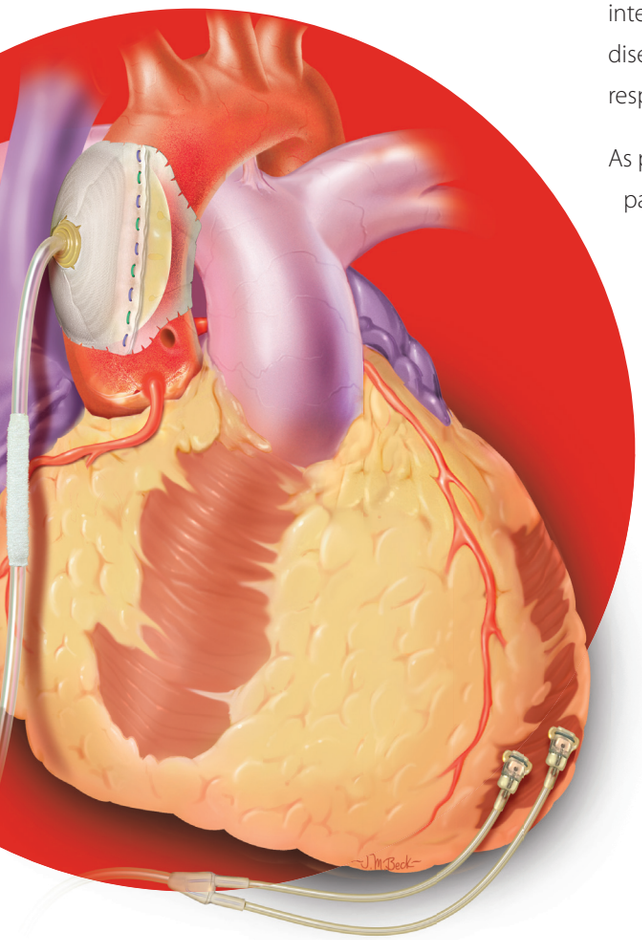
SUNSHINE HEART

2014 ANNUAL REPORT

The Next Step Forward

C-PULSE: The Next Step Forward

For some patients with moderate to severe heart failure there are few treatment options left. Medical therapy either alone or in combination with other early device options (i.e. CRT and neuromodulation) has been exhausted but the disease has not progressed to the extent of necessitating an LVAD. That space between drug therapy with or without other early device treatments, and later-stage treatment options is where the C-Pulse® Heart Assist System may provide an exciting alternative and offer relief from symptoms of NYHA Class III and ambulatory Class IV heart failure.



A true cardiac assist system by design, C-Pulse supports and off-loads the heart, intending to provide stabilization of disease progression and a more effective response to medical therapy.[1]

As published in JACC Heart Failure, patients implanted with the C-Pulse therapy experienced:

- 6/20 reduction in diuretics
- 4/20 successfully weaned off inotropes
- 5/20 sustained improvement as a result of the therapy and weaned off of the device

The C-Pulse System also allows for continual optimization of the therapy post-implant. Two important features of the C-Pulse System include:

- The ability to turn the system on and off, giving clinicians the ability to evaluate patients' hemodynamics and cardiac function in real time
- Ongoing adjustment of the therapy to optimize cardiac support in conjunction with other existing device implants, such as CRT and neuromodulation

The C-Pulse System also allows for continual optimization of the therapy post-implant.

The unique extra-vascular design of C-Pulse provides an improved safety profile versus later stage therapies. We are pleased with the development progress made on the next-generation C-Pulse design, which will allow us to offer therapy without the requirement for a driveline.

Ready to Move Forward

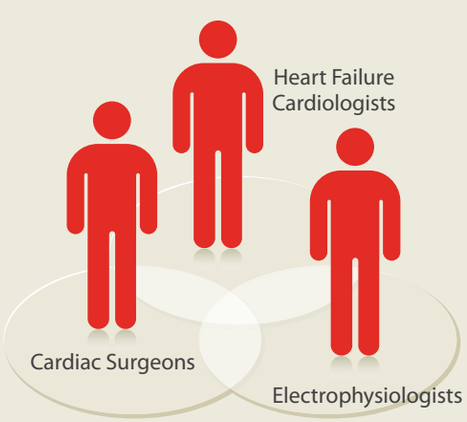
REFINING LEADERSHIP TO STRENGTHEN EXECUTION

In 2014, Sunshine Heart gained new leadership strength in the areas of marketing, finance, R&D, clinical and market development. This is critical as we move into the next phase of executing on our clinical studies and enhancing therapeutic acceptance for the C-Pulse System. As we create a new treatment paradigm, we continue to strategically recalibrate to address the needs of our clinicians and their patients.

Expanding Partnerships

NEW MODELS FOR MARKET DEVELOPMENT

For Sunshine Heart to be successful in clinical studies, we realize the need to use a different model to drive market development. The C-Pulse® System occupies a new therapeutic space between drugs, CRT/ICDs, and other later-stage options such as LVADS, inotropes, or heart transplants. Our efforts have expanded to focus on three key physicians that play a unique role in developing acceptance for C-Pulse. These include cardiac surgeons, heart failure cardiologists and electrophysiologists, often working in some combination to manage these patients.



