Filed Pursuant to Rule 424(b)(4)
Registration No. 333-182727
Registration No. 333-183202

2,875,000 Shares
Common Stock
$7.00 per share

We are selling 2,875,000 shares of our common stock. We have granted the underwriters a 30-day option to purchase up to an additional 431,250 shares from us to cover over-allotments, if any.

In accordance with a securities purchase agreement, dated February 6, 2012, by and among us and the purchasers party thereto, within 30 days after the closing of this offering, we will offer to sell those purchasers an aggregate of 25% of the number of shares sold in this offering plus the number of shares offered pursuant to the preemptive rights granted under the February 2012 securities purchase agreement, with the number of shares each purchaser will have a right to purchase being based on the purchaser's pro rata portion of the total number of shares sold pursuant to the February 2012 securities purchase agreement. Any sales made pursuant to these preemptive rights must be completed within 60 days of the date we provide notice to the purchasers of the transaction giving rise to their preemptive right thereunder. Any sales we make pursuant to the February 2012 securities purchase agreement as a result of this offering will be on the same terms and conditions as this offering. We intend to file with the Securities and Exchange Commission, or SEC, and have declared effective, a registration statement covering all shares we sell pursuant to any exercise of these preemptive rights. 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.

This is a public offering of our common stock. Our common stock is listed on the Nasdaq Capital Market under the symbol "SSH." The closing price of our common stock on the Nasdaq Capital Market on August 9, 2012 was $8.20 per share.

WE ARE AN "EMERGING GROWTH COMPANY" UNDER THE U.S. FEDERAL SECURITIES LAWS AND WILL BE SUBJECT TO REDUCED PUBLIC COMPANY REPORTING REQUIREMENTS. INVESTING IN OUR COMMON STOCK INVOLVES RISKS. SEE "RISK FACTORS" BEGINNING ON PAGE 8.

	Per Share	Total
Public offering price	$ 7.00	$ 20,125,000
Underwriting discount[(1)]	$ 0.49	$ 1,408,750
Proceeds, before expenses, to us	$ 6.51	$ 18,716,250

(1) In addition to the underwriters' discount paid by us, we have also committed to reimburse the underwriters for certain expenses up to an aggregate of $125,000. See "Underwriting."

The underwriters expect to deliver the shares of our common stock on or about August 15, 2012.

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

Sole Book-Running Manager

Canaccord Genuity

Co-Managers

Lazard Capital Markets

Cowen and Company

Craig-Hallum Capital Group

Northland Capital Markets

The date of this prospectus is August 9, 2012.

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You should rely only on the information contained in this prospectus and any free-writing prospectus that we authorize to be distributed to you. We have not, and the underwriters have not, authorized any other person to provide you with information different from that contained in this prospectus or any related free-writing prospectus that we authorize to be distributed to you. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any state where the offer or sale is not permitted. The information in this prospectus speaks only as of the date of this prospectus unless the information specifically indicates that another date applies, regardless of the time of delivery of this prospectus or of any sale of our common stock.

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.

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

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

PROSPECTUS SUMMARY

Investing in our common stock involves a high degree of risk. We believe the risks described under the caption "Risk Factors" below and elsewhere in this prospectus are the material risks we face. However, these risks may not be the only risks we face. Additional unknown risks or risks that we currently consider immaterial may also impair our business operations. If any of the events or circumstances described actually occurs, our business, financial condition or results of operations could suffer, and the trading price of our common stock could decline significantly. Investors should consider the specific risk factors discussed under the caption "Risk Factors" below and elsewhere in this prospectus, together with the "Special Note Regarding Forward-Looking Statements" and the other information contained in this prospectus, including our financial statements and the related notes, before investing in our common stock.

Our Business

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. We expect to submit an IDE application to the FDA in the second half of 2012 for approval to initiate our pivotal trial. 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 $6.7 million in the six months ended June 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 wit 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 throughou 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 device 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 th 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 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:

- plan for the commercial launch of the C-Pulse System in Europe;
- obtain IDE approval for our pivotal trial in the United States;
- conduct a pivotal trial in the United States;
- conduct trials in Europe to support reimbursement of the C-Pulse System; 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 t 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 coul 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 failu 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. A summary of the results from the six-month follow-up data as well as the twelve-month data, which became available in June 2012, can be found under "Business—Clinical Development" beginning on page 46 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 indication 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. We currently anticipate that we will have pivotal trial IDE approval in 2012, begin enrollment promptly thereafter, and complete our pivotal trial enrollment by the end of 2015. In July 2012, we obtained CE Mark approval for the C-Pulse System and completed a two-year follow-up fo a patient implanted with our system during our feasibility 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, representin 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 websit 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 ma 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 offered by us	2,875,000 shares of our common stock, par value $0.0001 per share.
Common stock to be outstanding immediately after this offering	9,152,538 shares
Over-allotment option	We have granted the underwriters an option to purchase up to an additional 431,250 shares of common stock within 30 days of the date of this prospectus in order to cover over-allotments, if any.
Use of proceeds	We estimate that the net proceeds to us from this offering, after deducting underwriting discounts and estimated offering expenses, will be approximately $18.0 million. We intend to use approximately $300,000 of the net proceeds from this offering to repay outstanding indebtedness owed to our outside legal counsel (see "Legal Matters") and the remainder of the net proceeds to fund our pivotal clinical trial and for general corporate purposes. General corporate purposes may include providing working capital and funding capital expenditures and research and development. See "Us of Proceeds."
	In addition, if the purchasers under our securities purchase agreement dated February 6, 2012 elect to purchase all shares we must offer them pursuant to that agreement, we would issue in the future pursuant to a separate registration statement, an additional 958,333 shares of our common stock and generate additional net proceeds of approximately $6.7 million. We intend to use any proceeds from sales of any additional shares pursuant to the February 2012 securities purchase agreement to fund our pivotal clinical trial and for general corporate purposes. We cannot determine at this time hov many shares, if any, the purchasers under the February 2012 securities purchase agreement will purchase pursuant to their preemptive rights thereunde
Nasdaq Capital Market symbol	SSH

The number of shares of our common stock outstanding after this offering is based on 6,277,538 shares outstanding as of July 20, 2012. The number of shares of our common stock outstanding as of that date excludes (a) 892,642 shares of common stock issuable upon the exercise of outstanding options to purchase our commo stock at a weighted average exercise price of $10.05 per share, (b) 1,564,649 shares of common stock issuable upon the exercise of outstanding warrants at a weighte average exercise price of A$7.49 per share (approximately $7.66 per share based on a conversion rate of A$1 to $1.0231) and (c) 123,820 shares of common stock reserved for future grants under our Amended and Restated 2011 Equity Incentive Plan, or 2011 Equity Incentive Plan.

Except as otherwise indicated, information in this prospectus:

- reflects a 1-for-200 reverse split of our outstanding common stock that was effected on January 27, 2012;
- assumes no exercise of the underwriters' over-allotment option to purchase up to 431,250 additional shares of our common stock from us; and
- assumes no exercise of the preemptive rights granted to the purchasers under our securities purchase agreement dated February 6, 2012.

RISK FACTORS

Our business faces many risks. We believe the risks described below are the material risks we face. However, the risks described below may not be the only risks we face. Additional unknown risks or risks that we currently consider immaterial may also impair our business operations. If any of the events or circumstances described below actually occurs, our business, financial condition or results of operations could suffer, and the trading price of our shares of common stock could decline significantly. Investors should consider the specific risk factors discussed below, together with the "Special Note Regarding Forward-Looking Statements" and the other information contained 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 $6.7 million for the six months ended June 30, 2012. As of June 30, 2012, our accumulated deficit was $71.9 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 completion of this offering 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. We expect to submit an IDE application to the FDA in the second half of 2012 for approval to initiate our pivotal trial. 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;
- 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.

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:

- 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.

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. We expect to submit an IDE application to the FDA in the second half of 2012 for approval to initiate our pivotal trial. 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 pivotal trial, we will need to receive approval from regulatory agencies in each country 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 2012, but there can be no assurance that our U.S. pivotal trial will begin or be completed on schedule or at all. Even if completed, we do not know if this trial will 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 2012. The trial will be designed to be a randomized trial that includes approximately 380 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 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.

