SUBSIDIARY

Consolidated Balance Sheets

Dollars in thousands, except per share amounts	Dec 31, 2011	Dec 31, 2010
Current assets		
Cash and cash equivalents	$ 6,563	$ 12,350
Accounts receivable, net	–	247
Other current assets	346	182
Total current assets	**6,909**	**12,779**
Property, plant and equipment	**522**	**120**
TOTAL ASSETS	**$ 7,431**	**$ 12,899**
Current liabilities		
Accounts payable	$ 1,857	$ 696
Accrued salaries, wages, and other compensation	978	114
Total current liabilities	**2,835**	**810**
Total liabilities	**2,835**	**810**
Stockholders' equity		
Preferred stock as of December 31, 2011 and December 31, 2010, $0.0001 par value per share; authorized 40,000,000 shares	–	–
Common stock as of December 31, 2011 and December 31, 2010, par value $0.0001 per share; authorized 100,000,000 shares; issued and outstanding 6,019,663 and 5,063,968, respectively	1	1
Additional paid-in capital	68,652	60,086
Accumulated other comprehensive income:		
Foreign currency translation adjustment	1,132	995
Accumulated deficit	(65,189)	(48,993)
Total stockholders' equity	**4,596**	**12,089**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 7,431**	**$ 12,899**

See notes to the consolidated financial statements

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SUNSHINE HEART, INC. AND SUBSIDIARY

Consolidated Statements of Operations and Comprehensive Loss

In thousands, except per share amounts	Year ended Dec 31, 2011		Year ended Dec 31, 2010	
Net sales	$	–	$	**407**
Operating expenses				
Selling, general and administrative		5,363		2,598
Research and development		11,199		6,229
Total operating expenses		16,562		8,827
Loss from operations		**(16,562)**		**(8,420)**
Interest income		251		150
Loss before income taxes		**(16,311)**		**(8,270)**
Income tax benefit		**115**		**(670)**
Net loss	$	**(16,196)**	$	**(7,600)**
Basic and diluted loss per share	$	**(2.98)**	$	**(2.63)**
Weighted average shares outstanding–basic and diluted		**5,442**		**2,885**
Other comprehensive income				
Foreign currency translation adjustments	$	**137**	$	**623**
Total comprehensive loss	$	**(16,059)**	$	**(6,977)**

See notes to the consolidated financial statements

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SUNSHINE HEART, INC. AND SUBSIDIARY

Consolidated Statements of Stockholders' Equity

(In thousands)	Outstanding Shares	Common Stock	Additional Paid in Capital	Accumulated Other Comprehensive	Accumulated Deficit	Stockholders' Equity

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

See notes to the consolidated financial statements

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SUNSHINE HEART, INC. AND SUBSIDIARY

Consolidated Statements of Cash Flows

	Year ended	
(In thousands)	**Dec 31, 2011**	**Dec 31, 2010**
Net loss	$ (16,196)	$ (7,600)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	50	32
Stock based compensation expense	939	78
Changes in asset and liabilities:		
Accounts receivable	258	(123)
Other current assets	(166)	(94)
Accounts payable and accrued expenses	2,026	496

Net cash used in operations	**(13,089)**	**(7,210)**
Cash flows used in investing activities:		
Purchase of property and equipment	(451)	(7)
Net cash used in investing activities	**(451)**	**(7)**
Cash flows provided by financing activities:		
Net proceeds from the sale of common stock	7,627	11,917
Net cash provided by financing activities	**7,627**	**11,917**
Effect of exchange rate changes on cash	126	623
Net increase (decrease) in cash and cash equivalents	(5,787)	5,322
Cash and cash equivalents−beginning of period	12,350	7,028
Cash and cash equivalents−end of period	**$ 6,563**	**$ 12,350**

See notes to the consolidated financial statements

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SUNSHINE HEART, INC. AND SUBSIDIARY

Notes to Consolidated Financial Statements

(in thousands, except share and per share data)

Note 1−Nature of Business and Significant Accounting Policies

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

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

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

The Company' s ability to continue as a going concern is dependent on the Company' s ability to raise additional capital based on the achievement of existing milestones as and when required. Should the future capital raising not be successful, the Company may not be able to continue as a going concern. Furthermore, the ability of the Company to continue as a going concern is subject to the ability of the Company to develop and successfully commercialize the product being developed. If the Company is unable to obtain such funding of an amount and timing necessary to meet its future operational plans, or to successfully commercialize its intellectual property, the Company may be unable to continue as a going concern. No adjustments have been made relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company not continue as a going concern.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Impairment of Long-lived Assets: Long-lived assets, such as property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If the impairment tests indicate that the carrying value of the asset is greater than the expected undiscounted cash flows to be generated by such asset, an impairment loss would be recognized. The impairment loss is determined as the amount by which the carrying value of such asset exceeds its fair value. We generally measure fair value by considering sale prices for similar assets or by discounting estimated future cash flows from such assets using an appropriate discount rate. Assets to be disposed of are carried at the lower of their carrying value or fair value less costs to sell. Considerable management judgment is necessary to estimate the fair value of assets, and accordingly, actual results could vary significantly from such estimates. There have been no impairment losses for long-lived assets, for the years ended December 31, 2011 and 2010.

