SUNSHINE HEART

2012 Annual Report

A strategy realized
A vision within reach

the strategy

More than three years ago we defined a strategy that would set the foundation for commercialization of the C-Pulse® Heart Assist System. Today, each building block of that plan is in place.

In the past year alone, we have made significant progress:

- Demonstrating 12-month durability in feasibility trial patients
- Enhancing all of our major components
- Clearing regulatory hurdles to begin our pivotal trial in the U.S.
- Receiving the CE Mark in Europe
- Developing the structure for commercialization in Europe
- Securing the NASDAQ listing and follow-on financing
- Transitioning the board to reflect shareholder migration to NASDAQ
- Initiating transfer of cuff assembly to in-house facility

Momentum continues to build as we now focus on execution of our U.S. and European clinical trials. We have put an experienced team in place to activate initial pivotal study investigational sites in the U.S. and post-market study sites in Europe that will generate additional meaningful data, help secure reimbursement on a country-by-country basis, and lay the foundation for successful commercialization. In addition, we have strengthened our finances with an equity line of credit that provides us opportunistic financing or a safety net.

Everything we have been working so hard to achieve is within reach: The opportunity to bring relief to heart failure patients worldwide, the ability to reduce the burden of re-hospitalization, and the return on your investment.

As a shareholder you will want to pay particular attention to our news in the coming months. There will be much to note regarding the U.S. COUNTER HF investigational pivotal study,* the European OPTIONS HF post-market study, and the continued progress of the fully implantable counterpulsation pump, eliminating the need for a percutaneous interface lead, thereby eliminating exit site infections.

Thank you for your continued support of our mission. Together, we have the opportunity to bring C-Pulse to a market in such great need of this solution that may offer so much to patients, providers, and payers alike.

Dave Rosa
Chief Executive Officer
April 5, 2013

*We are highly encouraged since the first pivotal study site has received approval for CMS reimbursement.

the vision

to offer a minimally invasive extra-aortic counterpulsation therapy for moderate to severe heart failure that provides symptomatic relief and halts disease progression

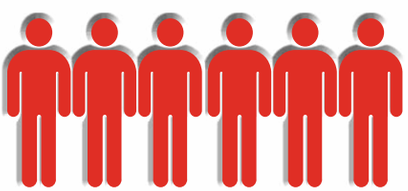
C-Pulse® has the potential to help many patients across the globe who today cannot engage in normal activities because of heart failure. These patients are frequently hospitalized, driving up healthcare system costs and limiting patient quality of life. In fact, in the U.S. the highest rates of re-hospitalization are due to worsening heart failure (approximately 25% rate at 30 days after initial hospitalization).

the market

in Class III Heart Failure

1.5M

U.S. Patients



3.7M

European Patients

Congestive heart failure (HF) is a serious and prevalent condition that affects millions of people.

the candidate

- Class III or ambulatory Class IV
- Failed drug therapy and CRT (if indicated), yet not ill enough for approved Class IV devices
- >18 years old
- Experiencing shortness of breath, dizziness when performing daily activities
- Poor quality of life; typically unable to drive, work, perform normal daily activities as well as issues sleeping

the momentum

NASDAQ IPO

In August, Sunshine Heart successfully completed its first public offering on NASDAQ (SSH). The outcome provided a great deal of confidence regarding the Company's ability to raise funds in the United States. With increased focus on the U.S. market, the Company has announced its delisting from the Australian Stock Exchange, reflecting the quick migration of ownership to the NASDAQ listing. This will increase company efficiency and reduce operating costs. It is expected to take effect by the end of Q2 2013.

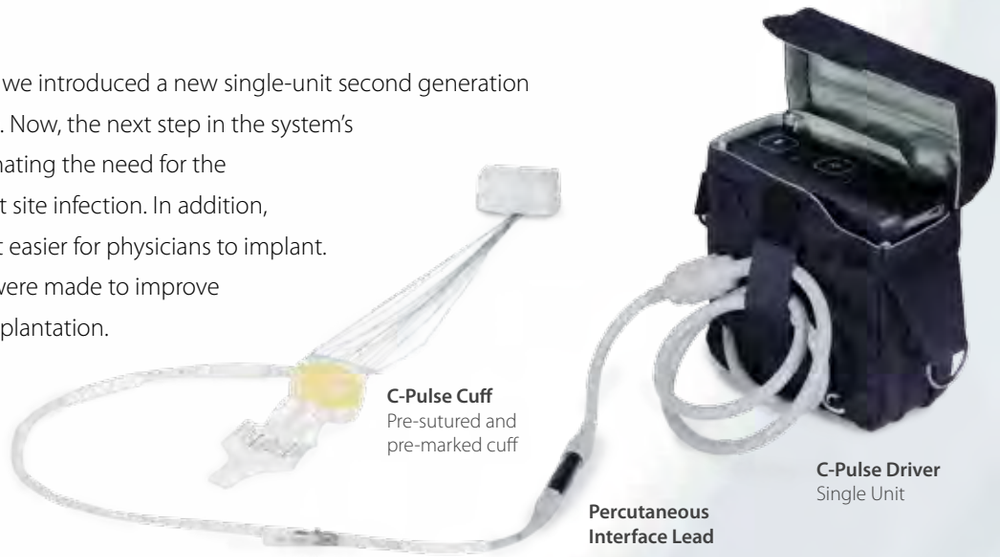
In-House Production

To reduce manufacturing costs and assure product supply, we have brought a key element of our production in house. The Company expects to begin manufacturing in the first half of 2013 at our Eden Prairie headquarters.

the product

Major Component Enhancements

Based on feedback from patients and doctors, we introduced a new single-unit second generation driver that is smaller, quieter and more reliable. Now, the next step in the system's evolution is to make it fully implantable, eliminating the need for the percutaneous interface lead and the risk of exit site infection. In addition, we made enhancements to our cuff to make it easier for physicians to implant. Other modifications to existing components were made to improve reliability or to increase the ease of use and implantation.



the test of things to come...

Feasibility Results

The feasibility trial sought to assess safety while obtaining performance data for evidence of efficacy at 6 months post implant. The outcomes enabled us to achieve FDA approval for the U.S. Investigational pivotal study and the CE Mark approval in Europe.

Key Safety Findings

Number of subjects with device-related safety events remained the same for 6 and 12 months.

- There were no device-related strokes, thromboembolic events or bleeds
- The main risk is related to infections
  - There were 8 exit-site infections, and
  - One sternal infection leading to an aortic disruption

Key Efficacy Findings

Subjects continued to improve from 6 months to 12 months.

- MLWHF: 87% and 100% responder rate (6 and 12 months, responder is ≥ 7 point decrease)
- NYHA : 80% and 83% responder rate (6 and 12 months, responder is ≥ 1 class reduction)
- 6MHW: 33% and 83% responder rate (6 and 12 months, responder demonstrated 50 meter increase)

Heart failure symptoms for two patients subsided to the point where they were disconnected from C-Pulse. Worsening heart failure re-hospitalizations rate was 5% at 6 months and 15% at 12 months.*

*The 10% increase was related to patient noncompliance (utilization rate of < 30% compared to required 80% utilization per the protocol).

U.S. Pivotal Trial

After achieving FDA conditional approval on the pivotal trial in just 27 days, the first site has been activated and has received CMS reimbursement approval. We anticipate that 30–40 centers will participate and expect enrollment to be completed by the second half of 2015.

Study Design Overview

- N=388,1:1 randomization (Treatment: Optimal Medical Therapy)
- Primary efficacy endpoint — freedom from worsening heart failure event resulting in hospitalization, LVAD implantation, heart transplant or death as compared to Optimal Medical Therapy
- Primary safety endpoint — all serious procedure and device-related adverse events as determined by CEC adjudication
- One year follow-up expected for safety

the face

Emmette was a super-responder in the feasibility trial. He was a Class IV HF patient and received C-Pulse therapy for 11 months. After significant improvement, he was weaned from the device and has been without it for more than two years.

> Prior to C-Pulse,
> **"I had to sleep on my knees so I could breathe … … The very first time that I got C-Pulse, I stopped having those feelings where I couldn't breathe."**

Visit sunshineheart.com/patients or scan this symbol with your smart phone for more patient perspectives.

the team

Board of Directors

John Erb (Chairman)

Geoff Brooke, M.D.