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 *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 June 30, 2012, we owned 12 issued patents in the United States and 8 patent applications in the United States, as well as 23 issued patents and 15 patent applications in foreign jurisdictions. We estimate that the U.S. patents 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 and This Offering

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 June 30, 2012 was approximately 950 shares, and for the period from July 1, 2012 to July 27, 2012, was approximately 557,326 shares. The reported average daily trading volume in our common stock on the ASX for the three-month period ended June 30, 2012, was approximately 430,591 CDIs (equivalent to approximately 2,513 shares), and for the period from July 1, 2012 to July 27, 2012, was approximately 2,683,738 CDIs (equivalent to approximately 13,419 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.

Future sales of our common stock could cause our stock price to decline.

If our stockholders sell substantial amounts of our common stock in the public market, the market price of our common stock could decrease significantly. The perception in the public market that we or our stockholders might sell shares of our common stock or CDIs could also depress the market price of our common stock. 2,833,887 shares of our common stock that will be outstanding immediately after completion of this offering will become eligible for sale in the public markets from time to time, subject to restrictions under the Securities Act of 1933 following the expiration of lock-up agreements entered into for the benefit of the underwriters by the holders of the common stock, including our directors and executive officers. The underwriters may, in their sole discretion and at any time or from time to time, release all or any portion of the shares of common stock subject to the lock-up agreements for sale in the public and private markets prior to the expiration of the lock-up. The market price for shares of our common stock may drop significantly when the restrictions on resale by our existing stockholders lapse or if those restrictions on resale are waived. A decline in the price of shares of our common stock might impede our ability to raise capital through the issuance of additional shares of our common stock or other equity securities.

In addition, pursuant to the securities purchase agreement, dated February 6, 2012, by and among us and the purchasers party thereto, prior to offering any equity, equity based and related securities, convertible

securities, debt, preferred stock or purchase rights during the one-year period following the closing of the transactions contemplated by the agreement, or within 30 days after the closing of any sale of these securities during that period, we must offer to issue to the purchasers under the securities purchase agreement, on the terms we are offering the securities to third parties, an aggregate of 25% of the securities we are offering. This right could result in us selling securities to purchasers under the securities purchase agreement, including in connection with this offering, at prices that are lower than the then-prevailing market price at the time of sale pursuant to the securities purchase agreement. This could result in dilution to our existing stockholders, including stockholders who purchase shares in this offering, and cause the price of our common stock to decline.

We also plan to file with the SEC registration statements on Form S-8 covering approximately 1 million shares of our common stock issuable under our equity plans. Once registered with the SEC, these shares of common stock would be freely tradable in the United States when issued pursuant to our equity plans and the related award agreements. In addition, we may sell additional shares of common stock in subsequent offerings to raise additional funding.

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 $2.75 to $17.25 for the period from July 1, 2012 to July 27, 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 $4.30 per share using a conversion rate of A$1 to $1.0231) to A$0.058 (equivalent to approximately $11.87 per share using a conversion rate of A$1 to $1.0231) for the period from July 1, 2012 to July 27, 2012. The price of our common stock could fluctuate significantly for many reasons, including the following:

- future announcements concerning us or our competitors;
- 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 July 20, 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 July 20, 2012), approximately 52.0% 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.

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 significant deficiencies or 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 significant deficiencies or 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.

If you purchase the common stock sold in this offering, you will experience immediate dilution in your investment.

The public offering price per share of common stock in this offering exceeds the net tangible book value per share of our common stock outstanding prior to this offering. As a result of this offering by us of 2,875,000 shares, and after deducting the underwriting discount and estimated offering expenses payable by us, you will experience immediate dilution of $4.96 per share, representing the difference between our as adjusted net tangible book value per share as of June 30, 2012 after giving effect to this offering, and the public offering price. You will experience additional dilution if the underwriters exercise their over-allotment option. In addition, if the purchasers under the securities purchase agreement, dated February 6, 2012, by and among us and the purchasers party thereto exercise their preemptive rights in connection with this offering, we could be required to sell shares of our common stock to those purchasers at the price to the public in this offering, which could be less than the market price of our common stock at the time of sale to those purchasers, which could result in dilution to purchasers in this offering and cause the price of our common stock to decline.

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 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. Forward-looking statements are not a guarantee of future performance or results, and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. Forward-looking statements are based on information available at the time the statements are made and involve known and unknown risks, uncertainties and other factors that may cause our results, levels of activity, performance or achievements to be materially different from the information expressed or implied by the forward-looking statements in this prospectus. These factors include:

- our ability to obtain additional financing;
- our dependence on a single product candidate;
- the cost, timing and results of our clinical trials, regulatory submissions and approvals;
- our dependence on a single or limited number of manufacturers and suppliers for critical components of our system;
- our ability to effectively manage our expected growth;
- our ability to develop sales, marketing and distribution capabilities;
- commercial acceptance of our system in jurisdictions where it is approved for sales and marketing;
- our estimates regarding our capital requirements and our need for additional financing;
- our ability to obtain adequate reimbursement from governments or other third-party payors;
- regulatory risks affecting us;
- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patent or other intellectual property rights or that our system is defective;
- our ability to protect and enforce our intellectual property rights; and
- other risk factors included under "Risk Factors" in this prospectus.

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

USE OF PROCEEDS

We estimate we will receive net proceeds from this offering of approximately $18.0 million, after deducting underwriting discounts and estimated offering expenses payable by us.

We intend to use approximately $300,000 of the net proceeds from this offering to repay outstanding indebtedness to our outside legal counsel (see "Legal Matters") and the remainder of the net proceeds to fund our pivotal clinical trial and for general corporate purposes. General corporate purposes may include providing working capital and funding capital expenditures and research and development. Other than the payment of outstanding indebtedness to our outside legal counsel, as of the date of this prospectus, we cannot specify with certainty all of the particular uses of the proceeds from this offering.

In addition, if the purchasers under our securities purchase agreement dated February 6, 2012 elect to purchase all shares we must offer them pursuant to that agreement, we estimate we would generate additional net proceeds of approximately $6.7 million. We intend to use any proceeds from the sale of any additional shares pursuant to the February 2012 securities purchase agreement to fund our pivotal clinical trial and for general corporate purposes. 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.

PRICE RANGE OF COMMON STOCK

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 (through August 9, 2012)	n/a	n/a	17.25	2.75

On August 9, 2012, the closing price of our common stock on the Nasdaq Capital Market was $8.20. As of July 20, 2012, we had 6,277,538 shares of common stock issued and outstanding, and there were 31 holders of record of our common stock.

DIVIDEND POLICY

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

DETERMINATION OF OFFERING PRICE

Our common stock is currently listed on the Nasdaq Capital Market. However, our underwriters are not obligated to make a market in our securities, and even if they choose to make a market, they can discontinue at any time without notice. Neither we nor the underwriters can provide any assurance that an active and liquid trading market in our securities will develop further or, if developed further, that the market will continue.

The public offering price of the securities offered by this prospectus was determined by negotiation between us and the underwriters. Among the factors considered in determining the public offering price of the shares were:

- our history and our prospects;
- the industry in which we operate;
- our past and present operating results;
- recent trading prices of our common stock on the Nasdaq Capital Market and of our CDIs on the ASX;
- the previous experience of our executive officers; and
- the general condition of the securities markets at the time of this offering.

The offering price stated on the cover page of this prospectus should not be considered an indication of the actual value of the shares. That price is subject to change as a result of market conditions and other factors, and we cannot assure you that the shares can be resold at or above the public offering price.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of June 30, 2012:

- on an actual basis; and
- on a pro forma as adjusted basis to give effect to our sale of 2,875,000 shares of common stock, after deducting the underwriting discounts and estimated offering expenses payable by us.

You should read this table in conjunction with "Use of Proceeds" above as well as our "Management's Discussion and Analysis of Financial Condition and Results of Operations" and financial statements and the related notes appearing elsewhere in this prospectus.

	As of June 30, 2012	
	Actual	Pro Forma
	(in thousands, except share data)	
Cash and cash equivalents	$ 1,772	$ 19,763
Stockholders' equity:		
Common stock, $0.0001 par value, 100,000,000 shares authorized, 6,277,538 issued and outstanding actual as of June 30, 2012, 9,152,538 pro forma	1	1
Additional paid-in capital	71,341	89,332
Accumulated other comprehensive loss:		
Foreign currency translation adjustment	1,195	1,195
Accumulated deficit	(71,892)	(71,892)
Total stockholders' equity	$ 645	$ 18,636
Total capitalization	$ 645	$ 18,636

The table and calculations above are based on the number of shares of common stock outstanding as of June 30, 2012, and exclude:

- an aggregate of 892,642 shares issuable upon the exercise of then outstanding options at a weighted average exercise price of $10.05 per share;
- an aggregate of 1,564,649 shares issuable upon the exercise of then outstanding warrants at a weighted average exercise price of A$7.49 per share (approximately $7.66 using a conversion rate of A$1.00 to $1.0231);
- an aggregate of 123,820 shares available for future grants under our 2011 Equity Incentive Plan;
- the 431,250 shares of common stock subject to the underwriters' over-allotment option; and
- any shares of common stock we might sell pursuant to the preemptive rights granted to the purchasers under our securities purchase agreement dated February 6, 2012.