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

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

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

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

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

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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 2,216,615 and 1,310,987 for the years ended December 31, 2011 and 2010, respectively, were excluded from the computation of loss per share as their effect was antidilutive due to the Company' s net loss in each of those years.

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

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

Subsequent Events: 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 amended disclosure requirements for the presentation of comprehensive income. The amended guidance eliminates the option

to present components of other comprehensive income ("OCI") as part of the statement of changes in equity. Under the amended guidance, all changes in OCI are to be presented either in a single continuous statement of comprehensive income or in two separate but consecutive financial statements. We adopted these changes effective January 1, 2012 and applied retrospectively for all periods presented. There was no impact to the consolidated results as the amendments related only to changes in financial statement presentation.

In May 2011, FASB issued ASU 2011-04*, Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in United States GAAP and IFRS.* This accounting update generally aligns the principles for fair value measurements and the related disclosure requirements under United States GAAP and International Financial Reporting Standards. From a United States 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:

	December 31, 2011	December 31, 2010

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

Note 3−Equity

Private Placement

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

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

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

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

Stock Options

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

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

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

The Company has granted stock options to certain employees and directors under the Amended and Restated 2002 Stock Plan and its 2011 Equity Incentive Plan (collectively the "Plans"). The Plans are designed to assist in the motivation and retention of employees and to recognize the importance of employees to the long-term performance and success of the Company. The Company has also granted stock options to certain consultants outside of the Plans. The majority of the options to purchase common stock vest on the anniversary of the date of 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 United States stock exchange. As of December 31, 2011, the Company expects that all such market and performance conditions will be met. Share-based compensation expense related to these awards is recognized on a straight-line basis over the related vesting term. It is the Company' s policy to issue new shares upon the exercise of options.

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

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

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

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

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

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

Warrants

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

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

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

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

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

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

Note 4−Income Taxes

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

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

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

	December 31, 2011	December 31, 2010
Income tax provision:		
Current:		
United States and state	(115)	–
Foreign	–	(670)
Deferred:		
United States and state	–	–
Foreign	–	–
Total income tax (benefit) expense	(115)	(670)

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

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

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

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

As of December 31, 2011, we had United States net operating loss (NOL) carryforwards of approximately $14.6 million for U.S. income tax purposes, which expire in 2023 through 2031, and NOLs in the Commonwealth of Australia of approximately $54.1 million which we can carry forward indefinitely. United States 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 United States 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 United States net operating losses.

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

We provide for a valuation allowance when it is more likely than not that we will not realize a portion of the deferred tax assets. We have established a valuation allowance for United States 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, 2011 and 2010, the valuation allowance increased by $6.6 million and $4.5 million, respectively. Changes in the valuation allowance do not equal the amounts reflected in the statutory rate reconciliation due to fluctuating currency exchange rates.

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

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

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

Note 5−Commitments and Contingencies

Leases

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

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Employee Benefits

All Australian employees are entitled to varying levels of benefits on retirement, disability or death. The superannuation plans provide accumulated benefits. Employees contribute to the plans at various percentages of their wages and salaries. Contributions by the Company of up to 9% of employees' wages and salaries are legally enforceable in Australia. For the years ended December 31, 2011 and 2010, the Company incurred expense of $82 and $64, respectively.

Note 6−Related Party Transaction

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

Note 7−Subsequent Events

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

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

Note 8−Segment and Geographic Information

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

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

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

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SUNSHINE HEART, INC.