Gaining Momentum

COUNTER HF™ U.S. PIVOTAL STUDY

COUNTER HF is a prospective, randomized multi-center investigational clinical study evaluating C-Pulse to determine the therapy safety and efficacy in treating NYHA Class III and ambulatory Class IV patients. We saw a strong finish in 2014, as fourth quarter enrollment numbers for the U.S. pivotal study came in higher than projected, with 13 patients. A total of 40 patients were enrolled at 21 activated U.S. centers. The study continues to make excellent progress and we anticipate continued growth over last year.

…Fourth quarter enrollment numbers for the U.S. pivotal study came in higher than projected…

Growing Confidence

OPTIONS HF EU POST-MARKET STUDY

We expect to see continued growth in European implants in the first quarter of 2015 and beyond. We anticipate further publication of these important data in 2016, and we are very pleased with the initial post market data outcomes. Investigators have applied the important lessons learned from our initial feasibility study and we look forward to sharing both the European clinical and economic data supporting the therapeutic value of C-Pulse.

- Finished 2014 with 12 patients implanted at five sites in Europe
- In the fourth quarter, two newly activated sites in Germany and Austria completed implants
- The study expects to implant up to 50 patients in up to 15 European centers

The EU Post-Market Study expects to enroll up to 50 patients in up to 15 European centers.

The Next Big Step

FULLY-IMPLANTABLE SYSTEM

The next-generation, fully-implantable C-Pulse® has the potential to revolutionize treatment acceptance by heart failure patients through the elimination of an external drive line. The fully implantable C-Pulse System continues to experience exciting progress. During the course of 2014, both acute and chronic animal studies were successfully completed. We have enhanced our in-house expertise in the software and hardware components of the C-Pulse next generation implantable pump and the energy transfer system that drives it.

In 2015, development continues on designing and testing the smaller, lighter implantable pump which eliminates the need for an external pump and exit site. With our continued progress, we are well positioned to be the first modern-day, cardiac assist company to achieve first-in-human clinical evaluation for a fully implantable heart assist system.

In summary, 2014 was a year of gained momentum and sustainability in our clinical trial enrollment. Looking forward, we will continue to focus on driving enrollment at our key trial sites and progressing the next generation technology.

For Sunshine Heart, 2014 was all about gaining momentum around our clinical studies and progressing our next generation technology.

As Sunshine Heart continues to mature, an increasing level of experience and sophistication are required as well. In order to meet our Company goals, the Company enhanced its leadership team in order to meet our key goals, execute our strategic plan and continue to position the Company for continued growth.

The company made strong headway with its COUNTER HF™ U.S. pivotal study, concluding 2014 with 40 enrollments and 21 activated centers. In addition, we have growing confidence in our OPTIONS HF European post-market study. With 14 activated clinical sites and improved alignment of resources, we expect continued progress throughout 2015.

In September 2014 we were proud to have had our feasibility study data published in the Journal of the American College of Cardiology (JACC HF).[1] We expect to release the results of new research and development initiatives as well as new data points during the course of 2015.

The C-Pulse® System is gaining traction with a growing number of additional sites throughout Europe. While other geographies have expressed an interest in gaining access to the therapy, the Company remains focused on our efforts to complete the COUNTER HF and OPTIONS HF studies. I'm pleased to report that the pace of enrollment in both studies continues to gain momentum.

On the research and development front, we believe the next generation, fully-implantable C-Pulse System will provide a higher level of patient satisfaction and comfort. The fully implantable system continues to experience exciting progress. In 2014 we successfully completed both acute and chronic animal studies with the pump. Given the progress shown thus far, we feel that first-in-human clinical studies are on the horizon, and it is very likely that Sunshine Heart may be the first modern-day, cardiac assist company to do a first-in-human study with a transcutaneous energy transfer system (TETS). The ability to eliminate the external driveline and exit site would greatly improve the acceptance of the therapy into the Class III heart failure market as well as potentially expand the utilization in other markets such as pulmonary hypertension and angina.

Success in the fully implantable space, with the elimination of an exit site, would greatly improve heart failure patient acceptance. It would expand the Class III heart failure space significantly and could open us up to consider other new markets, such as pulmonary hypertension and angina.

As part of delivering on our commitment to the next step forward in treating heart failure, we continue to evaluate and consider other technologies that may fit into our portfolio. At Sunshine Heart, we are truly committed to transforming the way heart failure is treated.

Dave Rosa
Chief Executive Officer
April 15, 2015

Board of Directors

John L. Erb (Chairman)

Geoffrey E. Brooke, M.D.

Paul R. Buckman

David A. Rosa (Chief Executive Officer)

Jon W. Salveson

Gregory D. Waller

Warren S. Watson

Company Secretary

Claudia Drayton

Company Headquarters

12988 Valley View Road
Eden Prairie, MN 55344
Website: www.sunshineheart.com
Phone: +1 952 345 4200

Corporate Officers

David A. Rosa
Chief Executive Officer

Brian Brown
Senior Vice President of Operations and Technology

Claudia Drayton
Chief Financial Officer

Dimitrios "Jim" Georgakopolous
Chief Scientific Officer

Debra Kridner
Executive Vice President of Regulatory Affairs and Quality Assurance

Kim Oleson
Senior Vice President of Clinical Affairs

Molly Wade
Vice President of Worldwide Patient Recruitment and Marketing

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: www.amstock.com
Phone: 1 800 937 5449

ANNUAL MEETING

May 21, 2015

1. Abraham WT, Aggarwal S, Prabhu S, et al. Ambulatory Extra-Aortic Counterpulsation in Patients With Moderate to Severe Chronic Heart Failure. *JACC*: Heart Failure, 2014;2(5):526-533. doi:10.1016/j.jchf.2014.04.014

SUNSHINE HEART

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www.sunshineheart.com

CAUTION: C-Pulse is an Investigational device. The device is limited by Federal (or United States) Law to Investigational use only.