DILUTION

If you invest in our common stock, 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 net tangible book value per share of our common stock immediately after completion of this offering. Net tangible book value per share represents total tangible assets less total liabilities, divided by the number of shares of common stock outstanding. As of June 30, 2012, the net tangible book value of our common stock was approximately $0.6 million, or approximately $0.10 per share.

After giving effect to our sale of 2,875,000 shares, deducting underwriting discounts and estimated offering expenses payable by us, and applying the net proceeds from this sale, the pro forma net tangible book value of our common stock would have been approximately $18.6 million, or $2.04 per share, as of June 30, 2012. This amount represents an immediate increase in net tangible book value to our existing stockholders of $1.94 per share and an immediate dilution to new investors of $4.96 per share.

The following table illustrates this per share dilution:

Public offering price per share		$ 7.00
Net tangible book value per share as of June 30, 2012	$ 0.10	
Pro forma increase per share attributable to new investors	$ 1.94	
Pro forma net tangible book value per share after this offering		$ 2.04
Dilution per share to new investors		$ 4.96

If the underwriters exercise in full their over-allotment option to purchase 431,250 shares of common stock offered in this offering, the pro forma net tangible book value after this offering would be approximately $21.4 million, representing an increase in net tangible book value of $2.13 per share to existing stockholders and immediate dilution in net tangible book value of $4.77 per share to new investors purchasing our common stock in this offering.

To the extent that any outstanding options or warrants are exercised or the purchasers under the February 2012 securities purchase agreement exercise their 60-day purchase right in connection with this offering, investors will experience further dilution.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this prospectus. Our actual results *could differ materially from those anticipated in the forward-looking statements included in this discussion as a result of certain factors, including, but not limited to, those discussed in "Risk Factors" and "Special Note Regarding Forward-Looking Statements" included elsewhere in this prospectus.*

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. We expect to submit an IDE application to the FDA in the second half of 2012 for approval to initiate our pivotal trial. 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 potential market for our system in targeted countries in Europe 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 and we have not commenced sales of our C-Pulse system outside of the United States. Our revenue consists 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. 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 expense shipping costs at the time we report the related revenue and record such costs in cost of sales.

Foreign Currency Translation and Transactions: Foreign denominated monetary assets and liabilities are translated at the rate of exchange prevailing at the balance sheet date. Results of operations are translated using the average rates prevailing during the reporting period. Our Australian subsidiary's functional currency is the Australian Dollar. Translation adjustments result from translating the subsidiary's

financial statements into our reporting currency, the U.S. Dollar. The translation adjustment has not been included in determining our net loss, but has been reported separately and is accumulated in a separate component of equity.

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

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

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

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

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

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

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

During the years ended December 31, 2011 and 2010 and through June 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 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: As noted above, 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 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. 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 them retrospectively for all periods presented. There was no impact to our consolidated results as the amendments related only to changes in financial statement presentation.

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 June 30, 2012, we had an accumulated deficit of $71.9 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 June 30, 2012 to Three Months Ended June 30, 2011

Revenue

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

Sales of the C-Pulse System to hospitals and clinics pursuant to research arrangements and with the appropriate regulatory approvals for sales in conjunction with our feasibility clinical trial historically have generated our revenue. We did not have any sales of our C-Pulse System device in the three month periods ended June 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 second half of 2012.

Research and Development Expense

Three Months Ended June 30, 2012	Three Months Ended June 30, 2011	Increase (Decrease)	% Change
$ 1,787,000	$ 2,374,000	$ (587,000)	(24.7)%

Our decrease in research and development expense for the three months ended June 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 System period to period. We expect our research and development expense will continue to be lower than the comparable prior year period in the third quarter 2012, then sequentially increase as we add personnel to support our pivotal clinical trial and pursue our development efforts.

Selling, General and Administrative Expense

Three Months Ended June 30, 2012	Three Months Ended June 30, 2011	Increase (Decrease)	% Change
$ 1,569,000	$ 1,178,000	$ 391,000	33.2%

Our increase in selling, general and administrative expense for the three months ended June 30, 2012 compared to the prior year was primarily caused by increased stock-based compensation expense resulting from current-year stock option grants, and increased professional fees and personnel additions in 2011 as we developed our infrastructure, and in preparation for European trials expected to commence in the second half of 2012. 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 June 30, 2012	Three Months Ended June 30, 2011	Increase (Decrease)	% Change
$ 4,000	$ 80,000	$ (76,000)	(95)%

Our decrease in interest income for the three months ended June 30, 2012 compared to the prior year was primarily caused by lower average cash balances during the three months ended of June 30, 2012 as compared to June 30, 2011.

Income Tax Benefit

Three Months Ended June 30, 2012	Three Months Ended June 30, 2011	Increase (Decrease)	% Change
$ (730,000)	$ —	$ (730,000)	N/A%

Our income tax benefit for the three months ended June 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 quarter. 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. At this time, we are working to complete our analysis

of the potential research and development tax credit refund that may be available for the period ended June 30, 2012.

Comparison of Six Months Ended June 30, 2012 to Six Months Ended June 30, 2011

Revenue

Six Months Ended June 30, 2012	Six Months Ended June 30, 2011	Increase (Decrease)	% Change
$ —	$ —	$ —	N/A

Sales of the C-Pulse System to hospitals and clinics pursuant to research arrangements and with the appropriate regulatory approvals for sales in conjunction with our feasibility clinical trial historically have generated our revenue. We did not have any sales of our C-Pulse System device in the six month periods ended June 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 second half of 2012.

Research and Development Expense

Six Months Ended June 30, 2012	Six Months Ended June 30, 2011	Increase (Decrease)	% Change
$ 3,953,000	$ 4,666,000	$ (713,000)	(15.3)%

Our decrease in research and development expense for the six months ended June 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 System period to period. We expect our research and development expense will continue to be lower than the comparable prior year period in the third quarter 2012, then sequentially increase as we add personnel to support our pivotal clinical trial and pursue our development efforts.

Selling, General and Administrative Expense

Six Months Ended June 30, 2012	Six Months Ended June 30, 2011	Increase (Decrease)	% Change
$ 3,509,000	$ 1,820,000	$ 1,689,000	92.8%

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

Six Months Ended June 30, 2012	Six Months Ended June 30, 2011	Increase (Decrease)	% Change
$ 29,000	$ 197,000	$ (168,000)	(85.3)%

Our decrease in interest income for the six months ended June 30, 2012 compared to the prior year was primarily caused by lower average cash balances during the six months ended June 30, 2012 as compared to the six months ended June 30, 2011.

Income Tax Benefit

Six Months Ended June 30, 2012	Six Months Ended June 30, 2011	Increase (Decrease)	% Change
$ (730,000)	$ —	$ (730,000)	N/A

Our income tax benefit for the six months ended June 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 quarter. 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. At this time, we are working to complete our analysis of the potential research and development tax credit refund that may be available for the period ended June 30, 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.

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 in the form of CDIs for net proceeds of $7.6 million in 2011, $11.9 million in 2010 and $2.1 million in the six months ended June 30, 2012. As of June 30, 2012 and December 31, 2011 and 2010, cash and cash equivalents were $1.8 million, $6.6 million, and $12.4 million, respectively.

We believe, based on our current operating plan, that the net proceeds from this offering, together with our cash balances, cash generated from our clinical trial and interest income, will be sufficient to meet our anticipated cash requirements through at least the next 12 months. 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 or convertible debt securities may result in dilution to our stockholders. If we raise additional funds through the issuance of 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.

Cash Flows from Operating Activities

Net cash used in operating activities was $13.1 million in 2011, $7.2 million in 2010, and $6.8 million and $6.2 million in the six months ended June 30, 2012 and 2011, respectively. The net cash used in each

of these periods primarily reflects the net loss for those periods, offset in part by depreciation, non-cash, stock-based compensation and the effects of changes in operating assets and liabilities.