Condensed Consolidated Balance Sheets

(Dollars in thousands, except share amounts)

	September 30, 2012 (unaudited)	December 31, 2011
Current assets		
Cash and cash equivalents	$ 17,446	$ 6,563
Other current assets	667	346
Total current assets	18,113	6,909
Property, plant and equipment, net	493	522
TOTAL ASSETS	$ 18,606	$ 7,431
Current liabilities		
Accounts payable	$ 1,590	$ 1,857
Accrued salaries, wages, and other compensation	681	978
Total current liabilities	2,271	2,835
Total liabilities	2,271	2,835
Commitments and contingencies	–	–
Stockholders' equity		
Preferred Stock as of September 30, 2012 and December 31, 2011, par value $0.0001 per share; authorized 40,000,000 shares	–	–
Common stock as of September 30, 2012 and December 31, 2011, par value $0.0001 per share; authorized 100,000,000 shares: issued and outstanding 9,247,388 and 6,019,663 shares, respectively	1	1
Additional paid-in capital	90,339	68,652
Accumulated other comprehensive loss:		

Foreign currency translation adjustment	1,183	1,132
Retained earnings	(75,188)	(65,189)
Total stockholders' equity	16,335	4,596
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$** 18,606	$ 7,431

See notes to the condensed consolidated financial statements.

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SUNSHINE HEART, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(In thousands, except per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2012	**2011**	**2012**	**2011**
Net sales	$ –	$ –	$ –	$ –
Cost of goods sold	–	–	–	–
Gross profit	–	–	–	–
Operating expenses				
Selling, general and administrative	1,495	1,430	5,004	3,250
Research and development	1,802	3,273	5,755	7,939
Total operating expenses	3,297	4,703	10,759	11,189
Loss from operations	(3,297)	(4,703)	(10,759)	(11,189)
Interest income	1	31	30	228
Loss before income taxes	(3,296)	(4,672)	(10,729)	(10,961)
Income tax benefit	–	–	(730)	–
Net loss	$ (3,296)	$ (4,672)	$ (9,999)	$ (10,961)
Basic and diluted loss per share	$ (0.42)	$ (0.84)	$ (1.49)	$ (2.09)
Weighted average shares outstanding – basic and diluted	7,789	5,582	6,727	5,249
Comprehensive loss	$ (3,308)	$ (4,812)	$ (9,948)	$ (10,916)

See notes to the condensed consolidated financial statements.

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SUNSHINE HEART, INC.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(in thousands)

	For the nine months ended September 30,	
	2012	2011
Cash flows used in operating activities:		
Net loss	$ (9,999)	$ (10,961)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	98	25
Loss on disposal of plant and equipment	63	6
Stock-based compensation expense	907	555
Expense for warrants issued in conjunction with service agreement	160	–
Changes in assets and liabilities		
Accounts receivable	–	259
Other current assets	(321)	(24)
Accounts payable and accrued expenses	(574)	480
Net cash used in operations	(9,666)	(9,660)
Cash flows used in investing activities:		
Purchases of property and equipment	(132)	(34)
Net cash used in investing activities	(132)	(34)
Cash flows provided by financing activities:		
Net proceeds from the sale of common stock	20,620	7,650
Net cash provided by financing activities	20,620	7,650
Effect of exchange rate changes in cash	61	38
Net increase (decrease) in cash and cash equivalents	10,883	(2,006)
Cash and cash equivalents - beginning of period	6,563	12,350
CASH AND CASH EQUIVALENTS - END OF PERIOD	$ 17,446	$ 10,344

See notes to the condensed consolidated financial statements.

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SUNSHINE HEART, INC. AND SUBSIDIARY

Notes to Condensed 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, Inc. was founded in November 1999 and incorporated in Delaware in August 2002 and its wholly-owned subsidiary, Sunshine Heart Company Pty Ltd. is located in St Leonards, New South Wales, Australia (together with Sunshine Heart, Inc., “we,” “our” or the “Company”). Our headquarters are located in Eden Prairie, MN. 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, or C-Pulse Heart 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. The C-Pulse Heart System 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.

We are in the process of pursuing regulatory approvals necessary to sell our system in the United States. We completed enrollment of our North American feasibility clinical trial in the first half of 2011. In November 2011, we announced the preliminary results of the six-month follow-up period for the feasibility study and we submitted the clinical data to the United States Food and Drug Administration, or FDA. In March 2012, the FDA notified us that it completed its review of the C-Pulse System feasibility trial data, concluded we met the applicable agency requirements, and indicated that we can move forward with an investigational device exemption, or IDE, application. In September 2012, we received conditional approval from the FDA for an IDE and expect to initiate our pivotal trial before the end of 2012, once the conditions to the approval have been removed.

We obtained CE Mark approval for the C-Pulse System in July 2012 and have taken initial steps to evaluate the market potential for our system in targeted countries that accept the CE Mark in anticipation of commencing commercial sales. In order to gain additional clinical data and support reimbursement in Europe, we also expect to initiate a post-market trial in Europe that will evaluate endpoints similar to those for our U.S. pivotal trial.