Paul Buckman

Donal O'Dwyer

Dave Rosa (Chief Executive Officer)

Jon Salveson

Greg Waller

Warren Watson

Company Secretary

Jeff Mathiesen

Company Headquarters

12988 Valley View Road
Eden Prairie, MN 55344
Website: sunshineheart.com
Phone: 952-345-4200

Executive Officers

Dave Rosa
Chief Executive Officer

Kevin Bassett
Senior Vice President of Technology and Operations

Debra Kridner
Executive Vice President of Clinical Research and Regulatory Affairs

Jeff Mathiesen
Chief Financial Officer

William Peters
Chief Technology Officer and Medical Director

Jim Yearick
Vice President of Marketing and Sales

Independent Registered Public Accounting Firm

Ernst & Young LLP
Minneapolis, MN

Transfer Agent and Registrar

American Stock Transfer &
Trust Company, LLC
6201 15th Avenue
Brooklyn, NY 11219
Website: amstock.com
Phone: 1-800-937-5449

Link Market Services Limited
Level 12
680 George Street
Sydney NSW 2000
Website: linkmarketservices.com.au
Phone: 61 2 8280 7111

Annual Meeting

Thursday, May 23, 2013

SUNSHINE HEART

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Eden Prairie, MN 55344
Phone +1 952 345 4200

www.sunshineheart.com

CAUTION: C-Pulse is an Investigational device. The device is limited by Federal (or United States) Law to Investigational use only. It is not available for sale in the United States.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the Fiscal Year Ended: December 31, 2012

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

For the Transition Period from to

Commission file number 001-35312

SUNSHINE HEART, INC.

(Exact Name of Registrant as Specified in its Charter)

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

12988 Valley View Road
Eden Prairie, Minnesota 55344
(Address of Principal Executive Offices including Zip Code)

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

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.0001 per share	The Nasdaq Stock Market LLC (Nasdaq Capital Market)

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

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

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

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

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

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

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

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

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

As of June 30, 2012, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of shares of the registrant's common stock held by non-affiliates of the registrant (based upon the June 29, 2012 closing sale price of $3.26 per share) was approximately $8.8 million.

The number of shares of the registrant's common stock, par value $0.0001 per share, outstanding as of March 1, 2013 was 9,509,867 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company's definitive Proxy Statement for the Annual Meeting of Stockholders to be held on May 23, 2013 (the ***"2013 Proxy Statement"***), which is expected to be filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, are incorporated by reference in Part III of this Annual Report on Form 10-K.

SUNSHINE HEART, INC.
ANNUAL REPORT ON FORM 10-K
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SPECIAL NOTE REGARDING FORWARD-LOOKING INFORMATION

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

PART I

Item 1. Business

Overview

Unless otherwise specified or indicated by the context, ***"Sunshine Heart," "Company," "we," "us"*** and ***"our"*** refer to Sunshine Heart, Inc. and its subsidiary.

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 U.S. Food and Drug Administration (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 investigational device exemption (***"IDE"***) application. In October 2012, we announced the results of the twelve-month follow-up period for the feasibility study. In November 2012, the FDA provided us with unconditional approval to initiate a pivotal trial. We currently anticipate that enrollment of our pivotal trial will begin during the first half of 2013. We expect to complete enrollment of our pivotal trial by the end of 2015 and do not anticipate marketing our system in the United States before 2017.

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

We incurred net losses of $14.1 million and $16.2 million in the years ended December 31, 2012 and 2011, respectively. 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 federal Patient Protection and Affordable Care Act enacted in 2010 (the ***"Patient Protection and Affordable Care Act"***), 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 the Centers for Medicare and Medicaid Services. 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 (***"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 (***"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 moderate to severe heart failure patients through the commercialization of our C-Pulse System, and to continue the development of the system to make it safer and more convenient for patients and physicians. We believe that our technology will provide us with a competitive advantage in the market for treating specific segments of heart failure patients. To achieve our objectives, we intend to:

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

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

- *Prepare for the Commercial Launch of the C-Pulse System in Europe* - We obtained CE Mark approval for the C-Pulse System in July 2012 and have taken initial steps to evaluate the market potential for our system in targeted countries in Europe in anticipation of commencing commercial sales. We initially plan to sell the C-Pulse System in Europe through experienced distributors in countries where our system is approved for reimbursement or where we otherwise believe there might be a potentially profitable market for our system. We expect our initial sales efforts in Europe will focus on Germany and Italy, which we believe are the largest potential markets for the C-Pulse System in Europe and have supported reimbursement for heart failure technologies in the past. We do not expect to receive reimbursement in Germany before 2014 and cannot be certain of when we will receive reimbursement in other targeted countries.

- *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 (***"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 and then via a mini-thoracotomy. During the feasibility study this minimally invasive procedure was developed 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 a 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 have implanted three additional patients with the C-Pulse System since the original 20 patients, one in the United States and two in Canada. We currently do not have plans to implant any additional patients in the United States because the FDA has granted us full approval of the IDE pivotal trial.

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. In July 2012 we also completed a two-year follow-up for a patient implanted with our system.

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 six and 12 months were more than three 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 six-minute period six months after implantation compared to their pre-implantation ability. This improvement doubled from six to 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 six months exclude one patient that received a heart transplant, one patient implanted with an LVAD, one patient death during surgery to treat a sternal infection, one patient death resulting from a non-device related drug allergic reaction, and one 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 six-month follow-up, excluding one patient who received a heart transplant at day 212, one patient removed from the study at day 232 due to issues with the PIL that led physician to implant an LVAD, and one 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.

Summary of Safety Device Events at Six 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 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 CEC. All events indicate number of patients with events.

(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 with contrast, which is used for the assessment of possible device infection, resulted in acute renal dysfunction.

(7) The two-patient increase from six months to 12 months was 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 re-hospitalization rate of 15% compares to a recent study control group re-hospitalization rate of over 40% at six months (n=280), which included NYHA Class III patients who had been previously hospitalized for heart failure. We believe that this population is similar to the majority of patients profiled in our feasibility study and our planned IDE study with the exception of NYHA Class IV ambulatory.

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

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

Research and Development

Our research and development expense totaled $8.0 million and $11.2 million for the years ended December 31, 2012 and 2011, 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 a single unit system, 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 first half of 2013, which is projected to extend to the end of 2015. We do not expect to market our system in the United States before 2017.

We obtained CE Mark approval in July 2012 and intend to initiate a post market trial of our system in Europe in the first half of 2013. The degree and timing of any commencement or expansion of this trial and any resulting revenues 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 and do not expect to receive reimbursement in Germany before 2014. 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 Annual Report on Form 10-K.

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 and interface lead are provided by outside suppliers and tested by us in-house. Our suppliers include large and small U.S.-based manufacturers of medical device components. The components for our system do not require significant customization for use in our system or necessitate any raw materials for which we believe our suppliers could not readily find alternative sources. We purchase from our suppliers primarily on a purchase order basis. We do not "second source" any components of our system, although we believe we could find alternative suppliers for each component of our system, other than the balloon, without materially interrupting production of our system at current levels. If the manufacturer of the balloon used in our system was unwilling or unable to supply this component for any reason, however, our business could be adversely affected. If we obtain regulatory approvals necessary to commercialize our C-Pulse System, all of our outsourced manufacturers will need to increase their production of our system or we will need to develop capabilities to manufacture the system ourselves.

Intellectual Property

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

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

Despite our patent rights and policies with regard to confidential information, trade secrets and inventions, we may be subject to challenges to the validity of our patents, claims that our system infringes the patent rights of others and the disclosure of our confidential information or trade secrets. These and other risks are described more fully under the heading "Risks Relating to our Intellectual Property" in the "Risk Factors" section of this Annual Report on Form 10-K.

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

Competition

Competition from medical device 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 B3 designation under IDE number G120201. By assigning the C-Pulse System a Category B3 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 based on our Category B3 designation, 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 (the ***"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 registration on a government-approved internet site. The results obtained from these trials are submitted to the FDA in support of a premarket approval (***"PMA"***) application.

During the IDE clinical trial products must be manufactured in accordance with the practices expected by the FDA under the IDE. Design of the products must be done under the Quality System Regulation ("QSR"). Once approved by FDA, the products must be manufactured in registered establishments and must be manufactured in accordance with the 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.

Once commercialized, we will be subject to an extensive set of post-market controls, including annual PMA reports, Medical Device Reports (MDRs) on serious adverse events, complaint handling and analysis under the QSR, export controls, advertising and promotion requirements, and potential post-market studies required by FDA.