Cash Flows from Investing Activities

Net cash used in investing activities was $451,000 in 2011, $7,000 in 2010, and $107,000 and $43,000 in the six months ended June 30, 2012 and 2011, respectively. The majority of cash used in investing activities in first half of 2012 and in 2011 was for leasehold improvements, furniture and equipment associated with the relocation of our headquarters. Cash used in investing activities in 2011 and in 2010 related to purchases of property and equipment.

Cash Flows from Financing Activities

Net cash provided by financing activities was $7.6 million in 2011, $11.9 million in 2010, and $2.1 million and $183,000 in the six months ended June 30, 2012 and 2011, respectively. Net cash provided by financing activities was primarily attributable to proceeds from sales of our common stock and warrants.

Capital Resource Requirements

As of June 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.

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. We expect to submit an IDE application to the FDA in the second half of 2012 for approval to initiate our pivotal trial. 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 $6.7 million in the six months ended June 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:

- **Plan 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.

- **Obtain IDE Approval for our 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. We anticipate that we will submit an IDE application to the FDA in the second half of 2012 and complete enrollment of our pivotal trial by the end of 2015.

- **Conduct Trials 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.

- **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.

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 two additional patients and currently do not have plans to implant any additional patients in the United States because the FDA notified us in March 2012 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 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 Hall Walk (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 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.

We submitted our pre-IDE in March 2012 and expect to submit an application for an IDE to the FDA in the second half of 2012 for approval to initiate our U.S. pivotal trial. Once the IDE application has been filed, the FDA, following its review, will notify us that the IDE application has been either unconditionally approved, approved with certain conditions or that there exist deficiencies in the application that must be addressed prior to approval. If the FDA identifies deficiencies, we will be provided the opportunity to submit additional information to the FDA to respond to the filing deficiencies. It is common for the FDA to require additional information before approving an IDE. We currently anticipate that we will have pivotal trial IDE approval in 2012, begin enrollment promptly thereafter, and complete our pivotal trial enrollment by the end of 2015.

Research and Development

Our research and development expense totaled $4.0 million for the six months ended June 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.

- 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 pivotal clinical trial in the second half of 2012, 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.

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 June 30, 2012, our portfolio consisted of 35 issued patents, of which 12 were issued in the United States and 23 were issued in other countries. We also had 23 patent applications pending, including 8 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, 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 June 30, 2012 we had 25 employees, consisting of 23 full-time and two part-time employees. None of our employees are covered by a collective bargaining agreement. We consider relations with our employees to be good.

Properties

We lease a 10,000 square foot facility in Eden Prairie, Minnesota that previously housed our corporate headquarters and substantially all of our functional areas, with the exception of a portion of our research and development activities. The lease expires September 30, 2012 and requires a monthly payment of approximately $11,000. On October 21, 2011 we entered into a lease for a 23,000 square foot facility also located in Eden Prairie, Minnesota. The lease period commenced December 1, 2011 and extends through March 31, 2016. This facility houses substantially all of our functional areas and replaced our corporate headquarters previously located at the other facility we lease in Eden Prairie. Monthly rent and electricity for our new headquarters total approximately $21,000.

Legal Proceedings

We are not currently involved in any material legal proceedings.

MANAGEMENT

Executive Officers and Directors

The following table sets forth information concerning our directors and executive officers as of August 9, 2012:

Name	Age	Position
David Rosa	48	Director; Chief Executive Officer
Kevin Bassett	44	Senior Vice President, Technology & Operations
Debra Kridner	60	Vice President Research & Regulatory Affairs
Jim Yearick	50	Vice President Marketing & Sales
Jeffrey Mathiesen	51	Chief Financial Officer and Secretary
Nicholas Callinan	66	Chairman of the Board, Director
Paul Buckman	56	Director
Dr. Geoffrey Brooke	56	Director
Dr. Mark Harvey	46	Director
Donal O'Dwyer	59	Director
Dr. William Peters	46	Director; Chief Technical Officer & Medical Director
Gregory Waller	62	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 Vice President of Clinical Research and Regulatory Affairs, a position she has held since November 2009 on a consultant basis and since March 2010 as an employee of our company. From 2008 to 2009, Ms. Kridner worked as a consultant for her company Kridner Consulting LLC, which performed consulting services for medical device companies. From 2004 to 2008, Ms. Kridner served as the Vice President of Clinical Research, Quality and Regulatory Affairs for St. Jude Medical's Cardiac Surgery and Interventional Cardiology for the Cardiovascular Division.

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

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

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

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.

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

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

Donal O'Dwyer: Director since July 2004. Mr. O'Dwyer retired as worldwide President of Cordis Cardiology, the cardiology division of the Johnson & Johnson subsidiary, in 2003. Cordis is a developer and manufacturer of breakthrough stents, catheters and guidewires for interventional medicine, minimally invasive computer-based imaging, and electrophysiology. Prior to joining Cordis, Mr. O'Dwyer served as President of the Cardiovascular Group, Europe of Baxter International Inc., a global 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.

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

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

Director Independence

Our board of directors currently consists of eight directors. Our board of directors has determined that six of our eight directors are independent directors, as defined under the applicable rules of the Nasdaq Stock Market. The independent directors are Messrs. Buckman, Brooke, Callinan, Harvey, O'Dwyer, 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
Nicholas Callinan	X	X	X
Mark Harvey		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	12/31/11	51,375	125,939	177,314
	6/30/11	103,234	—	103,234
Dr. Mark Harvey[3]	12/31/11	12,649	76,887	89,536
	6/30/11	—	—	—
Crispin Marsh[4]	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[5]	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.

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

(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.

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 July 20, 2012, Mr. Rosa beneficially owned approximately 1.7% 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 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.

	Option Awards			
Name	Number of Securities Underlying Unexercised Options(#) Exercisable	Number of Securities Underlying Unexercised Options(#) Unexercisable	Option Exercise Price ($)[1]	Option Expiration Date
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.

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

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.

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information with respect to the beneficial ownership of our outstanding common stock as of July 20, 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 6,277,538 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	1,448,356(2)	22.2%
Paul Buckman	4,382(3)	*
Nicholas Callinan	54,349(4)	*
Dr. Mark Harvey	1,880,439(5)	28.2%
Jeffrey Mathiesen	38,404(6)	*
Donal O'Dwyer	63,682(7)	1.0%
Dr. William Peters	90,834(8)	1.4%
David Rosa	106,156(9)	1.7%
Gregory Waller	3,165(10)	*
All directors, director nominees, named executive officers and other executive officers as a group (12 persons)	3,724,614(11)	52.0%
5% Stockholders:		
GBS Venture Partners Pty Ltd	1,443,671(12)	22.1%
Funds affiliated with CM Capital	1,877,498(13)	28.2%
Persons affiliated with Straus & Partners	653,057(14)	10.7%
New Emerging Medical Opportunities Fund LP	406,250(15)	6.4%

* Less than 1%.

(1) Based on 6,277,538 shares outstanding as of July 20, 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; 4,685 shares subject to outstanding options exercisable within 60 days of July 20, 2012; and 248,910 shares subject to outstanding warrants held by GBS exercisable within 60 days of July 20, 2012. Dr. Brooke is a managing director of GBS Venture Partners Pty Ltd which manages GBS Bioventures II/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 4,382 shares subject to outstanding options exercisable within 60 days of July 20, 2012.

(4) Includes 29,647 shares owned by Beraleigh Pty Ltd. and 17,202 shares subject to outstanding options exercisable within 60 days of July 20, 2012; and 7,500 shares subject to outstanding warrants held by Beraleigh Pty Ltd. exercisable within 60 days of July 20, 2012. Mr. Callinan is a director of Beraleigh Pty Ltd.

(5) Includes 750 shares owned by Dr. Harvey's pension fund, for which he has the power to make investment and voting decisions; 1,500,712 shares owned by venture capital funds affiliated with CM Capital; 376,786 outstanding warrants held by CM Capital and its affiliated funds exercisable within 60 days of July 20, 2012 and 2,191 shares subject to outstanding options exercisable within 60 days of July 20, 2012. Dr. Harvey shares voting and investment power with other partners and may be deemed to be a beneficial owner of the reported securities. Dr. Harvey disclaims indirect beneficial ownership of the reported securities except to the extent of his pecuniary interest. This report shall not be deemed an admission that Dr. Harvey is the beneficial owner of such securities for purposes of Section 16 or for any other purpose.