Our shares of common stock have been publicly traded in the U.S. on the NASDAQ since February 2012, and in the form of CHESS Depositary Interests, or CDIs, in Australia on the Australian Securities Exchange, or ASX, since September 2004.

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

During the years ended December 31, 2011 and 2010 and through September 30, 2012, the Company incurred losses from operations and net cash outflows from operating activities as disclosed in the consolidated statements of operations and cash flows, respectively. At December 31, 2011, we had an accumulated deficit of $65,189 and we expect to incur losses for the foreseeable future. To date, the Company has 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. All intercompany accounts and transactions between consolidated entities have been eliminated.

Unaudited Interim Consolidated Financial Information: The interim balance sheet as of September 30, 2012 and statements of operations and cash flows for the nine months ended September 30, 2012 and 2011 and related interim information contained in the notes to these financial statements are unaudited. The accompanying condensed consolidated financial statements have been prepared in accordance with Regulation S-X of the Securities Act of 1933, or Securities Act. 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. Certain information and disclosures normally included in the financial statements have been condensed or omitted pursuant to such rules and regulations, although management believes that disclosures are adequate to make information presented not misleading. Results for the nine months ended September 30, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012 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 U.S. 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.

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 2,551,456 and 2,216,615 for the nine months ended September 30, 2012 and 2011, 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 periods.

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 Financial Accounting Standards Board, or 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.

Recently Adopted Accounting Pronouncements

In May 2011, the FASB issued an update to accounting guidance for improved fair value measurement and disclosures. The update represents converged guidance between U.S. GAAP and IFRS, resulting in common requirements for measuring fair value and for disclosing information about fair value measurements. This new guidance was effective for our fiscal year beginning January 1, 2012 and the adoption of this guidance did not have an impact on our financial position, results of operations or cash flows.

In June 2011, the FASB issued amended disclosure requirements for the presentation of comprehensive income. The amended guidance eliminates the option to present components of other comprehensive income ("OCI") as part of the statement of changes in equity. Under the amended guidance, all changes in OCI are to be presented either in a single continuous statement of comprehensive income or in two separate but consecutive financial statements. We adopted these changes effective January 1, 2012 and applied retrospectively for all periods. There was no impact to the consolidated results as the amendments related only to changes in financial statement presentation.

There was no other accounting pronouncement adopted during the three-month period ended September 30, 2012 that had a material impact on our financial position, operating results or disclosures.

Recent Accounting Pronouncements to be Adopted

There were no new accounting pronouncements issued during the three-month period ended September 30, 2012 that are expected to have material impacts on our financial position, operating results or disclosures.

Note 2 − Equity

Private Placement

On February 8, 2012 we placed 256,875 shares of common stock (in the form of CDIs) at AU$8.00 per share, for proceeds, net of transaction costs of $2,061.

Public Offering

On August 15, 2012 we sold 2,875,000 shares of common stock in a public offering at $7.00 per share and on August 20, 2012, we sold 94,800 shares of common stock upon the exercise of the over-allotment option by our underwriters at $7.00 per share. Proceeds in the public offering and exercise of the over-allotment option, net of transaction costs were $18,552 in the aggregate.

Stock-Based Compensation

The Company recognizes all share-based payments, including grants of stock options and compensatory employee stock purchase plans, in the income statement as an operating expense, based on their fair value over the requisite service period. We recorded $594 and $313 of related compensation expense to selling, general and administrative expense and research and development expense, respectively, for the nine months ended September 30, 2012, as compared to $385 and $170, respectively, of related compensation expense for the nine months ended September 30, 2011. As of September 30, 2012,

a total of $3,321 of unrecognized compensation costs related to non-vested stock option awards was outstanding and is expected to be recognized within the next 3.5 fiscal years.

The Company uses the Black-Scholes option pricing model to determine the weighted average fair value of options. The volatility factor used in the Black-Scholes option pricing model is based on historical stock price fluctuations. The current forfeiture rate is based on a reasonable estimate by management. Expected dividend yield is based upon the Company' s historical and projected dividend activity and the risk free interest rate is based upon US Treasury rates appropriate for the expected term of the options. The expected term is based on estimates regarding projected employee stock option exercise behavior. Options for 31,875 shares were granted during the nine months ended September 30, 2012, and the weighted average fair value of these options was $196, determined using an expected dividend yield of 0%, an expected stock price volatility ranging from 98.3% to 98.6%, risk-free interest rates ranging from 1.38% to 1.43% and expected option lives of 6.5 years. There were no options granted in the nine months ended September 30, 2011.