CE 0344

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, 2014

☐ **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)

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

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 Act). Yes ☐ No ☒

As of June 30, 2014, 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 30, 2014 closing sale price of $5.60 per share) was approximately $93.5 million.

The number of shares of the registrant's common stock, par value $0.0001 per share, outstanding as of March 18, 2015 was 18,231,091 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement for the 2015 annual meeting of stockholders are incorporated by reference into Part III of this report to the extent described herein.

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

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 U.S. Securities and Exchange Commission (the ***"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 subsidiaries.

We are an early-stage medical device company focused on developing, manufacturing and commercializing our C-Pulse® Heart Assist System (the ***"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 study 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 had completed its review of the C-Pulse System feasibility study data and concluded we met the applicable agency requirements, and further indicated that we could move forward with an investigational device exemption (***"IDE"***) application. In October 2012, we announced the results of the 12-month follow-up period for the feasibility study. In November 2012, the FDA provided us with unconditional approval to initiate a pivotal study. The COUNTER HF™ study is designed to enroll 388 patients randomized 1:1 to treatment (C-Pulse implantation) versus optimal medical therapy, at up to 40 participating hospitals and clinics. The primary efficacy endpoint of the study is defined as freedom from worsening heart failure resulting in hospitalization, LVAD implantation, cardiac transplantation or heart failure related death. We commenced enrollment in our COUNTER HF study in September 2013 and concluded 2014 with 40 enrollments, 21 activated centers, and 12 additional centers committed to participate. On February 25, 2015, we announced that we had received unconditional approval from the FDA to conduct an interim analysis of COUNTER HF, which could reduce the overall duration of the trial. On March 6, 2015, we announced that COUNTER HF had reached a pre-determined pausing point and we temporarily suspended enrollment in accordance with the study protocol. The FDA has responded to our pause notification and has advised that we submit an IDE supplement to discuss the reasons for the temporary suspension and a plan for study resumption. We submitted the document to the FDA on March 16, 2015. This supplement carries up to a 30-day review period by the FDA.

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 have initiated a 50-patient post-market study in Europe that will evaluate endpoints similar to those for our U.S. pivotal study. We commenced enrollment in our OPTIONS HF study in the second quarter of 2013. We do not currently plan to commercialize the C-Pulse System in any European country unless the product is approved for reimbursement. We do not expect to receive reimbursement in Germany before 2016 and cannot be certain of when, or if, we will receive reimbursement in Germany or other targeted countries. The European OPTIONS HF study concluded 2014 with 12 implants performed in Europe.

We incurred net losses of $25.6 million and $21.8 million in the years ended December 31, 2014 and 2013, respectively. Historically, sales of the C-Pulse System to hospitals and clinics under contract in conjunction with our North American FDA clinical studies have generated all of our revenue. The C-Pulse System is not approved for commercial sale. However, the FDA has assigned the C-Pulse System to a Category B designation, making it eligible for reimbursement at certain U.S. sites during our clinical studies. Consequently, upon implant of the C-Pulse System, we are able to invoice hospitals and clinics that are eligible for reimbursement by Medicare, Medicaid or private insurance companies. As many private insurance companies and certain government institutions have a non-coverage policy for experimental or investigational procedures, we have not been successful in achieving reimbursement for some implant procedures. Therefore, we expect to continue to incur significant net losses as we continue to conduct clinical studies and pursue commercialization, and as we ramp up sales of our system.

Our Market Opportunity

Heart failure is one of the leading causes of death in the United States and other developed countries. The American Heart Association estimates that 5.7 million people in the United States age 20 and over are affected by heart failure, with an estimated 670,000 new cases diagnosed each year. Nearly 30% of heart failure patients are below the age of 60, and congestive heart failure is the highest U.S. chronic health care expense category.

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

The C-Pulse System is intended for NYHA Class III and ambulatory Class IV patients. It is estimated that approximately 1.5 million heart failure patients in the United States fall into this classification range, and we believe approximately 3.7 million patients in Europe are similarly affected.

Treatment alternatives currently available for Class III heart failure patients in the United States consist primarily of pharmacological therapies and cardiac 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. One product received FDA approval in the United States for Class IIIb patients, but that device is not reimbursed by the Centers for Medicare and Medicaid Services for Class IIIb patients. LVADs 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, by design these devices are in contact with the patient's bloodstream, requiring the lifelong use of blood-thinning drugs and increasing the risk of severe adverse events, including thrombosis, bleeding and neurologic events such as stroke.

Our Strategy

Our goal is to become a market leader in the treatment of moderate to severe heart failure through the commercialization of the 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 Study in the United States* - We completed enrollment of the North American feasibility clinical study 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 study and we submitted the clinical data to the FDA. In March 2012, the FDA notified us that it had completed its review of the C-Pulse System feasibility study data and concluded we met the applicable agency requirements, and further indicated that we could move forward with an IDE application. In November 2012, the FDA provided us with unconditional approval to initiate a pivotal study. We commenced enrollment in our COUNTER HF pivotal study in the third quarter of 2013. On February 25, 2015, we announced that we had received unconditional approval from the FDA to conduct an interim analysis of COUNTER HF, which could reduce the overall duration of the trial. On March 6, 2015, we announced that COUNTER HF had reached a pre-determined pausing point and we temporarily suspended enrollment in accordance with the study protocol. The FDA has responded to our pause notification and has advised that we submit an IDE supplement to discuss the reasons for the temporary suspension and a plan for study resumption. We submitted the document to the FDA on March 16, 2015. This supplement carries up to a 30-day review period by the FDA.