(6) Includes 11,875 shares held by UBS which is Mr. Mathiesen's IRA account and 2,500 shares owned by Mr. Mathiesen. Includes 19,716 shares subject to outstanding options exercisable within 60 days of July 20, 2012; and 4,313 shares acquirable on exercise of outstanding warrants exercisable within 60 days of July 20, 2012.

(7) 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 4,685 shares subject to outstanding options exercisable within 60 days of July 20, 2012; and 9,150 shares acquirable on exercise of outstanding warrants exercisable within 60 days of July 20, 2012.

(8) 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; 47,987 shares acquirable upon exercise of outstanding warrants exercisable within 60 days of July 20, 2012; and 2,041 shares subject to outstanding options exercisable within 60 days of July 20, 2012.

(9) Includes 1,000 shares owned by Mr. Rosa, and 105,156 shares subject to outstanding options exercisable within 60 days of July 20, 2012.

(10) Includes 3,165 shares subject to outstanding options exercisable within 60 days of July 20, 2012.

(11) Consists of (i) 2,833,887 shares beneficially owned by the current directors and executive officers; and (ii) 890,727 shares issuable upon exercise of outstanding options or warrants that are exercisable within 60 days of July 20, 2012.

(12) 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 July 20, 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.

(13) Based upon Form 3 filed with the SEC on February 28, 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 July 20, 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.

(14) 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.

(15) Based upon share registry provided to us by our transfer agent, Link Market Services Limited. Includes 93,750 shares subject to outstanding warrants. Jérôme G.P Fund, Director and CEO of Sectoral Asset Management holds investment and voting power over these shares as investment manager for New Emerging Medical Opportunities Fund LP. The address for New Emerging Medical Opportunities Fund LP is 1000 Sherbrooke St. West, #2120, Montreal, QC Canada H3A 3G4.

DESCRIPTION OF CAPITAL STOCK

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 July 20, 2012, we had 6,277,538 shares of our common stock issued and outstanding and we had 31 holders of record of our common stock. As of July 20, 2012, we had outstanding options to acquire 892,642 shares of common stock held by employees, directors, and consultants granted options to purchase our common stock, as well as outstanding warrants to purchase 1,564,649 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.

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.

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.

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:

- 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 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.

SHARES ELIGIBLE FOR FUTURE SALE

A liquid trading market for our common stock may not develop or be sustained after this offering. We cannot predict the effect, if any, that market sales of shares of our common stock or the availability of shares of our common stock for sale will have on the market price of our common stock. Sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options or in the public market after this offering, or the anticipation of these sales, could adversely affect the market prices of our common stock and could impair our future ability to raise capital through the sale of our equity securities.

Upon completion of this offering, based on our outstanding shares as of July 20, 2012, and assuming no exercise of outstanding options or warrants, we will have outstanding an aggregate of 9,152,538 shares of our common stock (9,583,788 shares if the underwriters' over-allotment option is exercised in full). Of these shares, all of the shares sold in this offering (plus any shares sold as a result of the underwriters' exercise of the over-allotment option) will be freely tradable without restriction or further registration under the Securities Act, unless those shares are purchased by our affiliates as that term is defined in Rule 144 under the Securities Act.

The remaining 6,277,538 shares of common stock to be outstanding after this offering will be "restricted securities" under Rule 144. Of these restricted securities, 2,833,887 shares will be subject to transfer restrictions for 90 days from the date of this prospectus pursuant to lock-up agreements. Restricted securities may be sold in the public market only if they have been registered or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act.

Pursuant to a securities purchase agreement, dated February 6, 2012, by and among us and the purchasers party thereto, within 30 days after the closing of this offering, we will offer to sell those purchasers an aggregate of 25% of the number shares sold in this offering plus the number of shares offered under these related preemptive rights, with the number of shares each purchaser will have a right to purchase being based on the purchaser's pro rata portion of the total number of shares sold pursuant to the February 2012 securities purchase agreement. Any sales we make pursuant to the February 2012 securities purchase agreement as a result of this offering will be on the same terms and conditions as this offering. 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 rights thereunder. We intend to file with the SEC and have declared effective, a registration statement covering all shares we sell pursuant to any exercise of these preemptive rights, and any shares we sell pursuant to these rights therefore would not be "restricted securities" under Rule 144.

Lock-up Agreements

All of our officers and directors and the venture capital funds affiliated with two of our directors have entered into lock-up agreements pursuant to which they have agreed, subject to limited exceptions, not to offer, sell or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or securities convertible into or exchangeable or exercisable for shares of common stock for a period of 90 days from the date of this prospectus without the prior written consent of Canaccord Genuity. Canaccord Genuity has advised us that it has no current intent or arrangement to release any of the shares subject to the lock-up agreements prior to the expiration of the lock-up period. There are no contractually specified conditions for the waiver of lock-up restrictions and any waiver is at the sole discretion of Canaccord Genuity, which may be granted by Canaccord Genuity for any reason. The 90-day lock-up period will be automatically extended if (i) during the last 17 days of the 90-day restricted period we issue an earnings release or announce material news or a material event or (ii) prior to the expiration of the 90-day restricted period, we announce

that we will release earnings results during the 16-day period following the last day of the 90-day period, in which case the restrictions described in this paragraph will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the announcement of the material news or material event. After the lock-up period, these shares may be sold, subject to applicable securities laws. See the "Underwriting" section.

Rule 144

In general, and beginning 90 days after the effective date of our Form 10 filed with the SEC, under Rule 144 as in effect on the date of this prospectus, a person who is not one of our affiliates at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months, would be entitled to sell an unlimited number of shares of our common stock provided current public information about us is available and, after owning such shares for at least one year, would be entitled to sell an unlimited number of shares of our common stock without restriction.

Beginning 90 days after the effective date of our Form 10 filed with the SEC, our affiliates who have beneficially owned shares of our common stock for at least six months are entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding; or
- the average weekly trading volume of our common stock on the Nasdaq Capital Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales under Rule 144 by our affiliates are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us. We cannot estimate the number of shares of our common stock that our existing stockholders will elect to sell under Rule 144.

Options and Warrants

As of July 20, 2012, we had outstanding options to purchase 892,642 shares of our common stock, of which options to purchase 276,050 shares were vested, with a weighted average per share exercise price of $10.05 and expiration dates between January 30, 2013 and November 1, 2021. We also had reserved an additional 123,820 shares of common stock for grants pursuant to our 2011 Equity Incentive Plan as of that date. We plan to file registration statements 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 July 20, 2012, warrants to purchase a total of 1,564,649 shares of our common stock were outstanding with a weighted average per share exercise price of A$7.49 (or approximately $7.66 based on a conversion rate of A$1.00 to $1.0231) 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 may be sold in the public market only if registered or pursuant to an exemption from registration, such as Rule 144.

Rule 701

In general, under Rule 701 of the Securities Act as currently in effect, any of our employees, consultants or advisors who purchase shares of our common stock from us pursuant to options granted prior to the completion of this offering under our existing 2011 Equity Incentive Plan or other written agreement is eligible to resell those shares 90 days after the effective date of our Form 10 in reliance on Rule 144, but without compliance with some of the restrictions, including the holding period, contained in Rule 144 and without regard to the volume of such sales or the availability of public information about us.

MATERIAL U.S. FEDERAL TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF OUR COMMON STOCK

The following discussion summarizes certain material U.S. federal income and estate tax considerations relating to the acquisition, ownership and disposition of our common stock purchased pursuant to this offering by a non-U.S. holder (as defined below). This discussion is based on the provisions of the U.S. Internal Revenue Code of 1986, as amended, final, temporary and proposed U.S. Treasury regulations promulgated thereunder and current administrative rulings and judicial decisions, all as in effect as of the date hereof. All of these authorities may be subject to differing interpretations or repealed, revoked or modified, possibly with retroactive effect, which could materially alter the tax consequences to non-U.S. holders described in this prospectus.

There can be no assurance that the IRS will not take a contrary position to the tax consequences described herein or that such position will not be sustained by a court. No ruling from the IRS or opinion of counsel has been obtained with respect to the U.S. federal income or estate tax consequences to a non-U.S. holder of the purchase, ownership or disposition of our common stock.

This discussion is for general information only and is not tax advice. All prospective non-U.S. holders of our common stock should consult their own tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock.