The Company' s stock options generally vest over four years of service and have a contractual life of 10 years. We have 1,032,741 shares authorized for grant under our Amended and Restated 2011 Equity Incentive Plan.

Warrants

Warrants to purchase 1,664,599 and 1,496,032 shares of common stock were outstanding at September 30, 2012 and December 31, 2011, respectively.

As part of the private placement on February 8, 2012, we issued 77,063 warrants to purchase common stock at an exercise price of AU$11.20 per share and a term of 4 years, and 8,553 warrants to purchase common stock at an exercise price of AU$8.00 per share with a term of 5 years.

On September 7, 2012, we issued 100,000 non-forfeitable and fully exercisable warrants to purchase common stock at an exercise price of $7.00 per share and a term of 5 years, pursuant to a professional services agreement extending through June 2013. These warrants were determined to have a fair value of $519, of which $160 was charged to expense during the third quarter 2012.

During the nine months ended September 30, 2012, 1,050 warrants were exercised at a price of AU$6.40 per share for total proceeds of AU$7.

Note 3 - Balance Sheet Information

Property, Plant and Equipment

Property, plant and equipment were as follows:

	September 30, 2012	December 31, 2011
Library	$ 1	$ 1
Office Furniture & Fixtures	98	177
Leasehold Improvements	145	251
Software	9	37
Production Equipment	384	293
Computer Equipment	141	134
Total	778	893
Accumulated Depreciation	(285)	(371)
	$ 493	$ 522

Depreciation expense for the three and nine month periods ended September 30, 2012 and 2011 was $36, $4, $98 and $25, respectively.

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Note 4 − Income Taxes

In June 2012, we received a $730 research and development tax credit refund, based upon qualified research and development expenditures of our Australian subsidiary for its tax period ended June 30, 2011. The Australian research and development tax credit is paid as a refundable credit to small and medium enterprises. We have not completed the Australian tax return for the period ended June 30, 2012; therefore, we have reflected no net benefit related to the Australian research and development tax credit for that period.

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3,000,000 Shares

SUNSHINE HEART

Sunshine Heart, Inc.

Common Stock
PROSPECTUS

, 2013

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PART II − INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distributions

Securities and Exchange Commission Registration Fee*	$	2,373.36
Legal Fees and Expenses		70,000
Accounting Fees and Expenses		30,000
Miscellaneous Expenses		7,626.64
Total	$	110,000

* **All expenses except the registration fee are estimates.**

Item 14. Indemnification of Directors and Officers

Our amended and restated certificate of incorporation, as amended, and amended and restated bylaws, as amended, provide that each person who was or is made a party or is threatened to be made a party to or is otherwise involved (including, without limitation, as a witness) in any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he or she is or was a director or an officer of Sunshine Heart, Inc. or is or was serving at our request as a director, officer, or trustee of another corporation, or of a partnership, joint venture, trust or other enterprise, including service with respect to an employee benefit plan, whether the basis of such proceeding is alleged action in an official capacity as a director, officer or trustee or in any other capacity while serving as a director, officer or trustee, shall be indemnified and held harmless by us to the fullest extent authorized by the Delaware General Corporation Law against all expense, liability and loss (including attorneys' fees, judgments, fines, ERISA excise taxes or penalties and amounts paid in settlement) reasonably incurred or suffered by such.

Section 145 of the Delaware General Corporation Law permits a corporation to indemnify any director or officer of the corporation against expenses (including attorney' s fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with any action, suit or proceeding brought by reason of the fact that such person is or was a director or officer of the corporation, if such person acted in good faith and in a manner that he reasonably believed to be in, or not opposed to, the best interests of the corporation, and, with respect to any criminal action or proceeding, if he or she had no reason to believe his or her conduct was unlawful. In a derivative action, (i.e., one brought by or on behalf of the corporation), indemnification may be provided only for expenses actually and reasonably incurred by any director or officer in connection with the defense or settlement of such an action or suit if such person acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, except that no indemnification shall be provided if such person shall have been adjudged to be liable to the corporation, unless and only to the extent that the court in which the action or suit was brought shall determine that the defendant is fairly and reasonably entitled to indemnity for such expenses despite such adjudication of liability.

Pursuant to Section 102(b)(7) of the Delaware General Corporation Law, our amended and restated certificate of incorporation eliminates the liability of a director to us or our stockholders for monetary damages for such a breach of fiduciary duty as a director, except for liabilities arising:

- from any breach of the director' s duty of loyalty to us or our stockholders;

- from acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;

- under Section 174 of the Delaware General Corporation Law; and

- from any transaction from which the director derived an improper personal benefit.