- *Conduct a Post-Market Study in Europe to Gain Additional Clinical Data* - 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 study. The OPTIONS HF study will evaluate endpoints similar to those for our U.S. pivotal study to aid our reimbursement efforts and gain additional clinical data. We commenced enrollment in our OPTIONS HF study in the second quarter of 2013.

- *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 directly and 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, the UK and Austria, which we believe are the largest potential markets for the C-Pulse System in Europe and which have supported reimbursement for heart failure technologies in the past. We do not expect to receive reimbursement in Germany before 2016 and cannot be certain of when, or if, we will receive reimbursement in Germany or 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 study, we have made several improvements to the C-Pulse System based on the feasibility study outcomes and feedback we received from surgeons and patients during the study. These changes include enhancements to our driver, cuff, and Percutaneous Interface Leads (***"PIL"***), among others. We have also completed initial animal studies of a next-generation, fully-implantable C-Pulse System, which would eliminate the need for a percutaneous driveline, thus addressing the risk of infections at the skin exit sites.

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 documented cases, reverse the heart failure process, thereby potentially preventing the need for later-stage heart failure devices, such as LVADs or artificial hearts, or for 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 results from our feasibility study, we also believe that some patients treated with the C-Pulse System may 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 around the patient's ascending aorta above the aortic valve. An electrocardiogram sensing lead is then attached to the heart to determine timing for cuff inflation and deflation in synchronization with the heartbeat. As the heart fills with blood, the C-Pulse cuff inflates to push blood from the aorta to the rest of the body and to the heart muscle via the coronary arteries. Just before the heart pumps, the C-Pulse cuff deflates to reduce the heart's workload through pressure changes, allowing the heart to pump with less effort. The C-Pulse cuff and electrical leads are connected to a single line that is run through the abdominal wall to connect to a power driver outside the body. The system's single unit driver and battery source are contained inside a carrying bag.

Surgeons in the feasibility phase of our clinical study 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. The first implant using this less invasive procedure was completed in 2010. Patients implanted via our minimally invasive procedure typically require a hospital stay of four to seven days in connection with implantation of the C-Pulse System, after which they return home. This compares to an average hospital stay of 14 days for patients implanted with the C-Pulse System via a full sternotomy. 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 aspects, which we believe differentiate our system from other products addressing moderate to severe heart failure. First, the C-Pulse System is placed outside a patient's vascular system. The C-Pulse cuff is placed around 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 like other devices, such as LVADs. Because the C-Pulse System remains outside the vascular system, there is 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 with a percutaneous driver lead, patients using our system have a risk of infection from the implantation procedure or from the driver lead exit site. Any untreated sternal/mediastinal infection arising from the implantation procedure or exit site infection could result in erosion of the aortic wall or an aortic disruption. 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.

Second, once implanted, the C-Pulse System does not need to be in constant operation, and patients can safely turn the device on or off at any time. This feature enables patients to disconnect from the device 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, to maximize the benefit from the C-Pulse System, patients are advised to turn off the system only for short periods of time and for specified activities. 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 study 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 study 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 study.

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 12-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)**	**Interpretation**
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 abilities. This improvement doubled from six to 12 months.**

(1) 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 the 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 Related 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 relationships 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 study 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 six-month and 12-month follow-up results 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 study. In March 2012, the FDA notified us that it had completed its review of the C-Pulse System feasibility study data and concluded we met the applicable agency requirements, and further indicated that we could move forward with an IDE application.

In November 2012, the FDA provided us with approval to initiate a pivotal study. The COUNTER HF study is designed to enroll 388 patients randomized 1:1 to treatment (C-Pulse implantation) versus optimal medical therapy, at up to 40 participating hospitals and clinics. The primary efficacy endpoint of the study is defined as freedom from worsening heart failure resulting in hospitalization, LVAD implantation, cardiac transplantation or heart failure related death. We commenced enrollment of the COUNTER HF pivotal study in the third quarter of 2013. On February 25, 2015, we announced that we had received unconditional approval from the FDA to conduct an interim analysis of COUNTER HF, which could reduce the overall duration of the trial. On March 6, 2015, we announced that COUNTER HF had reached a pre-determined pausing point and we temporarily suspended enrollment in accordance with the study protocol. The FDA has responded to our pause notification and has advised that we submit an IDE supplement to discuss the reasons for the temporary suspension and a plan for study resumption. We submitted the document to the FDA on March 16, 2015. This supplement carries up to a 30-day review period by the FDA.

Research and Development

Our research and development expense totaled $16.9 million and $13.5 million for the years ended December 31, 2014 and 2013, 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 study, 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 study. Changes and enhancements to the C-Pulse System, all of which have been completed and will be utilized in our pivotal study, include the following:

- Our next generation driver has been modified to be a single unit system that is 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.

- The 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 study. In addition, the PIL was lengthened to better secure and stabilize the PIL and driveline away from the exit site. After enhanced testing performed on the revised PIL, we believe the more robust design and increased length will alleviate wear concerns in future implants and improve the safety and reliability of the C-Pulse System for patients.