As used in this discussion, the term "non-U.S. holder" means a beneficial owner of our common stock that is not any of the following for U.S. federal income tax purposes:

- an individual who is a citizen or a resident of the United States;
- a corporation or other entity taxable as a corporation for U.S. federal income tax purposes that was created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate whose income is subject to U.S. federal income taxation regardless of its source;
- a trust (a) if a U.S. court is able to exercise primary supervision over the trust's administration and one or more U.S. persons have the authority to control all of the trust's substantial decisions or (b) that has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person; or
- an entity that is disregarded as separate from its owner if all of its interests are owned by a single person described above.

An individual may be treated, for U.S. federal income tax purposes, as a resident of the United States in any calendar year by being present in the United States on at least 31 days in that calendar year and for an aggregate of at least 183 days during a three-year period ending in the current calendar year. The 183-day test is determined by counting all of the days the individual is treated as being present in the current year, one-third of such days in the immediately preceding year and one-sixth of such days in the second preceding year. Residents are subject to U.S. federal income tax as if they were U.S. citizens.

This discussion assumes that a prospective non-U.S. holder will hold shares of our common stock as a capital asset (generally, property held for investment). This discussion does not address all aspects of U.S. federal income and estate taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances. In addition, this discussion does not address any aspect of U.S. state or local or non-U.S. taxes, or the special tax rules applicable to particular non-U.S. holders, such as:

- insurance companies and financial institutions;

- tax-exempt organizations;
- controlled foreign corporations and passive foreign investment companies;
- partnerships or other pass-through entities and investors therein;
- regulated investment companies or real estate investment trusts;
- pension plans;
- persons who received our common stock as compensation;
- brokers and dealers in securities;
- owners that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment; and
- former citizens or residents of the United States subject to tax as expatriates.

If a partnership or other entity treated as a partnership for U.S. federal income tax purposes is a beneficial owner of our common stock, the treatment of a partner in the partnership generally will depend on the status of the partner and the activities of the partnership. We urge any beneficial owner of our common stock that is a partnership and partners in that partnership to consult their tax advisors regarding the U.S. federal income tax consequences of acquiring, owning and disposing of our common stock.

Distributions on Our Common Stock

Any distribution on our common stock paid to non-U.S. holders will generally constitute a dividend 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 our current and accumulated earnings and profits will generally constitute a return of capital to the extent of the non-U.S. holder's adjusted tax basis in our common stock, and will be applied against and reduce the non-U.S. holder's adjusted tax basis. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in "—Gain on Sale, Exchange or Other Disposition of Our Common Stock."

Dividends paid to a non-U.S. holder that are not treated as 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% on the gross amount paid, unless the non-U.S. holder is entitled to an exemption from or reduced rate of withholding under an applicable income tax treaty. In order to claim the benefit of a tax treaty or to claim an exemption from withholding, a non-U.S. holder must provide a properly executed IRS Form W-8BEN (or successor form) prior to the payment of dividends. A non-U.S. holder eligible for a reduced rate of withholding pursuant to an income tax treaty may be eligible to obtain a refund of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS.

Dividends paid to a non-U.S. holder that are treated as effectively connected with a trade or business conducted by the non-U.S. holder within the United States (and, if an applicable income tax treaty so provides, are also attributable to a permanent establishment or a fixed base maintained within the United States by the non-U.S. holder) are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. To obtain the exemption, a non-U.S. holder must provide us with a properly executed IRS Form W-8ECI (or successor form) prior to the payment of the dividend. Dividends received by a non-U.S. holder that are treated as effectively connected with a U.S. trade or business generally are subject to U.S. federal income tax at rates applicable to U.S. persons. A non-U.S. holder that is a corporation may, under certain circumstances, be subject to an additional "branch profits tax" imposed at a rate of 30%, or such lower rate as specified by an applicable income tax treaty between the United States and such holder's country of residence.

A non-U.S. holder who provides us with an IRS Form W-8BEN or Form W-8ECI must update the form or submit a new form, as applicable, if there is a change in circumstances that makes any information on such form incorrect.

Gain On Sale, Exchange or Other Disposition of Our Common Stock

In general, a non-U.S. holder will not be subject to any U.S. federal income tax or withholding on any gain realized from the non-U.S. holder's sale, exchange or other disposition of shares of our common stock unless:

- the gain is effectively connected with a U.S. trade or business (and, if an applicable income tax treaty so provides, is also attributable to a permanent establishment or a fixed base maintained within the United States by the non-U.S. holder), in which case the gain will be taxed on a net income basis generally in the same manner as if the non-U.S. holder were a U.S. person, and, if the non-U.S. holder is a corporation, the additional branch profits tax described above in "Distributions on Our Common Stock" may also apply;

- 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 the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax on the net gain derived from the disposition, which may be offset by U.S.-source capital losses of the non-U.S. holder, if any; or

- we are, or have been at any time during the five-year period preceding such disposition (or the non-U.S. holder's holding period, if shorter), a "U.S. real property holding corporation."

Generally, we will be a "U.S. real property holding corporation" if the fair market value of our U.S. real property interests equals or exceeds 50% of the sum of the fair market values of our worldwide real property interests and other assets used or held for use in a trade or business, all as determined under applicable U.S. Treasury regulations. We believe that we have not been and are not currently, and do not anticipate becoming in the future, a "U.S. real property holding corporation" for U.S. federal income tax purposes.

Backup Withholding and Information Reporting

We must report annually to the IRS and to each non-U.S. holder the amount of distributions paid to such holder and the amount of tax withheld, if any. Copies of the information returns filed with the IRS to report the distributions and withholding may also be made available to the tax authorities in a country in which the non-U.S. holder is a resident under the provisions of an applicable income tax treaty or agreement.

The United States imposes a backup withholding tax on the gross amount of dividends and certain other types of payments (currently at a rate of 28%). Dividends paid to a non-U.S. holder will not be subject to backup withholding if proper certification of foreign status (usually on IRS Form W-8BEN) is provided, and we do not have actual knowledge or reason to know that the non-U.S. holder is a U.S. person. In addition, no backup withholding or information reporting will be required regarding the proceeds of a disposition of our common stock made by a non-U.S. holder within the United States or conducted through certain U.S. financial intermediaries if we receive the certification of foreign status described in the preceding sentence and we do not have actual knowledge or reason to know that such non-U.S. holder is a U.S. person or the non-U.S. holder otherwise establishes an exemption. Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Backup withholding is not an additional tax. Amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that certain required information is furnished to the IRS in a timely manner.

Foreign Account Tax Compliance Act

The Foreign Account Tax Compliance Act, commonly referred to as FATCA, which was ended in 2010, will generally impose a withholding tax of 30% on dividends and the gross proceeds from sales or other dispositions of our common stock paid to a "foreign financial institution" unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which would include certain account holders that are foreign entities with U.S. owners). This legislation will also generally impose a withholding tax of 30% on dividends and the gross proceeds from sales or other dispositions of our common stock paid to a "non-financial foreign entity" unless such entity provides the withholding agent with a certification identifying the direct and indirect U.S. owners of the entity. These withholding taxes could potentially be imposed on dividends paid on our common stock after December 31, 2013, and on gross proceeds from sales or other dispositions of our common stock after December 31, 2014. Under certain circumstances, a holder of our common stock may be eligible for a refund or credit of such taxes. All prospective investors should consult with their own tax advisors regarding the possible implications of this legislation on their investment in our common stock.

U.S. Federal Estate Tax

An individual non-U.S. holder who is treated as the owner, or who has made certain lifetime transfers, of an interest in our common stock will be required to include the value of the common stock in his or her gross estate for U.S. federal estate tax purposes, and may be subject to U.S. federal estate tax unless an applicable estate tax treaty provides otherwise.

UNDERWRITING

We are offering the shares of common stock described in this prospectus through a number of underwriters. Canaccord Genuity Inc. is acting as sole book-running manager of the offering and as representative of the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has agreed, severally and not jointly, to purchase, the number of shares indicated next to its name in the following table:

Underwriters	Number of Shares
Canaccord Genuity Inc.	1,351,250
Lazard Capital Markets LLC	646,875
Cowen and Company, LLC	503,125
Craig-Hallum Capital Group LLC	258,750
Northland Capital Markets	115,000
Total	2,875,000

The underwriters are offering the common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the underwriters to pay for and accept delivery of the common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriting agreement provides that the underwriters are obligated to take and pay for all of the common stock if any such shares are purchased, other than those shares covered by the over-allotment option described below.