We carry insurance policies insuring our directors and officers against certain liabilities that they may incur in their capacity as directors and officers. In addition, we expect to enter into indemnification agreements with each of our directors and executive officers prior to completion of the offering.

The Company has entered into indemnification agreements with each of its directors and executive officers. Pursuant to the indemnification agreements, the Company agrees to hold harmless and indemnify its directors and executive officers to the fullest extent authorized or permitted by the provisions of the Company' s amended and restated certificate of incorporation, amended and restated by-laws and the DGCL, including for any amounts that such director or officer becomes obligated to pay because of any claim to which such director or officer is made or threatened to be made a party, witness or participant, by reason of such director' s or officer' s service as a director, officer, employee or other agent of the Company.

There are certain exceptions from the Company' s obligation to indemnify its directors and executive officers pursuant to the indemnification agreements, including for "short-swing" profit claims under Section 16(b) of the Securities Exchange Act of 1934, as amended, losses that are as a result of conduct that is established by a final judgment as knowingly fraudulent or deliberately dishonest or that constituted willful misconduct, or that constituted a breach of the duty of loyalty to the Company or resulted in any improper personal profit or advantage, where payment is actually made to a director or officer under an insurance policy, indemnity clause, bylaw or agreement, except in respect of any excess beyond payment under such insurance, clause, bylaw or agreement, for indemnification which is not lawful, or in connection with any proceeding initiated by such director or officer, or any proceeding against the Company or its directors, officers, employees or other agents, unless (i) such indemnification is expressly required to be made by law, (ii) the proceeding was authorized by the board of directors of the Company, (iii) such indemnification is provided by the Company, in its sole discretion, pursuant to the powers vested in the Company under the DGCL, or (iv) the proceeding is initiated to enforce a claim for indemnification pursuant to the indemnification agreement.

All agreements and obligations of the Company contained in the indemnification agreements shall continue during the period when the director or officer who is a party to an indemnification agreement is a director, officer, employee or other agent of the Company (or is or is serving at the request of the Company as a director, officer, employee or other agent of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise) and shall continue thereafter so long as such director or officer shall be subject to any possible claim or threatened, pending or completed action, suit or proceeding, whether civil, criminal, arbitrational, administrative or investigative. In addition, the indemnification agreements provide for partial indemnification and advance of expenses.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, may be permitted to our directors, officers or controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the Securities and Exchange Commission this indemnification is against public policy as expressed in the Securities Act of 1933, as amended, and is, therefore, unenforceable.

Item 15. 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
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
Matthew Dormer	Warrants to Purchase Common Stock	3,525 Warrants	11/13/10	A$5.60	N/A
Summer Street Research Partners and its registered representatives	Warrants to purchase Common Stock	8,553 Warrants	2/8/12	A$8.00	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
Institutional and high net worth Australian investors	Common Stock	6,900 Common Shares	5/9/11	N/A	A$44,157
Institutional and high net worth Australian investors	Common Stock	5,000 Common Shares	5/23/11	N/A	A$32,000
Institutional and high net worth Australian investors	Common Stock	53 Common Shares	6/6/11	N/A	A$335
Malcolm Legget	Common Stock	194 Common Shares	6/22/11	N/A	A$586
Accredited Investors party to Securities Purchase Agreement dated 7/25/11	Common Stock and Warrants to purchase Common Stock	572,222 Common Shares 171,667 Warrants	7/27/11	A$8.00 per share purchase price for Common Stock A$11.20 per share exercise price for Warrants	A$4,577,774
Summer Street Research Partners	Warrants to purchase Common Stock	9,091 Warrants	7/27/11	A$8.00	N/A

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

Institutional and high net worth Australian investors	Common Stock 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
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 and its registered representatives	Warrants to purchase Common Stock	8,553 Warrants	2/8/12	A$8.00	N/A
Accredited Investors party to Service Agreement	Warrants to purchase Common Stock	100,000 Warrants	9/7/12	$7.00	N/A
Institutional and high net worth Australian investors	Common Stock	31,346 Common Shares	10/16/12	N/A	A$200,614

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

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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	595,590	A$	7.00
8/18/11	15,000	A$	10.40
8/19/11	29,210	A$	12.80
11/2/11	88,755	A$	8.20
11/29/11	66,370	A$	8.20
1/10/12	29,375	A$	7.40
3/12/12	2,500	$	11.78
11/12/12	253,000	$	6.46

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 Equity Incentive Plan to our officers, directors, employees and consultants in reliance upon an available exemption from the registration requirements of the Securities Act, including those contained in Rule 701 promulgated under Section 3(b) of the Securities Act. Among other things, we relied on the fact that, under Rule 701,

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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 2002 Stock Plan and our 2011 Equity Incentive Plan qualify as compensatory benefit plans.