We have also completed initial animal studies of a next-generation, fully implantable C-Pulse System, 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. These studies have shown 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 studies and perform research and developments to the C-Pulse System, including 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 who participate in our clinical studies per the terms of the clinical study contracts. We have solicited hospitals and clinics for our studies through our employees, who select hospitals and clinics for participation based on an assessment of their expertise in the area of moderate and severe heart failure and their understanding of our system. We completed enrollment in our North American feasibility clinical study in the first half of 2011 and we did not generate any revenue from sales of our system during 2012 and through the first half of 2013. We commenced enrollment in our pivotal clinical study in the third quarter of 2013.

We obtained CE Mark approval in July 2012. In the second quarter of 2013, we initiated enrollment in a 50-patient post-market study of our system in Europe, which may include data from other geographies (e.g., Canada). However, the pace of enrollment and resulting revenues, if any, in Europe 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, the UK and Austria, 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 2016. We initially plan to sell the C-Pulse System in Europe through employees and 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 studies 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 studies. We outsource most of the manufacture of our system to suppliers with our activities primarily directed toward supply chain management and distribution of our system to clinics and hospitals. A number of critical components of the 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. In 2013, we moved the assembly of the balloon and cuff, along with the related marking and packaging operations, to our Eden Prairie, Minnesota facility. These processes occur under a clean room environment. Our quality system complies with the latest requirements of ISO 13485:2003, Active Medical Device Directive (AIMD) 90/385/EEC and the US FDA Quality Systems Regulations 21 CFR Part 820.

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 the C-Pulse System, all of our outsourced manufacturers would need to increase their production of our system or we would 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 December 31, 2014, our portfolio consisted of 68 issued patents, of which 18 were issued in the United States and 50 were issued in other countries. We also had 36 patent applications pending, including 8 in the United States as of that date. Our patents and patent applications cover various aspects of both the methodology as well as the design of the C-Pulse System device and related components.

We have developed technical knowledge that, although non-patentable, we consider to be significant in enabling us to compete. It is our policy to enter into confidentiality agreements with each of our employees and consultants prohibiting the disclosure

of any confidential information or trade secrets. In addition, these agreements provide that any inventions or discoveries by employees and consultants relating to our business will be assigned to us and become our sole property.

Despite our patent rights and policies with regard to confidential information, trade secrets and inventions, we may be subject to challenges to the validity of our patents, claims that our system infringes the patent rights of others and the disclosure of our confidential information or trade secrets. These and other risks are described more fully under the heading "Risks Relating to our Intellectual Property" in the "Risk Factors" section of this 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 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., HeartWare International Inc., Jarvik Heart, Inc., ReliantHeart, 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;
- risk management;
- 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; 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, will help our system effectively compete in the markets where it is approved for sale.

Third-Party Reimbursement

If approved in the United States, we expect the C-Pulse System to be purchased primarily by customers, such as hospitals, who then would bill various third-party payers for the services provided to the patients. These payers, which include 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 and Medicaid Services, and a majority of private insurers have approved reimbursement for the C-Pulse System in clinical studies. 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 payers 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 and its regulations. The 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 studies 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 studies may begin. The results obtained from clinical studies are then submitted to the FDA in support of a premarket approval (***"PMA"***) application.

Clinical studies are subject to registration on a government-approved internet site and are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical studies must be conducted under the oversight of an institutional review board (***"IRB***") for the relevant clinical study sites and they must comply with FDA regulations, including but not limited to those relating to good clinical practices. To conduct a clinical study, we are also required to obtain the patients' informed consent in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. We, the FDA or the IRB could suspend a clinical study at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

During clinical studies 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 (the ***"QSR"***). Once approved by the 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 (the ***"HITECH Act"***), 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 federal 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 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 positions 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 a new federal statute 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 payers. 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 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 adversely 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.

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

Political, economic and regulatory influences are subjecting the health care industry to potential fundamental changes that could substantially affect our results of operations. Government and private sector initiatives to limit the growth of health care 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 (collectively, the ***"Affordable Care Act"***) were enacted into law in the United States in March 2010. As a U.S. headquartered company that expects significant future sales in the United States once the C-Pulse System is approved for sale, this health care reform law will materially impact us. Certain provisions of the law just recently became, or are not yet effective, and there are many programs and requirements for which the details have not yet been fully established or consequences not fully understood. On June 28, 2012, the U.S. 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 health care is developed and delivered, and may adversely affect our business and results of operations. Further, we cannot predict what health care 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 health care 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 have required 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 devices. We do not currently believe that we will be subject to these taxes until the C-Pulse System is approved for commercial sale in the United States. 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 it can be marketed in those countries.

The primary regulatory environment in Europe is that of the European Union, which consists of 28 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 studies, 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.

The regulatory agency in Canada is Health Canada. Medical Devices are governed under the Health Products and Food Branch in the office of the Therapeutic Products Directorate (TPD). The Medical Device regulation is SOR-98-282 which governs clinical studies. We currently have an investigational study ongoing at one clinical site in Canada.

Anti-Corruption/Anti-Bribery Laws

We are 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 results 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, 2014, we had 55 employees, consisting of 54 full-time and 1 part-time employees. None of our employees are covered by a collective bargaining agreement. We consider relations with our employees to be good.