The underwriters have advised us that they propose to offer the shares of common stock directly to the public at the public offering price set forth on the cover page of this prospectus, and to selected dealers at the public offering price less a selling concession not in excess of $0.294 per share. After the public offering of the shares, the underwriters may change the offering price and other selling terms.

Over-allotment Option

We have granted to the underwriters an option to purchase up to an aggregate of 431,250 additional shares of common stock from us at the public offering price less the underwriting discount. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. The underwriters have up to 30 days from the date of this prospectus to exercise this over-allotment option. If any shares are purchased with this over-allotment option, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

Discounts and Expenses

The following table shows the public offering price, the total underwriting discounts to be paid to the underwriters by us and the proceeds, before expenses, to us, both on a per share basis and in total. These amounts are shown assuming both no exercise and full exercise of the over-allotment option.

		Total	
	Per Share	Without Over-allotment Exercise	With Over-allotment Exercise
Public offering price	$ 7.00	$ 20,125,000	$ 23,143,750
Underwriting discounts paid by us	0.49	1,408,750	1,620,063
Proceeds, before expenses, to us	6.51	18,716,250	21,523,687

We estimate expenses payable by us in connection with the offering of common stock, other than the underwriting discounts referred to above, will be approximately $725,000. This amount includes our commitment to reimburse the underwriters for certain expenses up to an aggregate amount of $125,000.

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments that the underwriters may be required to make in respect of those liabilities.

Potential Strategic Investment

A strategic investor, which is not a current stockholder of our company, has indicated an interest in purchasing approximately $3 million of our common stock in this offering at the public offering price. However, because this indication of interest is not a binding agreement or commitment to purchase, the underwriters may determine to sell more, less or no shares in this offering to this investor, or this investor may determine to purchase more, less or no shares in this offering. The underwriters will receive the same discounts and commissions from any shares of our common stock purchased by this strategic investor as they will from any other shares of our common stock sold to the public in this offering. In connection with this investment, we intend to enter into an agreement with this investor pursuant to which it will have the right to designate a board observer, who would be entitled to attend all meetings of our board of directors, and all committees thereof, in each case subject to customary exclusions, as well as the right to review certain of our clinical and regulatory data. The investor would maintain these observation and inspection rights for two years following the date we receive approval from the FDA to sell our C-Pulse System in the United States so long as it beneficially owns at least 50% of the number of shares purchased in this offering.

Lock-up Agreements

We and our executive officers and directors and the venture capital funds affiliated with two of our directors have entered into lock-up agreements with the underwriters. Under these agreements, we and each of these persons may not, without the prior written approval of Canaccord Genuity Inc., subject to limited exceptions (including as needed to comply with the preemptive rights granted to purchasers under our February 2012 securities purchase agreement), offer, sell, assign, transfer, contract to sell, or otherwise dispose of, or announce the intention to otherwise dispose of, or enter into any swap or other arrangement that transfers any economic consequences of ownership of our common stock or securities convertible into or exercisable or exchangeable for our common stock. These restrictions will be in effect for a period of 90 days after the date of this prospectus. Notwithstanding the termination of the lock-up period outlined

above, and subject to certain exceptions, in the event that either (i) during the last 17 days of the lock-up period, we issue an earnings release or material news or a material event relating to us occurs, or (ii) prior to the expiration of the lock-up period, we announce that we will release earnings results during the 16-day period beginning on the last day of the lock-up period, then the expiration of the lock-up period will be extended until the expiration of the 18-day period beginning on the date of the issuance of an earnings release or the occurrence of the material news or material event, as applicable, unless the underwriter waives, in writing, such extension. At any time and without public notice, Canaccord Genuity may in its sole discretion release all or some of the securities from these lock-up agreements.

Price Stabilization, Short Positions and Penalty Bids

Until distribution of the shares of our common stock is completed, SEC rules may limit the underwriters from bidding for and purchasing shares of our common stock. However, the underwriters may engage in transactions that stabilize the price of the shares of our common stock, such as bids or purchases to peg, fix or maintain that price.

If the underwriters create a short position in our common stock in connection with this offering (i.e., if they sell more shares of our common stock than are listed on the cover page of this prospectus), the underwriters may reduce that short position by purchasing shares of our common stock in the open market. The underwriters may also elect to reduce any short position by exercising all or part of the over-allotment option described above. Purchases of shares of our common stock to stabilize its price or to reduce a short position may cause the price of shares of our common stock to be higher than it might be in the absence of such purchases.

The underwriters also may impose a penalty bid, whereby the underwriters may reclaim selling concessions allowed to other broker-dealers in respect of the common stock sold in the offering for their account if the underwriters repurchase the shares in stabilizing or covering transactions. These activities may stabilize, maintain or otherwise affect the market price of the common stock, which may be higher than the price that might otherwise prevail in the open market. The imposition of a penalty bid may also affect the price of the shares of our common stock in that it discourages resales of those shares of our common stock. The underwriters have advised us that these transactions may be effected on the Nasdaq Capital Market or otherwise. Neither we nor the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of shares of our common stock. In addition, neither we nor the underwriters make any representation that the underwriters will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

This prospectus may be made available in electronic format on websites or through other online services maintained by the underwriters of the offering, or by their affiliates. Other than the prospectus in electronic format, the information on such websites and any information contained in any other website maintained by the underwriters or any of their affiliates is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or the underwriters in their capacity as underwriters and should not be relied upon by investors.

Other Relationships

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they

may receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

Lazard Frères & Co. LLC referred this transaction to Lazard Capital Markets LLC and will receive a referral fee from Lazard Capital Markets LLC in connection therewith.

Northland Capital Markets is the trade name for certain capital markets and investment banking services of Northland Securities, Inc., member FINRA/SIPC.

Sales Pursuant to Preemptive Rights

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 February 2012 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. We intend to file with the SEC and have declared effective a registration statement covering all shares that we sell pursuant to any exercise of these preemptive rights. Any shares to be issued and sold pursuant to the preemptive rights granted under the February 2012 securities purchase agreement will not be sold through underwriters, and the underwriters in this offering will not otherwise be entitled to receive compensation for any sales of additional shares made pursuant to the preemptive rights granted under the February 2012 securities purchase agreement.

European Economic Area

In relation to each member state of the European Economic Area that has implemented the Prospectus Directive, or each Relevant Member State, with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, or the Relevant Implementation Date, no offer of any securities that are the subject of the offering contemplated by this prospectus has been or will be made to the public in that Relevant Member State other than any offer where a prospectus has been or will be published in relation to such securities that has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the relevant competent authority in that Relevant Member State in accordance with the Prospectus Directive, except that with effect from and including the Relevant Implementation Date, an offer of such securities may be made to the public in that Relevant Member State:

(1) to any legal entity which is a "qualified investor" as defined in the Prospectus Directive;

(2) to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or

(3) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of securities shall require us or any of the underwriters to publish a prospectus pursuant

to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer to the public" in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe the securities, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

United Kingdom

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (1) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, and/or (2) high net worth entities falling within Article 49(2)(a) to (d) of the Order and other persons to whom it may lawfully be communicated (each such person being referred to as a relevant person).

This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

Notice to Residents of Australia

Neither this prospectus, nor any other disclosure document in relation to the offer of shares of our common stock has been, or needs to be, lodged with the Australian Securities and Investments Commission. This prospectus is not a Prospectus under Chapter 6D of the Corporations Act 2001 (Cth) (Corporations Act).

An offer of shares of our common stock is made in Australia only to persons to whom it is lawful to offer shares without disclosure under one or more of the exemptions set out in section 708 of the Corporations Act (an Exempt Person). By accepting this offer, an offeree represents that the offeree is an Exempt Person.

No shares of our common stock will be issued or sold in circumstances that would require the giving of a Prospectus under Chapter 6D of the Corporations Act.

This prospectus is not financial product advice and has been prepared without taking account of any individual's objectives, financial situation or needs. Accordingly, before any eligible investor takes any action in response to this document, that investor should review this document, consider their own objectives, financial situation and needs and seek professional advice if in any doubt.

LEGAL MATTERS

The validity of the shares of common stock offered hereby and certain other legal matters will be passed upon for us by Faegre Baker Daniels LLP, Minneapolis, Minnesota. The underwriters have been represented in connection with this offering by Jones Day, Palo Alto, California.