On January 15, 2012, the Company entered into a Common Stock Purchase Agreement (the ***"Purchase Agreement"***) with Aspire Capital Fund, LLC, an Illinois limited liability company (***"Aspire Capital"***), which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $25 million of shares of the Company' s common stock (the ***"Purchase Shares"***) over the two-year term of the Purchase Agreement.

Upon execution of the Purchase Agreement, the Company issued 80,257 shares of its common stock to Aspire Capital in consideration for entering into the Purchase Agreement (the ***"Commitment Shares"***). The Purchase Shares may be sold by the Company to Aspire Capital on any business day the Company selects in two ways: (1) through a regular purchase of up to 50,000 shares at a known price based on the market price of our common stock prior to the time of each sale, and (2) through a VWAP purchase of a number of shares up to 30% of the volume traded on the purchase date at a price equal to the lessor of the closing sale price or 95% of the volume weighted average price for such purchase date.

The issuance of the Commitment Shares and all other shares of common stock that may be issued from time to time to Aspire Capital under the Purchase Agreement is exempt from registration under the Securities Act, pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder.

Item 16. Exhibits

Exhibit Number	Exhibit Description	Incorporated By Reference Form	File Number	Date of First Filing	Exhibit Number	Filed Herewith
3.1	Certificate of Incorporation, as amended.	10	001-35312	February 1, 2012	3.1	
3.2	Amended and Restated Bylaws.	10	001-35312	September 30, 2011	3.2	
10.1	Form of Indemnity Agreement between the registrant and each of its officers and directors. *	10	001-35312	September 30, 2011	10.1	
10.2	Sunshine Heart, Inc. Amended and Restated 2002 Stock Plan. *	10	001-35312	December 16, 2011	10.2	
10.3	Form of Notice of Stock Option Grant and Option Agreement for Amended and Restated 2002 Stock Plan. *	10	001-35312	September 30, 2011	10.3	

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Exhibit Number	Exhibit Description	Incorporated By Reference Form	File Number	Date of First Filing	Exhibit Number	Filed Herewith
10.4	Amended and Restated Sunshine Heart, Inc. 2011 Equity Incentive Plan, as amended. *	14A	001-35312	July 27, 2012	App. A	
10.5	Form of Stock Option Grant Notice and Option Agreement for 2011 Equity Incentive Plan. *	10	001-35312	September 30, 2011	10.5	
10.6	Form of Senior Management Stock Option Grant Notice and Option Agreement for 2011 Equity Incentive Plan. *	10	001-35312	September 30, 2011	10.6	
10.7	Form of Change in Control Agreement for the registrant' s executive officers. *	10	001-35312	December 16, 2011	10.7	

10.8	Form of Stock Option Grant Notice and Form of Option Agreement (Director). *	8-K	001-35312	September 18, 2012	10.1	
10.9	Form of Warrant to Purchase Common Stock issued to investors pursuant to Securities Purchase Agreement dated September 15, 2010.	10	001-35312	September 30, 2011	10.8	
10.10	Form of Warrant to Purchase Common Stock issued to Summer Street Research Partners.	10	001-35312	September 30, 2011	10.9	
10.11	Form of Warrant to Purchase Common Stock issued to investors pursuant to Securities Purchase Agreement dated July 21, 2011.	10	001-35312	September 30, 2011	10.12	

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Exhibit Number	Exhibit Description	Incorporated By Reference Form	File Number	Date of First Filing	Exhibit Number	Filed Herewith
10.12	Form of Warrant to Purchase Common Stock issued to Matthew Dormer and Summer Street Research Partners.	10	001-35312	September 30, 2011	10.13	
10.13	Employment Agreement, dated November 1, 2009, by and between the registrant and David A. Rosa. *	10	001-35312	September 30, 2011	10.14	
10.14	Letter Agreement, dated August 3, 2004, between the registrant and WSP Trading Limited. *	10	001-35312	September 30, 2011	10.15	
10.15	Lease Agreement, dated September 15, 2010, by and between the registrant and CSM Properties, Inc.	10	001-35312	December 16, 2011	10.16	
10.16	License, Supply & Manufacturing Agreement, dated April 26, 2010,	10	001-35312	February 14, 2012	10.17	

	by and between the registrant and DSM PTG, Inc. #					
10.17	Lease Agreement, dated October 21, 2011, by and between the registrant and Silver Prairie Crossroads, LLC.	10	001-35312	December 16, 2011	10.18	
10.18	Form of Securities Purchase Agreement, dated February 6, 2012.	10	001-35312	February 8, 2012	10.19	
10.19	Form of Warrant to Purchase Common Stock issued to investors pursuant to Securities Purchase Agreement dated February 6, 2012.	10	001-35312	February 8, 2012	10.20	