Corporate Information

Sunshine Heart, Inc. was incorporated in Delaware on August 22, 2002. We began operating our business in November 1999 through Sunshine Heart Company Pty Limited, which currently is a wholly owned Australian subsidiary of Sunshine Heart, Inc. In September of 2004, Chess Depositary Instruments (***"CDIs"***) representing beneficial ownership of our common stock began trading on the Australian Securities Exchange (the ***"ASX"***) under the symbol "SHC." Initially, 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 represented 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 (***"NASDAQ"***) 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 occurred 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 requirements that are otherwise applicable generally to U.S. public companies. These provisions include an exemption from the attestation requirement in the assessment of our internal control over financial reporting by our independent auditors pursuant to section 404 (b) of the Sarbanes-Oxley Act of 2002. The provisions of the JOBS Act do not preclude us from the requirement to make our own internal assessment of the effectiveness of our internal controls over financial reporting.

We may take advantage of these provisions for up to five years following our initial public offering 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 billion in annual revenue, have more than $700 million in market value of our shares of common stock held by non-affiliates, or issue more than $1 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these reduced requirements. In addition, 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.

Item 1A. Risk Factors.

Our business faces many risks. We believe the risks described below are the material risks we face. However, the risks described below may not be the only risks we face. Additional unknown risks or risks that we currently consider immaterial may also impair our business operations. If any of the events or circumstances described below actually occurs, our business, financial condition or results of operations could suffer, and the trading price of our shares of common stock could decline significantly. Investors should consider the specific risk factors discussed below, together with the "Cautionary Note Regarding Forward-Looking Statements" and the other information contained in this 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 $25.6 million and $21.8 million for the years ended December 31, 2014 and 2013, respectively. As of December 31, 2014, our accumulated deficit was $126.6 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 studies, 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 NASDAQ. 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 studies, 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.

The report of our independent registered public accounting firm issued in connection with its audit of our financial statements for the fiscal year ended December 31, 2014 expresses substantial doubt about our ability to continue as a going concern. 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 United States and, although we have CE Mark approval, we have not commenced commercial sales in the European Union. To date, we have generated only limited revenue from our clinical studies. The report of our independent registered public accounting firm issued in connection with its audit of our financial statements for the fiscal year ended December 31, 2014 expresses substantial doubt about our ability to continue as a going concern. 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 studies, 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 NASDAQ. Substantial additional funding will be needed and may not be available on terms favorable to us, or at all. In addition, the risk that we may not be able to continue as a going concern may make it more difficult to obtain necessary additional funding 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, the 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, the 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, which we believe has the largest market potential for our product. We completed enrollment of our North American feasibility clinical study 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 had completed its review of the C-Pulse System feasibility study data and concluded we met the applicable agency requirements, and further indicated that we could move forward with an IDE application. In November 2012, the FDA provided us with unconditional approval to initiate a pivotal study. The COUNTER HF™ study is designed to enroll 388 patients randomized 1:1 to treatment (C-Pulse implantation) versus optimal medical therapy, at up to 40 participating hospitals and clinics. The primary efficacy endpoint of the study is defined as freedom from worsening heart failure resulting in hospitalization, LVAD implantation, cardiac transplantation or heart failure related death. We commenced enrollment in the U.S. Counter HF study in September 2013 and concluded 2014 with 40 enrollments, 21 activated centers, and 12 additional centers committed to participate. On February 25, 2015, we announced that we had received unconditional approval from the FDA to conduct an interim analysis of COUNTER HF, which could reduce the overall duration of the trial. On March 6, 2015, we announced that COUNTER HF had reached a pre-determined pausing point and we temporarily suspended enrollment in accordance with the study protocol. The FDA has responded to our pause notification and has advised that we submit an IDE supplement to discuss the reasons for the temporary suspension and a plan for study resumption. We submitted the document to the FDA on March 16, 2015. This supplement carries up to a 30-day review period by the FDA.

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 limited sales, marketing or established distribution operations and will need to expand our expertise in these areas.

We currently have limited 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 have commenced the OPTIONS HF clinical study and plan to commercialize our system outside of the United States, which exposes us to risks associated with international operations.

We plan to commercialize our system outside of the United States and have commenced a post-market clinical study 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;
- difficulties in selling in countries where other companies and their products may be more established, have greater brand recognition and a history of selling multiple product lines to our target customers;
- 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 the C-Pulse System. The loss of any of these manufacturer or supplier relationships could delay future clinical studies or prevent or delay commercialization of the C-Pulse System.

We rely on third parties to manufacture the C-Pulse System and to supply us with all of the critical components of the 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 studies 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 would require FDA and European submissions, such as IDE supplements, PMA supplements and change notifications. 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 the C-Pulse System could be interrupted for an extended period of time and become significantly more expensive. This could delay completion of future clinical studies or commercialization of the C-Pulse System and adversely affect our business, results of operations and financial condition. 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 the 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 businesses. We currently anticipate that we will continue to rely on third-party manufacturers and suppliers for the production of the 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, results of operations, financial condition and prospects would be harmed.

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, all of which will involve significant expense. 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, results of operations and financial condition.

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 further develop, conduct clinical studies, and obtain reimbursement and regulatory approvals for, our products;
- 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 our ability to receive additional financing, as well as future revenues from sales of the C-Pulse System. We may be unable to reduce our expenditures in a timely manner to compensate for any unexpected shortfall in financing or revenue. Accordingly, a significant shortfall in demand for our system or available financing could have an immediate and material impact on our business, results of operations 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., HeartWare International Inc., Jarvik Heart, Inc., ReliantHeart, 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 significantly 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 business, results of operations and financial condition.

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, results of operations and financial condition.