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 (***"HIPAA"***), the Health Information Technology for Economic and Clinical Health Act of 2009 (***"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 Medicare and Medicaid. 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 programs 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, (i) 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, (ii) 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, (iii) restrictions on marketing communications and a prohibition on covered entities or business associates from receiving remuneration in exchange for protected health information and (iv) 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.

The Patient Protection and Affordable Care Act and Health Care and Education Affordability Reconciliation Act of 2010

Political, economic and regulatory influences are subjecting the healthcare industry to potential fundamental changes that could substantially affect our results of operations. Government and private sector initiatives to limit the growth of healthcare costs, including price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments and alternative payment models, are continuing in many countries where we do business, including the United States. These changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective treatments. Our strategic initiatives include measures to address this trend; however, there can be no assurance that any of our strategic measures will successfully address this trend.

The Patient Protection and Affordable Care Act and Health Care and Education Affordability Reconciliation Act of 2010 (the ***"Affordable Care Act"***) were enacted into law in the United States in March 2010. As a U.S. headquartered company with significant sales in the United States, this healthcare reform law will materially impact us. Certain provisions of the law will not be effective until 2014 and 2015 and there are many programs and requirements for which the details have not yet been fully established or consequences not fully understood. However, on June 28, 2012, the United States Supreme Court upheld the constitutionality of the law's mandate requiring individuals to purchase health insurance but rejected specific provisions that would have penalized states that did not expand their current Medicaid programs. As a result of this ruling and other factors, we expect implementation of most of the major provisions of the law to continue, some of which (e.g., comparative effectiveness research, an independent payment advisory board, and pilot programs to evaluate alternative payment methodologies) could meaningfully change the way healthcare is developed and delivered, and may adversely affect our business and results of operations. Further, we cannot predict what healthcare programs and regulations will be ultimately implemented at the federal or state level, or the effect of any future legislation or regulation in the United States or internationally. However, any changes that lower reimbursements, reduce medical procedure volumes or increase cost containment pressures on us or other participants in the healthcare industry could adversely affect our business and results of operations.

Sunshine Act

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. Implementing regulations require us to collect this data beginning in August 2013 for reporting to the Centers for Medicare and Medicaid Services in 2014 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.

Medical Device Tax

Effective January 1, 2013, as a result of the passage of the Affordable Care Act, manufacturers of certain medical devices are subject to an excise tax on the sale of the devices. We do not currently believe that we will be subject to these taxes until our C-Pulse System is approved for commercial sale in the U.S. The tax is 2.3% of the sale price of the applicable medical device. The manufacturer is responsible for remitting these taxes to the Federal Government.

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. The EU Commission is in the process of revising the Directives and we may face more strenuous requirements in the EU in the future. 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 federal Foreign Corrupt Practices Act (the ***"FCPA"***) and other countries' anti-corruption/anti-bribery regimes, such as the U.K. Bribery Act. The FCPA prohibits improper payments or offers of payments to foreign governments and their officials for the purpose of obtaining or retaining business. Safeguards we implement to discourage improper payments or offers of payments by our employees, consultants, sales agents or distributors may be ineffective, and violations of the FCPA and similar laws may result in severe criminal or civil sanctions, or other liabilities or proceedings against us, any of which would likely harm our reputation, business, financial condition and result of operations.

Other Regulations

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

Employees

As of December 31, 2012 we had 30 employees, consisting of 29 full-time and one part-time employee(s). None of our employees are covered by a collective bargaining agreement. We consider relations with our employees to be good.

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 (***"CDIs"***), representing beneficial ownership of our common stock have been traded on the Australian Securities Exchange (***"ASX"***) under the symbol "SHC". Historically, each CDI represented one share of our common stock. In connection with the 1-for-200 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 Exchange Act. Our common stock began trading on the Nasdaq Capital Market on February 16, 2012.

On February 5, 2013, we received conditional approval from the ASX to delist from the official list of the ASX. The delisting is expected to occur at the close of trading on May 6, 2013.

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

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

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

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

We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We will cease to be an emerging growth company if we have more than $1.0 billion in annual revenue, have more than $700.0 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 the reduced burdens afforded by the JOBS Act. 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.

On February 5, 2013, we received conditional approval from the ASX to delist from the official list of the ASX. The delisting will be effective upon the close of trading on May 6, 2013.

Executive Officers

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

Name	Age	Position
David Rosa	48	Director; Chief Executive Officer
Kevin Bassett	45	Senior Vice President, Technology & Operations
Debra Kridner	60	Executive Vice President, Clinical Research & Regulatory Affairs
Jim Yearick	50	Vice President, Marketing & Sales
Jeffrey Mathiesen	52	Chief Financial Officer and Secretary
Dr. William Peters	47	Director; Chief Technical Officer and Medical Director (1)

(1) On January 29, 2013, Dr. William Peters resigned from the Board of Directors of the Company. Dr. Peters' resignation was not based on any disagreement with the Company.

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. Bassett 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, 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 that of Senior Vice President from 2006 to 2010.

Debra Kridner: Ms. Kridner is our Executive Vice President of Clinical Research and Regulatory Affairs, a position she has held since October 2012. Prior to that time, Ms. Kridner was Vice President of Clinical Research and Regulatory Affairs from November 2009 on a consultant basis and since March 2010 as an employee of our Company. From 2008 to 2009, Ms. Kridner worked as a consultant for her company Kridner Consulting LLC, which performed consulting services for medical device companies. From 2004 to 2008, Ms. Kridner served as the Vice President of Clinical Research, Quality and Regulatory Affairs for St. Jude Medical's Cardiac Surgery and Interventional Cardiology for the Cardiovascular Division.

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.

Item 1A. Risk Factors

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

Risks Relating to Our Business

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

We are an early-stage company with a history of incurring net losses. We have incurred net losses since our inception, including net losses of $14.1 million and $16.2 million for the years ended December 31, 2012 and 2011, respectively. As of December 31, 2012, our accumulated deficit was $79.3 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 in the U.S. and, although we have CE Mark, we have not commenced commercial sales in the EU. 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, 2012. 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 Nasdaq Capital Market and the ASX. Additional funding will likely be needed and may not be available on terms favorable to us, or at all. If we raise additional funding through the issuance of equity securities, our stockholders may suffer dilution and our ability to use our net operating losses to offset future income may be limited. If we raise additional funding through debt financing, we may be required to accept terms that restrict our ability to incur additional indebtedness, require us to use our cash to make payments under such indebtedness, force us to maintain specified liquidity or other ratios or restrict our ability to pay dividends or make acquisitions. If we are unable to secure additional funding, our development programs and our commercialization efforts would be delayed, reduced or eliminated, our relationships with our suppliers and manufacturers may be harmed, and we may not be able to continue our operations.

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

Our near-term prospects are highly dependent on the development of a single product, our C-Pulse System, and we have no other product candidates in active development at this time. We are in the process of pursuing regulatory approvals necessary to sell our system in the United States. We completed enrollment of our North American feasibility clinical trial in the first half of 2011. In November 2011, we announced the preliminary results of the six-month follow-up period for the feasibility study and we submitted the clinical data to the FDA. In March 2012, the FDA notified us that it completed its review of the C-Pulse System feasibility trial data, concluded we met the applicable agency requirements, and indicated that we can move forward with an IDE application. In November 2012, the FDA provided us with unconditional approval to initiate a pivotal trial. We currently anticipate that enrollment

of the pivotal trial will begin in the first half of 2013. We expect to complete enrollment of our pivotal trial by the end of 2015 and do not anticipate marketing our system in the United States before 2017.

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

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

We currently have no sales, marketing or established 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 post-market 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 under FDA and European regulations and may require FDA and

European submissions, such as PMA Supplement and change notification. 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 or other regulatory agencies.

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 $10.0 million aggregate limit. However, if there are product liability claims against us, our insurance may be insufficient to cover the expense of defending against such claims, or may be insufficient to pay or settle such claims. Furthermore, we may be unable to obtain adequate product liability insurance coverage for commercial sales of any of our approved products. If such insurance is insufficient to protect us, our results of operations will be harmed. If any product liability claim is made against us, our reputation and future sales will be damaged, even if we have adequate insurance coverage. Even if a product liability claim against us is without merit or if we are not found liable for any damages, a product liability claim could result in decreased demand for our system, injury to our reputation, diversion of management's attention from operating our business, withdrawal of clinical trial participants, significant costs of related litigation, loss of revenue or the inability to commercialize the C-Pulse System.