On July 3, 2012 we issued a promissory note to Faegre Baker Daniels LLP, our outside legal counsel, in the principal amount of $282,707.64 with interest at 3% per annum accruing thereon for fees for legal services due and payable to Faegre Baker Daniels LLP by us. This note is due and payable on the earliest to occur of (a) the closing by us of a debt or equity financing that results in aggregate gross proceeds to us of at least $4,000,000 or (b) September 30, 2012. A portion of the proceeds from this offering will be used to repay such note.

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 our 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.

INDEX TO FINANCIAL STATEMENTS

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.

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

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

SUNSHINE HEART, INC. AND SUBSIDIARY

Consolidated Statements of Stockholders' Equity

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

See notes to the consolidated financial statements

SUNSHINE HEART, INC. AND SUBSIDIARY

Consolidated Statements of Cash Flows

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

See notes to the consolidated financial statements

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.

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

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

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

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

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

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

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

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

Property, Plant and Equipment: Property and equipment is stated at cost less accumulated depreciation. Depreciation is computed based upon the estimated useful lives of the respective assets. Leasehold improvements are amortized using the straight-line method over the shorter of the lease term or the estimated useful life of the assets. Repairs and maintenance costs are expensed as incurred. Major betterments and improvements, which extend the useful life of the item, are capitalized and depreciated. The cost and accumulated depreciation of property, plant and equipment retired or otherwise disposed of are

removed from the related accounts, and any residual values are charged or credited to expenses. Depreciation expense has been calculated using the following estimated useful lives:

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

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

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

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

New Accounting Pronouncements: In June 2011, the FASB issued 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.

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.

	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.

	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)

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)

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.

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.

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.

SUNSHINE HEART, INC.

Condensed Consolidated Balance Sheets

(Dollars in thousands, except share amounts)

	June 30, 2012 (unaudited)	December 31, 2011
Current assets		
Cash and cash equivalents	**$ 1,772**	$ 6,563
Other current assets	**632**	346
Total current assets	**2,404**	6,909
Property, plant and equipment, net	**503**	522
TOTAL ASSETS	**$ 2,907**	$ 7,431
Current liabilities		
Accounts payable	**$ 1,643**	$ 1,857
Accrued salaries, wages, and other compensation	**619**	978
Total current liabilities	**2,262**	2,835
Total liabilities	**2,262**	2,835
Commitments and contingencies	**—**	—
Stockholders' equity		
Preferred Stock as of June 30, 2012 and December 31, 2011, par value $0.0001 per share; authorized 40,000,000 shares	**—**	—
Common stock as of June 30, 2012 and December 31, 2011, par value $0.0001 per share; authorized 100,000,000 shares: issued and outstanding 6,277,538 and 6,019,663 shares, respectively	**1**	1
Additional paid-in capital	**71,341**	68,652
Accumulated other comprehensive loss:		
Foreign currency translation adjustment	**1,195**	1,132
Retained earnings	**(71,892)**	(65,189)
Total stockholders' equity	**645**	4,596
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 2,907**	$ 7,431

See notes to the condensed consolidated financial statements.

SUNSHINE HEART, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(In thousands, except per share amounts)

	Three months ended June 30,		Six months ended June 30,	
	2012	2011	2012	2011
Net sales	$ —	$ —	$ —	$ —
Cost of goods sold	—	—	—	—
Gross profit	—	—	—	—
Operating expenses				
Selling, general and administrative	1,569	1,178	3,509	1,820
Research and development	1,787	2,374	3,953	4,666
Total operating expenses	3,356	3,552	7,462	6,486
Loss from operations	(3,356)	(3,552)	(7,462)	(6,486)
Interest income	4	80	29	197
Loss before income taxes	(3,352)	(3,472)	(7,433)	(6,289)
Income tax benefit	(730)	—	(730)	—
Net loss	$ (2,622)	$ (3,472)	$ (6,703)	$ (6,289)
Basic and diluted loss per share	$ (0.42)	$ (0.68)	$ (1.08)	$ (1.24)
Weighted average shares outstanding—basic and diluted	6,277	5,088	6,223	5,083
Comprehensive loss	$ (2,610)	$ (3,352)	$ (6,640)	$ (6,104)

See notes to the condensed consolidated financial statements.

SUNSHINE HEART, INC.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(in thousands)

	For the six months ended June 30,	
	2012	**2011**
Net loss	**$ (6,703)**	$ (6,289)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	**63**	30
Loss on disposal of plant and equipment	**63**	—
Stock-based compensation expense	**621**	42
Changes in assets and liabilities		
Accounts receivable	**—**	223
Other current assets	**(286)**	(15)
Accounts payable and accrued expenses	**(573)**	(203)
Net cash used in operating activities	**(6,815)**	(6,212)
Cash flows used in investing activities:		
Purchases of property and equipment	**(107)**	(43)
Net cash used in investing activities	**(107)**	(43)
Cash flows provided by financing activities:		
Net proceeds from the sale of common stock	**2,068**	183
Net cash provided by financing activities	**2,068**	183
Effect of exchange rate changes in cash	**63**	185
Net decrease in cash and cash equivalents	**(4,791)**	(5,887)
Cash and cash equivalents—beginning of period	**6,563**	12,350
CASH AND CASH EQUIVALENTS—END OF PERIOD	**$ 1,772**	$ 6,463

See notes to the condensed consolidated financial statements.

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. The Company's headquarters are located in Eden Prairie, MN and the Company also has 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, or C-Pulse 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 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. The Company received approval from the U.S. Food and Drug Administration, or FDA, to conduct a U.S. feasibility clinical trial with the C-Pulse System. Our shares of common stock in the form of CHESS Depositary Interests, or CDIs, have been publicly traded 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 June 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. (collectively, "Sunshine Heart" or the "Company"). All intercompany accounts and transactions between consolidated entities have been eliminated.

Unaudited Interim Consolidated Financial Information: The interim balance sheet as of June 30, 2012 and statements of operations and comprehensive loss and cash flows for the six months ended June 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, as amended. 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 six months ended June 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 United States 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 2,457,291 and 1,233,845 for the six months ended June 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 June 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 June 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.

Stock-Based Compensation

The Company recognizes all share-based payments, including grants of stock options and compensatory employee stock purchase plans, in the statement of operations as an operating expense, based on their fair value over the requisite service period. We recorded $402 and $219 of related compensation expense to selling, general and administrative expense and research and development expense, respectively, for the six months ended June 30, 2012, as compared to $31 and $11, respectively, of related compensation expense for the six months ended June 30, 2011. As of June 30, 2012, a total of $3,647 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 six months ended June 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 six months ended June 30, 2011.

The Company's stock options generally vest over four years of service and have a contractual life of 10 years. We have 1,019,856 shares authorized for grant under our Amended and Restated 2011 Equity Incentive Plan.

Warrants

Warrants to purchase 1,564,649 and 1,496,032 shares of common stock were outstanding at June 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.

Note 3—Balance Sheet Information

Property, Plant and Equipment

Property, plant and equipment were as follows:

	June 30, 2012	December 31, 2011
Library	$ 1	$ 1
Office Furniture & Fixtures	95	177
Leasehold Improvements	145	251
Software	9	37
Production Equipment	375	293
Computer Equipment	127	134
Total	752	893
Accumulated Depreciation	(249)	(371)
	$ 503	$ 522

Depreciation expense for the three and six month periods ended June 30, 2012 and 2011 was $32, $21, $63 and $30, respectively.

Note 4—Income Taxes

We received a $730 research and development tax credit refund in the quarter ended June 30, 2012, 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 not reflected a benefit related to the Australian research and development tax credit for that period.

Note 5—Subsequent Events

Public Stock Offering

On July 17, 2012, we filed a registration statement on Form S-1 with the Securities and Exchange Commission ("SEC") for a public offering of our common stock for proceeds of up to $28.75 million before related commissions and expenses. We expect to complete the offering in the third quarter 2012 and use the net proceeds to fund our pivotal clinical trial and for general corporate purposes.

CE Mark

On July 23, 2012, we received CE Mark for our C-Pulse Heart Assist System. We expect to commence a post-market clinical trial in select countries in Europe beginning in the second half of 2012.

Table of Contents

2,875,000 Shares

Sunshine Heart, Inc.

Common Stock

PROSPECTUS

Canaccord Genuity

Lazard Capital Markets

Cowen and Company

Craig-Hallum Capital Group

Northland Capital Markets

August 9, 2012