We may be sued for product liability, which could harm our business, results of operations and financial condition.

The design, manufacture and marketing of medical devices carries a significant risk of product liability claims. Our system treats Class III and ambulatory Class IV heart failure for patients who typically have serious medical issues. As a result, our exposure to product liability claims may be heightened because the people who use our system have a high risk of suffering adverse outcomes, regardless of the safety or efficacy of our system. In addition, because our system has been implanted in a limited number of patients to date, we cannot assure you that we are currently aware of all material risks related to use of our system or that could lead to product liability claims against us.

We may be held liable if any product we develop and commercialize causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or consumer use. The safety studies we must perform and the regulatory approvals required to commercialize our system will not protect us from any such liability. We carry product liability insurance with a $10 million aggregate limit. However, if there are product liability claims against us, our insurance may be insufficient to cover the expense of defending against such claims, or may be insufficient to pay or settle such claims. Furthermore, we may be unable to obtain adequate product liability insurance coverage for commercial sales of any of our approved products. If such insurance is insufficient to protect us, our business, results of operations and financial condition 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 study participants, significant costs of related litigation, loss of revenue or the inability to commercialize the C-Pulse System.

If we acquire other businesses, products or technologies, we will be subject to risks that could hurt our business.

We may pursue acquisitions to obtain complementary businesses, products or technologies. Any such acquisition may not produce the revenues, earnings or business synergies that we anticipate and an acquired business, product or technology might not perform as we expect. Our management could spend a significant amount of time, effort and money in identifying, pursuing and completing the acquisition. If we complete an acquisition, we may encounter significant difficulties and incur substantial expenses in integrating the operations and personnel of the acquired company into our operations. In particular, we may lose the services of key employees of the acquired company and we may make changes in management that impair the acquired company's relationships with employees, vendors and customers. Additionally, we may acquire development-stage companies that are not yet profitable and which require continued investment, which could decrease our future earnings or increase our futures losses.

Any of these outcomes could prevent us from realizing the anticipated benefits of an acquisition. To pay for an acquisition, we might use stock or cash. Alternatively, we might borrow money from a bank or other lender. If we use stock, our stockholders would experience dilution of their ownership interests. If we use cash or debt financing, our financial liquidity would be reduced. As a result of our annual impairment testing, we may be required to capitalize a significant amount of intangibles, including goodwill, which may lead to significant amortization or write-off charges. These amortization charges and write-offs could decrease our future earnings or increase our future losses.

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 studies for the C-Pulse System. Any failure or significant delay in successfully completing our pivotal study or obtaining regulatory approvals could harm our business, results of operations, financial condition and prospects and require us to seek additional funding.

Upon completion of the six-month follow-up period for our feasibility study, we submitted the study's clinical data to the FDA in November 2011. In November 2012, the FDA provided us with unconditional approval to initiate a pivotal study. The COUNTER HF™ study is designed to enroll 388 patients randomized 1:1 to treatment (C-Pulse implantation) versus optimal medical therapy, at up to 40 participating hospitals and clinics. The primary efficacy endpoint of the study is defined as freedom from worsening heart failure resulting in hospitalization, LVAD implantation, cardiac transplantation or heart failure related death. We commenced enrollment in the U.S. Counter HF study in September 2013 and concluded 2014 with 40 enrollments, 21 activated centers, and 12 additional centers committed to participate. On February 25, 2015, we announced that we had received unconditional approval from the FDA to conduct an interim analysis of COUNTER HF, which could reduce the overall duration of the trial. On March 6, 2015, we announced that COUNTER HF had reached a pre-determined pausing point and we temporarily suspended enrollment in accordance with the study protocol. The FDA has responded to our pause notification and has advised that we submit an IDE supplement to discuss the reasons for the temporary suspension and a plan for study resumption. We submitted the document to the FDA on March 16, 2015. This supplement carries up to a 30-day review period by the FDA.

Completion of the pivotal study could be delayed, and adverse events during the study could cause us to modify the existing design, repeat or terminate the study. If the study is delayed, if it must be repeated or if it is terminated, our costs associated with the study 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 study 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 complete our pivotal clinical study, we must demonstrate the safety and efficacy of the C-Pulse System by meeting the study'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 study 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 study, we will need to receive approval from regulatory agencies in each country outside the European Union 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 study, or experience significant delays in the study, or if the results of the study do not meet its safety and efficacy endpoints, our ability to obtain regulatory approval to commercialize our system and to generate revenues will be significantly harmed.

We will need to obtain FDA approval to commercialize our system in the United States.

We will need to obtain FDA approval to commercialize our system in the United States, which will require us to conduct clinical studies in the United States and to complete those studies 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, which we believe is the largest potential market for the C-Pulse System. We do not currently have the necessary regulatory approvals to commercialize the C-Pulse System in the United States. We can offer no assurance that our clinical studies 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 the C-Pulse System, we will be required to receive a PMA from the FDA. A PMA must be supported by data from pre-clinical and clinical studies to demonstrate safety and efficacy. A clinical study 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 study in the United States. Enrollment in our U.S. pivotal study began in September 2013, but there can be no assurance that our U.S. pivotal study will be completed on schedule or at all. Even if completed, we do not know if this study 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 the 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 IDE or 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 the 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, results of operations or financial condition.

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

Our U.S. pivotal study commenced during September 2013. The study has been designed to be a randomized study that includes approximately 388 patients and is expected to involve approximately 40 sites. Conducting a clinical study of this size is a complex and uncertain process.