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		Incorporated By Reference				
Exhibit Number	Exhibit Description	Form	File Number	Date of First Filing	Exhibit Number	Filed Herewith
10.20	Form of Warrant to Purchase Common Stock issued to Summer Street Research Partners and registered representatives on February 8, 2012.	10-K	001-35312	March 23, 2012	10.21	
10.21	Common Stock Purchase Agreement, dated as of January 15, 2013, by and between the Company and Aspire Capital Fund, LLC.	8-K	001-35312	January 16, 2013	10.1	
10.22	Registration Rights Agreement, dated as of January 15, 2013, by and between the Company and Aspire Capital Fund, LLC.	8-K	001-35312	January 16, 2013	4.1	
21	Subsidiaries of the registrant.					X
23.1	Consent of Ernst & Young LLP.					X
24.1	Power of Attorney					X

*Indicates management contract or compensatory plan or arrangement.

#Confidential treatment granted with respect to certain portions of this exhibit. The omitted portions have been filed separately with the Securities and Exchange Commission.

Item 17. Undertakings

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales of securities are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar

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value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser,

(A) Each prospectus filed by a registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(5) If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any

statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(b) The undersigned registrant hereby undertakes to deliver or cause to be delivered with the prospectus, to each person to whom the prospectus is sent or given, the latest annual report to security holders that is incorporated by reference in the prospectus and furnished pursuant to and meeting the requirements of Rule 14a-3 or Rule 14c-3 under the Securities Exchange Act of 1934; and, where interim financial information required to be presented by Article 3 of Regulation S-X are not set forth in the prospectus, to deliver, or cause to be delivered to each person to whom the prospectus is sent or given, the latest quarterly report that is specifically incorporated by reference in the prospectus to provide such interim financial information.

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 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 Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in

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the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the claim has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized in the city of Eden Prairie, State of Minnesota on this 28th day of January, 2013.

SUNSHINE HEART, INC.

By: /s/ David A. Rosa
David A. Rosa
Chief Executive officer

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

Signature	Title	Date

/s/ David A. Rosa David A. Rosa	President & Chief Executive Officer (Principal Executive Officer) and Director	January 28, 2013
/s/ Jeffrey Mathiesen Jeffrey Mathiesen	Chief Financial Officer (Principal Financial and Accounting Officer)	January 28, 2013
/s/ Paul Buckman Paul Buckman	Director	January 28, 2013
/s/ Geoffrey Brooke Geoffrey Brooke	Director	January 28, 2013
/s/ William Peters, M.D. William Peters, M.D.	Director	January 28, 2013
/s/ Donal O' Dwyer Donal O' Dwyer	Director	January 28, 2013
/s/ Gregory Waller Gregory Waller	Director	January 28, 2013
/s/ John Erb John Erb	Director	January 28, 2013

Exhibit 21

Sunshine Heart, Inc.
List of Subsidiaries

Name	Jurisdiction of Organization
Sunshine Heart Company Pty Ltd	Australia

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption "Experts" and to the use of our report dated March 23, 2012, except for the change in the presentation of comprehensive income, discussed in Note 1 to the consolidated financial statements, as to which the date is July 17, 2012, in the Registration Statement (Form S-1) and the related Prospectus of Sunshine Heart, Inc. for the registration of 3,000,000 shares of its common stock.

/s/ Ernst & Young LLP
Minneapolis, Minnesota
January 28, 2013

Exhibit 24.1

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David A. Rosa and Jeffrey Mathiesen and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement and any and all additional registration statements pursuant to Rule 462(b) of the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or either of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities indicated below on January 28, 2013.

Signature	Title
/s/ David A. Rosa David A. Rosa	President & Chief Executive Officer (Principal Executive Officer) and Director
/s/ Jeffrey Mathiesen Jeffrey Mathiesen	Chief Financial Officer (Principal Financial and Accounting Officer)
/s/ Paul Buckman Paul Buckman	Director
/s/ Geoffrey Brooke Geoffrey Brooke	Director
/s/ William Peters, M.D. William Peters, M.D.	Director
/s/ Donal O' Dwyer Donal O' Dwyer	Director
/s/ Gregory Waller Gregory Waller	Director
/s/ John Erb John Erb	Director