Risks Relating to Regulation

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

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

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

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

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

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

Even if we obtain foreign regulatory approvals, we will need to obtain FDA approval to commercialize our system in the United States, which will require us to 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 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 from the FDA. A PMA must be supported by data from 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 received FDA approval of our IDE application in November 2012 that will allow us to commence a clinical trial in the United States. We intend to commence our U.S. pivotal trial in the first half of 2013, but

there can be no assurance that our U.S. pivotal trial will begin or be completed on schedule or at all. Even if completed, we do not know if this trial will meet its objectives or end-points to show the safety and efficacy of our system so as to support an application for a PMA.

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

- take a significant period of time;
- require the expenditure of substantial resources;
- involve rigorous pre-clinical and clinical testing;
- require changes to the product;
- require submissions to the FDA, such as PMA Supplements; and
- result in failure to support approval of the product or limitations on the indicated uses of the product.

Increased attention to safety and oversight issues in light of recent, widely publicized events concerning the safety of certain food, drug and medical device products could cause the FDA to take a more cautious approach in connection with approvals for devices such as ours, which could delay or prevent FDA approval of our C-Pulse System.

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

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

We intend to commence our U.S. pivotal trial in the first half of 2013. The trial will be designed to be a randomized trial that includes approximately 388 patients and is expected to involve approximately 40 sites. Conducting a clinical trial of this size is a complex and uncertain process.

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

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

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

- ongoing discussions with regulatory authorities regarding the scope or design of our preclinical results or clinical trial or requests for supplemental information with respect to our preclinical results or clinical trial results;
- our or our clinical sites' 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 related data collection and analysis. While we are obligated by regulation to monitor the sites for compliance, we have limited oversight over the clinical investigators and sites 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 sites fail to meet FDA requirements in conducting the trial, we can be held responsible. 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. We are required to demonstrate and maintain compliance with the QSR by controlling our suppliers and requiring that they manufacture in conformance to QSR. A contractor that manufactures a completed device for us is directly subject to the QSR but we also are held responsible by FDA. A contractor that manufactures a component is not subject to the QSR. In those cases we are responsible to FDA for requiring by contract that the component meet QSR standards. 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 are also subject to the international standard ISO 13485 in other jurisdictions. Like the QSR, ISO 13485 holds us responsible under the Purchasing Controls section for obtaining compliance with the standard by all of our suppliers.

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 the 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. 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 Medicare and Medicaid. 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 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 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 beginning in August 2013 and to report to the Centers for Medicare and Medicaid Services starting in 2014 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 $1.0 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 federal Foreign Corrupt Practices Act 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.

The expanded regulations under the HITECH Act have increased the possibility that device manufactures might be considered Business Associates in the future, exposing us to penalties for potential breaches of the HIPAA Security Regulation.

Risks Relating to our Intellectual Property

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

Our success depends in part on our ability to obtain and maintain protection in the United States and other countries of the intellectual property relating to or incorporated into our technology and system. As of January 22, 2013, we owned 12 issued patents in the United States and 9 patent applications in the United States, as well as 37 issued patents and 21 patent applications in foreign jurisdictions. We estimate that most of the currently issued U.S. patents will expire between approximately 2020 and 2024. Our pending and future patent applications may not issue as patents or, if issued, may not issue in a form that will provide us any competitive advantage. Even if issued, existing or future patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of terms of patent protection we may have for our system. Changes in patent laws or their interpretation in the United States and other countries could also diminish the value of our intellectual property or narrow the scope of our patent protection. In addition, the legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. In order to preserve and enforce our patent and other intellectual property rights, we may need to make claims or file lawsuits against third parties. This can entail significant costs to us and divert our management's attention from developing and commercializing our system.

Intellectual property litigation could be costly and disruptive to us.

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

- stop clinical trials or delay or abandon commercialization of our system;
- attempt to obtain a license to sell or use the relevant technology or substitute technology, which license may not be available on reasonable terms or at all; or
- redesign our system.

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

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

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

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

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

In addition, some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 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 Related to Ownership of Our Common Stock

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

Our common stock has been listed for trading on the Nasdaq Capital Market only since February 16, 2012 and has experienced limited trading volume. Our common stock has been listed on the ASX in the form of CDIs since 2004 and has also experienced limited trading volume on that exchange. The average daily trading volume in our common stock on the Nasdaq Capital

Market for the three-month period ended December 31, 2012 was approximately 92,000 shares. The reported average daily trading volume in our common stock on the ASX for the three-month period ended December 31, 2012, was approximately 803,000 CDIs (equivalent to approximately 4,000 shares). There can be no assurance that an active public market for our shares will continue to develop in the United States. If an active trading market does not continue to develop in the United States, the market price and liquidity of our common stock would be adversely affected.

The price of our common stock may fluctuate significantly.

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

- future announcements concerning us or our competitors;
- 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 the ability of our common stockholders to influence the outcome of key transactions, including changes of control.

As of December 31, 2012, our executive officers and directors and entities affiliated with them beneficially owned, in the aggregate (including options or warrants exercisable currently or within 60 days of December 31, 2012), approximately 37.5% of our outstanding common stock. Our executive officers, directors and affiliated entities, if acting together, would be able to control all matters requiring approval by our stockholders, including the election of directors and the approval of mergers, financings or other significant corporate transactions. The concentration of ownership of our common stock may have the effect of delaying, preventing or deterring a change of control of our Company, could deprive our stockholders and CDI holders of an opportunity to receive a premium for their common stock and CDIs as part of a sale of our Company and may affect the market price of our common stock and CDIs. This significant concentration of stock ownership may adversely affect the trading price of our common stock and CDIs due to investors' perception that conflicts of interest may exist or arise.

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

As of December 31, 2012, we had U.S. net operating loss (***"NOL"***) carryforwards of approximately $26.6 million for U.S. income tax purposes, which expire from 2022 through 2032. To the extent these NOL 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 of 1986, as amended (the ***"Internal Revenue Code"***) generally imposes an annual limitation on the amount of

NOL 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 NOL carryforwards. In addition, our ability to utilize the current NOL carryforwards might be further limited by future issuances of our common stock.

As of December 31, 2012, we had tax losses in the Commonwealth of Australia of approximately $55.5 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 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 appreciates.

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

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

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

In connection with becoming a company required to file reports with the SEC, we are required to comply with the internal control evaluation and certification requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (***"SOX"***). 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 of SOX 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 Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). During the course of our ongoing evaluation of the internal controls, we may identify areas requiring improvement, and may have to design enhanced processes and controls to address issues identified through this review. Remediating any deficiencies, significant deficiencies or material weaknesses that we or our independent registered public accounting firm may identify may require us to incur significant costs and expend significant time and management resources. We cannot assure you that any of the measures we implement to remedy any such deficiencies will effectively

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

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 (the ***"DGCL"***), 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 DGCL 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 DGCL, 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.

Two of our seven directors reside outside of the United States, principally in Australia. A substantial portion of the assets of these 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 certain of our directors in securities litigation or other claims.

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 SOX, 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 stockholder 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 $1.0 billion in non-convertible debt in a three-year period, or if the market value of our common stock held by non-affiliates exceeds $700.0 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 DGCL 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.

On February 5, 2013, we received conditional approval from the ASX to delist from the official list of the ASX. The delisting is expected to occur at the close of trading on May 6, 2013.

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We lease a 23,000 square foot facility located in Eden Prairie, Minnesota. The lease period commenced December 1, 2011 and extends through March 31, 2016. This facility serves as our corporate headquarters and houses substantially all of our functional areas. Monthly rent and electricity for our new headquarters total approximately $21,000. Previously we leased a 10,000 square foot facility in Eden Prairie, Minnesota that housed our corporate headquarters and substantially all of our functional areas, with the exception of a portion of our research and development activities. That lease expired September 30, 2012 and required a monthly payment of approximately $11,000.

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

Item 3. Legal Proceedings

We are not currently subject to any material legal proceedings.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information. Commencing February 16, 2012, our shares of common stock began trading on the Nasdaq Capital Market under the symbol "SSH." Our shares of common stock have also traded in the form of CDIs on the ASX under the symbol "SHC" since September 2004. On January 29, 2013, we announced our intention to de-list from the official list of the ASX during the first half of the 2013 calendar year.

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$)	Low (US$)
Nasdaq Capital Market				
Year Ended December 31, 2013				
First Quarter (through March 1, 2013)	n/a	n/a	8.13	5.21
Year Ended December 31, 2012				
First Quarter (from February 16, 2012)	n/a	n/a	22.90	8.50
Second Quarter	n/a	n/a	8.85	2.50
Third Quarter	n/a	n/a	13.30	3.01
Fourth Quarter	n/a	n/a	8.54	6.08
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

Stockholders of Record. As of February 28, 2013, we had 9,509,867 shares of common stock issued and outstanding, and there were 44 holders of record of our common stock. One stockholder of record, CHESS Depositary Nominees, or CDN, held shares of our common stock on behalf of approximately 1,059 CDI holders.

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

Unregistered Sales of Equity Securities

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

Name or Class of Person to Whom Sold	Type of Securities	Amount of Securities	Date of Sale	Exercise Price per Share	Aggregate Offering Consideration
Institutional Australian Investor	Common Stock	12,500 Common Shares	2/8/12	A$8.00 per share purchase price	A$ 100,000
	Warrants to purchase Common Stock	3,750 Warrants		A$11.20 per share exercise price	
Accredited Investors party to Securities Purchase Agreement dated 2/6/12	Common Stock	244,375 Common Shares	2/8/12	A$8.00 per share purchase price	A$ 1,955,000
	Warrants to purchase Common Stock	73,313 Warrants		A$11.20 per share exercise price	
Summer Street Research Partners and its registered representatives	Warrants to purchase Common Stock	8,553 Warrants	2/8/12	A$8.00	N/A
Institutional and high net worth Australian investors	Common Stock	1,000 Common Shares	5/1/12	N/A	A$ 6,400
Institutional and high net worth Australian investors	Common Stock	50 Common Shares	8/15/12	N/A	A$ 320
Institutional and high net worth Australian investors	Common Stock	31,346 Common Shares	10/16/12	N/A	A$ 200,614

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

No underwriters were used in connection with the transactions described above. All sales set forth above were for cash.

The sales to the Accredited Investors on February 8, 2012 were made in reliance upon the exemption from registration requirements of the Securities Act available under Section 4(2) of the Securities Act and Rule 506 of Regulation D. The purchasers of the securities in the transaction made in reliance upon Section 4(2) of the Securities Act and Rule 506 of Regulation D represented that they were sophisticated persons and that they intended to acquire the securities for investment only and not with a view to, or for sale in connection with, any distribution thereof, and appropriate legends were affixed to the share certificates and instruments issued in such sales. We believe that these purchasers either received adequate information about us or had adequate access, through their relationships with us, to such information.

The sales to the Institutional Australian Investor on February 8, 2012 were made in reliance upon the exemption from registration requirements of the Securities Act available under Rule 903 of Regulation S. The purchasers of the securities in this transaction represented that they were outside of the United States when each such person originated its buy order for the securities, no offers were made to persons in the United States, the Company implemented the offering restrictions required by Regulation S, the purchasers agreed to offer or sell the securities acquired only in compliance with the restrictions and conditions imposed by Regulation S during the applicable distribution compliance period and we agreed to refuse to register any transfer of the securities not made in accordance with Regulation S, pursuant to registration under the Securities Act, or pursuant to an available exemption from registration.

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

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

Date of Issuance	Number of Options Granted		Exercise Price per Share
1/10/12	29,375	A$	7.40
3/12/12	2,500	$	11.78
11/12/12	253,000	$	6.46

No consideration was paid to us by any recipient of any of the foregoing options for the grant of such options. All of the stock options described above were granted under the 2002 Plan or our 2011 Equity Incentive Plan, as amended (the ***"2011 Plan"***) to the Company's officers, directors, employees and consultants in reliance upon an available exemption from the registration requirements of the Securities Act, including those contained in Rule 701 promulgated under Section 3(b) of the Securities Act. Among other things, we relied on the fact that, under Rule 701, companies that are not subject to the reporting requirements of Section 13 or Section 15(d) of the Exchange Act are exempt from registration under the Securities Act with respect to certain offers and sales of securities pursuant to "compensatory benefit plans" as defined under that rule. We believe that our 2002 Plan and our 2011 Plan qualify as compensatory benefit plans.

On January 15, 2013, the Company entered into a Common Stock Purchase Agreement (the ***"Purchase Agreement"***) with Aspire Capital Fund, LLC, an Illinois limited liability company (***"Aspire Capital"***), which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $25.0 million of shares of the Company's common stock (the ***"Purchase Shares"***) over the two-year term of the Purchase Agreement.

Upon execution of the Purchase Agreement, the Company issued 80,257 shares of its common stock to Aspire Capital in consideration for entering into the Purchase Agreement (the ***"Commitment Shares"***). The Purchase Shares may be sold by the Company to Aspire Capital on any business day the Company selects in two ways: (i) through a regular purchase of up to 50,000 shares at a known price based on the market price of our common stock prior to the time of each sale, and (ii) through a VWAP purchase of a number of shares up to 30% of the volume traded on the purchase date at a price equal to the lesser of the closing sale price or 95% of the volume weighted average price for such purchase date. On February 19, 2013, we sold to Aspire Capital 146,886 shares of common stock (the ***"Initial Purchase Shares"***) for an aggregate purchase price of $1.0 million.

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

Use of Proceeds from Sales of Registered Securities

None.

Stock Repurchases

None.

Item 6. Selected Financial Data

Not applicable.

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

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

Overview

We are a medical device company developing innovative technologies for cardiac and coronary disease. The Company's primary product, the C-Pulse® Heart Assist System (the ***"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.

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 investigational device exemption application. In November 2012, the FDA provided us with unconditional approval to initiate a pivotal trial. We currently anticipate that enrollment of our pivotal trial will begin during the first half of 2013.

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

Critical Accounting Policies and Estimates

Revenue Recognition

We recognize revenue when (i) persuasive evidence of a customer arrangement exists; (ii) the price is fixed or determinable and free of contingencies or uncertainties; (iii) collectability is reasonably assured; and (iv) product delivery has occurred, which is when product title transfers to the customer, or services have been rendered. Sales are not conditional based on customer acceptance provisions or installation obligations. Our C-Pulse System is not approved for commercial sale in the United States. We currently have no revenue, but we anticipate that any revenue we generate will consist solely of sales of the C-Pulse System to hospitals and clinics pursuant to research arrangements and with appropriate regulatory approvals for sales in conjunction with our clinical trials. For clinical trial implant revenue, the product title generally transfers on the date the system is implanted. We do not charge hospitals and clinics for shipping. We expect to expense shipping costs at the time we report the related revenue and record these costs in cost of sales.

Foreign Currency Translation and Transactions

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

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

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, 2012 and 2011, we incurred losses from operations and net cash outflows from operating activities as disclosed in the consolidated statements of operations and cash flows, respectively.

Our ability to continue as a going concern is dependent on our ability to raise additional capital based on the achievement of existing milestones as and when required. Our directors, after due consideration, believe that we will be able to raise new equity capital as required to fund our business plan. Should our future efforts to raise capital not be successful, we may not be able to continue as a going concern. Furthermore, our ability to continue as a going concern is subject to our ability to develop and successfully commercialize our C-Pulse System being developed. If we are unable to obtain such funding of an amount and on a timeline necessary to meet our future operational plans, or to successfully commercialize our intellectual property, we may be unable to continue as a going concern. No adjustments have been made relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should we not continue as a going concern.

Accounting Standards Applicable to Emerging Growth Companies

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

Internal Controls and Procedures

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

Recent Events

Stock Purchase Agreement

On January 15, 2013, we entered into a common stock purchase agreement with Aspire Capital Fund, LLC. Under the terms of the Purchase Agreement, Aspire Capital has committed to purchase up to $25.0 million of share purchases. In consideration for entering into the Purchase Agreement, concurrent with the execution of the Purchase Agreement, we issued 80,257 shares of our common stock to Aspire Capital for no consideration. On February 14, 2013, the related S-1 registration statement for the issuance of up to 3 million shares under the Purchase Agreement went effective. On February 19, 2013, we issued 146,886 shares at $6.808 to Aspire Capital for net proceeds of $1.0 million pursuant to the Purchase Agreement.

ASX Delisting

On February 5, 2013, we received conditional approval from the ASX to delist from the official list of the ASX. The delisting will be effective upon the close of trading on May 6, 2013.

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 December 31, 2012, we had an accumulated deficit of $79.3 million and we expect to incur losses for the foreseeable future. To date, we have been funded by private and public equity financings. Although we believe that we will be able to successfully fund our operations, there can be no assurance that we will be able to do so or that we will ever operate profitably.

Results of Operations

Comparison of Year Ended December 31, 2012 to Year Ended December 31, 2011

Revenue

Year Ended December 31, 2012	Year Ended December 31, 2011	Increase (Decrease)	% Change
$ —	$ —	$ —	N/A

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

Research and Development Expense

Year Ended December 31, 2012	Year Ended December 31, 2011	Increase (Decrease)	% Change
$ 8,003,000	$ 11,199,000	$ (3,196,000)	(28.5)%

Our decrease in research and development expense for 2012 as compared to the prior year was primarily caused by the completion of our feasibility trial enrollment in 2011 and the reduction of related support costs, as well as the completion of certain development activities related to our C-Pulse System in the prior year. We expect our research and development expense will increase in 2013 from 2012 as we add personnel to support our U.S. pivotal clinical trial.

Selling, General and Administrative Expense

Year Ended December 31, 2012	Year Ended December 31, 2011	Increase (Decrease)	% Change
$ 6,866,000	$ 5,363,000	$ 1,503,000	28.0%

Our increase in selling, general and administrative expense in 2012 as compared to the prior year was primarily caused by increased stock-based compensation expense resulting from stock option grants in the second half of 2011 as well as in 2012, and increased professional fees and personnel additions beginning 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 first half of 2013.

Interest Income

Year Ended December 31, 2012	Year Ended December 31, 2011	Increase (Decrease)	% Change
$ 33,000	$ 251,000	$ (218,000)	(86.9)%

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

Income Tax Benefit

Year Ended December 31, 2012	Year Ended December 31, 2011	Increase (Decrease)	% Change
$ 771,000	$ 115,000	$ 656,000	570.4%

Our income tax benefit in 2012 resulted from a $730,000 research and development tax credit in Australia for the tax year ended June 30, 2011 and the balance from a research and development credit in the state of Minnesota for the tax year ended December 31, 2011. 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.

We have not completed the tax return for our Australian subsidiary for the year ended June 30, 2012 and cannot be sure that the research and development expenditures of our subsidiary during that period will result in a tax refund.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations primarily through a series of equity issuances, including the issuance of common shares for net proceeds of $20.8 million and $7.6 million in the years ended December 31, 2012 and 2011, respectively. As of December 31, 2012 and 2011, cash and cash equivalents were $14.2 million and $6.6 million, respectively.

We believe, based on our current operating plan, that the net proceeds from the sale of stock to Aspire Capital, if completed in its entirety, and our cash balances and cash generated from our clinical trials will be sufficient to meet our anticipated cash requirements for at least the next 12 months, but that we will require additional funding to complete our pivotal trial. From time to time we may seek to sell additional equity or convertible debt securities or enter into credit facilities. The sale of additional equity, debt, or convertible debt securities may result in dilution to our stockholders. If we raise additional funds through the issuance of debt, convertible debt or enter into credit facilities, these securities and debt holders could have rights senior to those of our common stock, and this debt could contain covenants that would restrict our operations and would require us to use cash for debt service rather than our operations. We may require additional capital beyond our currently forecasted amounts. Although we have successfully financed our operations through the issuance of common stock and warrants to date, any such required additional capital may not be available to us on acceptable terms, or at all.

Cash Flows from Operating Activities

Net cash used in operating activities was $13.1 million in each of the years ended December 31, 2012 and 2011. The net cash used in each of these periods primarily reflects the net loss for those periods, offset in part by depreciation, amortization of warrants issued for services, stock-based compensation and the effects of changes in operating assets and liabilities.

Cash Flows from Investing Activities

Net cash used in investing activities was $158,000 and $451,000 in the years ended December 31, 2012 and 2011, respectively. The majority of cash used in investing activities in 2012 and 2011 was for leasehold improvements, furniture and equipment associated with the relocation of our headquarters.

Cash Flows from Financing Activities

Net cash provided by financing activities was $20.8 million and $7.6 million in the years ended December 31, 2012 and 2011, respectively. Net cash provided by financing activities was attributable to proceeds from sales of our common stock and warrants.

Capital Resource Requirements

As of December 31, 2012, we did not have any material commitments for capital expenditures.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 8. Financial Statements and Supplementary Data

Report of Independent Registered Public Accounting Firm

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of Sunshine Heart, Inc. and subsidiary as of December 31, 2012 and 2011, and the related statements of operations, stockholders' equity, and cash flows for each of the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Sunshine Heart, Inc. at December 31, 2012 and 2011, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

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

/s/ Ernst & Young LLP

Minneapolis, Minnesota
March 12, 2013

SUNSHINE HEART, INC. AND SUBSIDIARY

Consolidated Balance Sheets

Dollars in thousands, except per share amounts	Dec 31, 2012	Dec 31, 2011
Current assets		
Cash and cash equivalents	$ 14,224	$ 6,563
Other current assets	333	346
Total current assets	**14,557**	**6,909**
Property, plant and equipment, net	**479**	**522**
TOTAL ASSETS	**$ 15,036**	**$ 7,431**
Current liabilities		
Accounts payable	$ 1,156	$ 1,857
Accrued salaries, wages, and other compensation	931	978
Total current liabilities	**2,087**	**2,835**
Total liabilities	**2,087**	**2,835**
Stockholders' equity		
Preferred stock as of December 31, 2012 and December 31, 2011, $0.0001 par value per share; authorized 40,000,000 shares	—	—
Common stock as of December 31, 2012 and December 31, 2011, par value $0.0001 per share; authorized 100,000,000 shares; issued and outstanding 9,282,724 and 6,019,663, respectively	1	1
Additional paid-in capital	91,017	68,652
Accumulated other comprehensive income:		
Foreign currency translation adjustment	1,185	1,132
Accumulated deficit	(79,254)	(65,189)
Total stockholders' equity	**12,949**	**4,596**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 15,036**	**$ 7,431**

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, 2012	Year ended Dec 31, 2011
Net sales	**$ —**	**$ —**
Operating expenses		
Selling, general and administrative	6,866	5,363
Research and development	8,003	11,199
Total operating expenses	14,869	16,562
Loss from operations	**(14,869)**	**(16,562)**
Interest income	33	251
Loss before income taxes	**(14,836)**	**(16,311)**
Income tax benefit	**771**	**115**
Net loss	**$ (14,065)**	**$ (16,196)**
Basic and diluted loss per share	**$ (1.98)**	**$ (2.98)**
Weighted average shares outstanding—basic and diluted	**7,099**	**5,442**
Other comprehensive income		
Foreign currency translation adjustments	**$ 53**	**$ 137**
Total comprehensive loss	**$ (14,012)**	**$ (16,059)**

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, 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**
Comprehensive loss:						
Net loss					(14,065)	(14,065)
Foreign currency translation adjustment				53		53
Total comprehensive loss						(14,012)
Stock based compensation			1,248			1,248
Issuance of common stock, net	3,264		20,837			20,837
Issuance of warrants for service agreement			280			280
Balance December 31, 2012	**9,283**	**$ 1**	**$ 91,017**	**$ 1,185**	**$ (79,254)**	**$ 12,949**

See notes to the consolidated financial statements

SUNSHINE HEART, INC. AND SUBSIDIARY

Consolidated Statements of Cash Flows

(In thousands)	Year ended Dec 31, 2012	Year ended Dec 31, 2011
Net loss	$ (14,065)	$ (16,196)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	138	50
Stock based compensation expense	1,248	939
Abandonment of fixed assets	63	—
Amortization of warrants for service agreements	280	—
Changes in assets and liabilities:		
Accounts receivable	—	258
Other current assets	13	(166)
Accounts payable and accrued expenses	(760)	2,026
Net cash used in operations	**(13,083)**	**(13,089)**
Cash flows used in investing activities:		
Purchase of property and equipment	(158)	(451)
Net cash used in investing activities	**(158)**	**(451)**
Cash flows provided by financing activities:		
Net proceeds from the sale of common stock	20,837	7,627
Net cash provided by financing activities	**20,837**	**7,627**
Effect of exchange rate changes on cash	65	126
Net increase (decrease) in cash and cash equivalents	7,661	(5,787)
Cash and cash equivalents—beginning of period	6,563	12,350
Cash and cash equivalents—end of period	**$ 14,224**	**$ 6,563**

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, Inc. was founded in November 1999 and incorporated in Delaware in August 2002. We are headquartered in Eden Prairie, Minnesota 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 U.S. feasibility clinical trial with the C-Pulse System. Our shares of common stock in the form of CHESS Depositary Interests have been publicly traded in Australia on the Australian Securities Exchange 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, 2012 and 2011, the Company incurred losses from operations and net cash outflows from operating activities as disclosed in the consolidated statements of operations and cash flows, respectively. At December 31, 2012, the Company had an accumulated deficit of $79.3 million and expects to incur losses for the foreseeable future. To date, the Company has been funded by private and public equity financings. Although the Company believes that it will be able to successfully fund its operations, there can be no assurance the Company we will be able to do so or that the Company 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 future capital raising be unsuccessful, the Company may not be able to continue as a going concern. Furthermore, the ability of the Company to continue as a going concern is subject to the ability of the Company to develop and successfully commercialize the product being developed. If the Company is unable to obtain such funding of an amount and timing necessary to meet its future operational plans, or to successfully commercialize its intellectual property, the Company may be unable to continue as a going concern. No adjustments have been made relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company not continue as a going concern.

Basis of Presentation

The accompanying consolidated financial statements include the accounts of Sunshine Heart, Inc. and its wholly-owned subsidiary, Sunshine Heart Company Pty Ltd. All 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 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.

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 $138 and $50 for the years ended December 31, 2012 and 2011, 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, 2012 and 2011.

Revenue Recognition

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

Foreign Currency Translation and Transactions

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

Stock-Based Compensation

The Company recognizes 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.

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 (***"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 2,746,497 and 2,216,615 for the years ended December 31, 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 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 $8,003 and $11,199 for the years ended December 31, 2012 and 2011, 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 trading on the ASX in Australia such that one CDI represents 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.

Note 2—Balance Sheet Information

Property, Plant and Equipment

Property, plant and equipment were as follows:

	December 31, 2012	December 31, 2011
Office Furniture & Fixtures	$ 102	$ 178
Leasehold Improvements	145	251
Software	12	37
Production Equipment	425	293
Computer Equipment	118	134
Total	802	893
Accumulated Depreciation	(323)	(371)
	$ 479	$ 522

Note 3—Equity

Private Placement

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.

In February 2012, the Company placed 256,875 shares of common stock (in the form of CDIs) for proceeds, net of transaction costs, of $2,061.

Public Offering

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

Stock Options

The Company recognized share-based compensation expense related to stock options and grants of common stock to employees, directors and consultants of $1,248 and $939 during the years ended December 31, 2012 and 2011, 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, 2012 and 2011:

	December 31, 2012	December 31, 2011
Selling, general and administrative	$ 806	$ 621
Research and development	442	318
Total	$ 1,248	$ 939

As of December 31, 2012 and December 31, 2011, the total compensation cost related to all non-vested awards not yet recognized was $4,099 and $4,582, respectively. This amount is expected to be recognized over the remaining weighted-average period of 8.61 years as of December 31, 2012 and 9.21 years as of December 31, 2011.

The Company has granted stock options to certain employees and directors under the Amended and Restated 2002 Stock Plan and the 2011 Equity Incentive Plan (collectively, the ***"Plans"***). The Plans are designed to assist in the motivation and retention of employees and to recognize the importance of employees to the long-term performance and success of the Company. The Company has also granted stock options to certain consultants outside of the Plans. The majority of the options to purchase common stock vest on the anniversary of the date of grant, which ranges from one to four years. Additionally, certain stock options vest upon the closing price of the Company's common stock reaching certain minimum levels, as defined in the agreements. Finally, certain other stock options vest upon the meeting of certain Company milestones, such as the signing of specific agreements and the completion of the Company's anticipated listing on a U.S. stock exchange. As of December 31, 2012, 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, 2012 and 2011.

	Options Outstanding	Weighted Average Exercise Price	Remaining Average Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, December 31, 2010	126,698	$ 28.00	7.26	$ 819
2011 Grants	794,926	7.64		
2011 Exercises	1,560	6.58		
2011 Forfeitures/expirations	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	7.64	24,013
2012 Grants	284,875	6.63		
2012 Exercises	3,990	3.10		
2012 Forfeitures/expirations	54,473	7.65		
Outstanding, December 31, 2012	1,113,244	9.47	8.61	1,163
Exercisable at December 31, 2012	418,439	$ 13.08	7.76	$ 1,163

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, 2012 and 2011 was $14 and $3, respectively. Of the 694,805 non-vested options at December 31, 2012, none were held by consultants. Total cash proceeds from exercised options were $12 and $10 for the years ended December 31, 2012 and 2011, respectively.

The weighted-average fair value of stock options granted during the years ended December 31, 2012 and 2011 was $4.97 and $6.62, 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 stockholders, and currently does not anticipate paying any cash dividends in the foreseeable future. As a result the Company has assumed a dividend yield of 0%. The 2011 risk free interest rate is based upon the rates of U.S Treasury bins with a term equal to the expected term of the option. 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, 2012 and 2011.

	Year ended December 31	
	2012	2011
Expected dividend yield	0%	0%
Risk-free interest rate	1.52%	1.43%
Expected volatility	101%	100%
Expected life (in years)	5.0	6.5

Warrants

Warrants to purchase 1,663,253 and 1,496,032 shares of common stock were outstanding at December 31, 2012 and 2011, respectively.

As part of the private placement completed during 2011, the Company issued (i) 10,623 warrants to purchase common stock at an exercise price of AU$8.00 per share, with a stated life of five years, and (ii) 276,501 warrants to purchase common stock at an exercise price of AU$11.20 per share, with a stated life of four years.

As part of the private placement completed during 2012, the Company issued (i) 8,553 warrants to purchase common stock at an exercise price of AU$8.00 per share, with a stated life of five years, and (ii) 77,063 warrants to purchase common stock at an exercise price of AU$11.20 per share, with a stated life of four years.

On September 7, 2012, we issued 100,000 non-forfeitable and fully exercisable warrants to purchase common stock, having an exercise price of $7.00 per share and a term of five years, pursuant to a professional services agreement extending through June 2013. These warrants were determined to have a fair value of $519, of which $280 was charged to expense during 2012. These warrants were issued pursuant to the terms and conditions of the Company's Amended and Restated 2011 Equity Incentive Plan.

During the years ended December 31, 2012 and 2011, 32,396 and 14,879 warrants were exercised at a price of AU$6.40 and AU$6.40 for total proceeds of $212 and $99, respectively.

Note 4—Income Taxes

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

	December 31, 2012	December 31, 2011
Domestic	$ (13,373)	$ (11,252)
Foreign	(692)	(4,944)
Total	$ (14,065)	$ (16,196)

The components of income tax expense for the years ended December 31, 2012 and 2011 consist of the following:

	December 31, 2012	December 31, 2011
Income tax provision:		
Current:		
United States and state	$ (41)	$ (115)
Foreign	(730)	—
Deferred:		
United States and state	—	—
Foreign	—	—
Total income tax (benefit) expense	$ (771)	$ (115)

Actual income tax expense differs from statutory federal income tax benefit for the years ended December 31, 2012 and 2011 as follows:

	December 31, 2012	December 31, 2011
Statutory federal income tax benefit	$ (5,043)	$ (5,555)
State tax benefit, net of federal taxes	(866)	(727)
Foreign tax	57	199
R&D tax credit rebate	(771)	(265)
Valuation allowance increase	5,932	6,121
Other	(80)	112
Total income tax (benefit) expense	$ (771)	$ (115)

Deferred taxes as of December 31, 2012 and 2011 consist of the following:

	December 31, 2012	December 31, 2011
Deferred tax assets (liabilities):		
Accrued expenses	$ 56	$ 115
Stock based compensation	1,256	658
Capitalized patent costs	117	126
Deferred rent	81	78
Fixed assets	(50)	(76)
R&D credits	139	150
Other	7	7
Net operating losses	28,066	22,357
	29,672	23,415
Less: valuation allowance	(29,672)	(23,415)
	$ —	$ —

As of December 31, 2012, we had U.S. net operating loss carryforwards of approximately $26.6 million for U.S. federal income tax purposes, which expire in years 2022 through 2032, and NOLs in the Commonwealth of Australia of approximately $55.5 million which we can carry forward indefinitely. U.S. NOL carryforwards cannot be used to offset taxable income in foreign jurisdictions. In addition, future utilization of NOL 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% change in ownership of a company over a three-year period. No formal study has been prepared as of the balance sheet date to determine any applicable limitations on the utilization of the U.S. NOLs.

We received a $730 fully refundable research and development tax credit in 2012, determined as a combined average of 44% of 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 for total research and development expenses of our Australian subsidiary. We have not completed the Australian tax return for the period ended June 30, 2012, and we cannot be reasonably assured of the amount or eligibility of the refundable research and development credit resulting from our research and development expenses. Therefore, we have reflected $0 net benefit related to the research and development credit for twelve months ended June 30, 2012. During 2012, we also received refundable research and development tax credits totaling $156 for the state of Minnesota for the fiscal year ended June 30, 2011 and the six months ended December 31, 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 year ended December 31, 2012; therefore, we have reflected $0 net benefit related to the Minnesota research and development credit for 2012.

We provide for a valuation allowance when it is more likely than not that we will not realize a portion of the deferred tax assets. We have established a valuation allowance for U.S. and foreign deferred tax assets due to the uncertainty that enough taxable income will be generated in those taxing jurisdictions to utilize the assets. Therefore, we have not reflected any benefit of such deferred tax assets in the accompanying financial statements. For the years ended December 31, 2012 and 2011, the valuation allowance increased by $6.3 million and $6.6 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, 2012 or December 31, 2011.

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, 2012 and 2011 we recorded no accrued interest or penalties related to uncertain tax positions.

The fiscal tax years ended June 30, 2008 through December 31, 2012 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, 2012.

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 $256 and $274 for the years ended December 31, 2012 and 2011, respectively. Future minimum lease payments under non-cancelable operating leases as of December 31, 2012 were approximately $194, $262, $267, $67 and $0 for each the years ended December 31, 2013, through 2017, respectively.

Employee Benefits

All U.S. employees and 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, 2012 and 2011, the Company incurred expenses of $30 and $82, respectively.

In 2012, the Company converted its health insurance plan to a high deductible plan with a Health Savings Account. The Company incurred an expense of $18 in 2012.

Note 6—Related Party Transaction

During the year ended December 31, 2012 and 2011, we paid $0 and $9 to SCP Technology and Growth Pty Limited, a company controlled by a former 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, 2012 or December 31, 2011. In September 2011, we sold 14,375 shares of our common stock to Jeffrey Mathiesen, our Chief Financial Officer, at the price of AU$8.00 per share as part of a private placement.

Note 7—Subsequent Events

Common Stock Purchase Agreement

On January 15, 2013, we entered into a Common Stock Purchase Agreement with Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $25.0 million in shares of our common stock (the ***"Purchase Shares"***) over a two-year period at purchase prices determined in accordance with the Purchase Agreement. Pursuant to the terms of the Purchase Agreement, we have filed and maintain a registration statement on Form S-1 with the SEC under which we have registered 3,000,000 shares of our common stock for resale by Aspire.

In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital 80,257 shares of our common stock as a commitment fee (the ***"Commitment Shares"***). The Purchase Agreement provides that we may not issue and sell more than 1,298,653 shares of our common stock, including the Commitment Shares (13.99% of the Company's outstanding shares as of January 15, 2013, the date of the Purchase Agreement), without stockholder approval as required by the applicable listing rules of the ASX. In the event our securities cease to be listed on the ASX, the maximum shares of our common stock without shareholder approval increase to 1,856,616 shares, or 19.99% of the Company's outstanding shares as of January 15, 2013.

As of March 1, 2013, we have sold 146,886 shares of common stock to Aspire Capital pursuant to the Purchase Agreement and, including the Commitment Shares, an aggregate of 227,143 shares of common stock have been issued to Aspire Capital pursuant to the Purchase Agreement.

The Purchase Agreement contains customary representations, warranties, covenants, closing conditions and indemnification and termination provisions by, among and for the benefit of the parties. The Purchase Agreement may be terminated by us at any time, at our discretion, without any cost or penalty to us. Aspire Capital has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of our shares. We did not pay Aspire Capital any expense reimbursement in connection with the transaction. There are no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement.

ASX Delisting

On February 5, 2013, we received conditional approval from the ASX to delist from the official list of the ASX. The delisting will be effective upon the close of trading on May 6, 2013.

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.

Beginning in 2012, interest income has been primarily earned in the United States. Previously, interest income was primarily earned in Australia.

At December 31, 2012, long-lived assets are located primarily in the United States.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2012, the end of the period covered by this Annual Report on Form 10-K. This evaluation was done under the supervision and with the participation of management, including our Chief Executive Officer (***"CEO"***) and Chief Financial Officer (***"CFO"***). Disclosure controls and procedures means controls and other procedures that are designed to provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act, such as this Annual Report on Form 10-K, is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed such that information is accumulated and communicated to our management, including our CEO and CFO, as appropriate to allow timely decisions regarding required disclosure. Based on this evaluation, our CEO and CFO have concluded that as of December 31, 2012, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Under the supervision and with the participation of our management, including our CEO and CFO, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2012 based on the criteria in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (***"COSO"***). Based on our evaluation under the framework in *Internal Control — Integrated Framework* issued by the COSO, our management concluded that our internal control over financial reporting was effective as of December 31, 2012.

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to rules of the SEC that permit us to provide only management's report in this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the most recent fiscal quarter ended December 31, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item with respect to executive officers is contained in Item 1 of this Annual Report on Form 10-K under the heading "Executive Officers" and with respect to other information relating to our directors and executive officers will be set forth in our 2013 Proxy Statement under the caption "Proposal 1 — Election of Directors," which will be filed no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and is incorporated herein by reference.

The information required by this item under Item 405 of Regulation S-K is incorporated herein by reference to the section titled "Section 16(a) Beneficial Ownership Reporting Compliance" of our 2013 Proxy Statement, which will be filed no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K. The information required by this item under Item 407(d)(4) and (d)(5) of Regulation S-K is incorporated herein by reference to the section titled "Information Regarding the Board of

Directors and Corporate Governance—Board Committees—Audit Committee" of our 2013 Proxy Statement, which will be filed no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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

Item 11. Executive Compensation

Information related to security ownership required by this item is incorporated herein by reference to the sections titled "Executive Compensation" and "Certain Relationships and Related Transactions—Compensation Committee Interlocks and Insider Participation" of our 2013 Proxy Statement, which will be filed no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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

Information related to security ownership required by this item is incorporated herein by reference to the sections titled "Security Ownership" and "Equity Compensation Plans" of our 2013 Proxy Statement, which will be filed no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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

Information required by this item is incorporated herein by reference to the sections titled "Certain Relationships and Related Transactions—Related Party Transactions," and "Information Regarding the Board of Directors and Corporate Governance—Director Independence" of our 2013 Proxy Statement, which will be filed no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 14. Principal Accounting Fees and Services

Information required by this item is incorporated herein by reference to the section titled "Proposal 4 - Ratification of Selection of Independent Auditor" of our 2013 Proxy Statement, which will be filed no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

PART IV

Item 15. Exhibits and Financial Statement Schedules

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

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

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

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

SIGNATURES

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

Dated: March 12, 2013

SUNSHINE HEART, INC.

By: /S/ DAVID ROSA
David Rosa
President and Chief Executive Officer

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

Signature	Title	Date
/S/ DAVID ROSA David Rosa	President, Chief Executive Officer and Director (principal executive officer)	March 12, 2013
/S/ JEFFREY MATHIESEN Jeffrey Mathiesen	Chief Financial Officer (principal financial and accounting officer)	March 12, 2013
/S/ PAUL BUCKMAN Paul Buckman	Director	March 12, 2013
/S/ DR. GEOFFREY BROOKE Dr. Geoffrey Brooke	Director	March 12, 2013
/S/ JOHN ERB John Erb	Director	March 12, 2013
/S/DONAL O'DWYER Donal O'Dwyer	Director	March 12, 2013
/S/ GREGORY WALLER Gregory Waller	Director	March 12, 2013
/S/ WARREN WATSON Warren Watson	Director	March 12, 2013

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