Completion of enrollment of our study could be delayed for a variety of reasons, including:

- reaching agreement on acceptable terms with prospective clinical study sites;
- manufacturing sufficient quantities of the C-Pulse System;
- obtaining institutional review board approval to conduct the study 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 study.

In addition, the completion of the study and our other ongoing clinical studies could be delayed, suspended or terminated for several reasons, including:

- ongoing discussions with regulatory authorities regarding the scope or design of our pre-clinical results or clinical study or requests for supplemental information with respect to our pre-clinical results or clinical study results;
- our or our clinical sites' failure or inability to conduct the clinical studies in accordance with regulatory requirements;
- sites currently participating in the study may drop out of the study, 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 study;
- patients may not achieve the required clinical end-points of the study;
- patients may not remain in or complete clinical studies at the rates we expect;
- patients may experience serious adverse events or side effects during the study, which, whether or not related to our system, could cause the FDA or other regulatory authorities to place the clinical study on hold; and
- clinical investigators may not perform clinical studies on our anticipated schedule or consistent with the clinical study protocol and good clinical practice requirements.

If our pivotal study is delayed, it will take us longer to ultimately commercialize a product or result in our being unable to do so. Our development costs will also increase if we have material delays in our pivotal study or if we need to perform more or larger clinical studies 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 study at all, which could prevent us from receiving regulatory approval for the C-Pulse System altogether. Any of the foregoing could harm our business, results of operations, financial condition and prospects and cause us to seek additional funding.

If we fail to obtain an adequate level of reimbursement for our system by third-party payers, 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 payers significantly affect the market for our system. Reimbursement by third-party payers 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 payers 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 payers in the United States, which we believe is the largest potential market for our system, our business, results of operations, financial condition 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 studies, 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. We do not currently plan to commercialize the C-Pulse System in any country unless the product is approved for reimbursement. Our failure to receive international reimbursement or pricing approvals would significantly harm our operations, financial condition and prospects.

We believe that future reimbursement may be subject to increased restrictions both in the United States and in international markets. Future legislation, regulation or reimbursement policies of third-party payers may adversely affect the demand for 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 payers continually attempt to contain or reduce the costs of health care by challenging the prices charged for health care products and services. If reimbursement for our 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 depend on clinical investigators and clinical sites to enroll patients in our clinical studies, and on other third parties to manage the studies 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 studies, including our U.S. pivotal study, 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 studies. If these clinical investigators and clinical sites fail to enroll a sufficient number of patients in our clinical studies, to ensure compliance by patients with clinical protocols or to comply with regulatory requirements, we will be unable to complete these studies, which could prevent us from obtaining regulatory approvals for our system. Our agreements with clinical investigators and clinical study sites for clinical testing place substantial responsibilities on these parties and, if these parties fail to perform as expected, our studies could be delayed or terminated. If sites fail to meet FDA requirements in conducting the studies, 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 studies may be extended, delayed or terminated, or the clinical data may be rejected by the FDA, our costs will increase 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 on third parties to manufacture the C-Pulse System. We are required to demonstrate and maintain compliance with the applicable QSR by controlling our suppliers and requiring that they manufacture in conformance with the QSR. A contractor that manufactures a completed device for us is directly subject to the QSR but we also are held responsible by the FDA.

A contractor that manufactures a component is not subject to the QSR. In those cases we are responsible to the 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 studies 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 in one jurisdiction, 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 may otherwise 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, results of operations and financial condition.

Legislative or regulatory reforms may adversely affect our ability to sell the C-Pulse System profitably.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the clearance or approval, manufacture and marketing of a medical device. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and the C-Pulse System. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations will be changed, and what the impact of such changes, if any, may be. For example, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions that may prevent or delay approval or clearance of the C-Pulse System. For example, in 2011, the FDA announced a Plan of Action to modernize and improve the FDA's premarket review of medical devices, and has implemented, and continues to implement, reforms intended to streamline the premarket review process. In addition, as part of the Food and Drug Administration Safety and Innovation Act of 2012, Congress enacted several reforms entitled the Medical Device Regulatory Improvements and additional miscellaneous provisions which will further affect medical device regulation both pre- and post-approval. Any change in the laws or regulations that govern the approval processes relating to the C-Pulse System could make it more difficult and costly to obtain approval for the C-Pulse System. Other jurisdictions might change approval regulations that could affect marketability of the C-Pulse System. For example, the European Union is modifying the Medical Device Directive and the Active Implantable Directive, which will increase requirements on devices such as the C-Pulse System.

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 payers or the medical community. The degree of market acceptance of any of the devices that we may develop will depend on a number of factors, including:

- the perceived effectiveness 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 the 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 payers and the medical community, we may not generate product revenue and we may not become profitable or be able to sustain profitability.

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 comply or have not fully complied with such laws, we could face substantial penalties.

If we are successful in achieving regulatory approval to market the 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 the FCPA. These laws may impact, among other things, our proposed sales, and marketing and education programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal health care program such as 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 False Claim Act actions. The 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 with *qui tam* provisions. States had 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 Affordable Care Act includes provisions known as the Physician Payments Sunshine Act, which require 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 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, we are subject to the FCPA and other countries' anti-corruption/anti-bribery regimes, such as the U.K. Bribery Act. The FCPA prohibits improper payments or offers of payments to foreign governments and their officials for the purpose of obtaining or retaining business. Safeguards we implement to discourage improper payments or offers of payments by our employees, consultants, sales agents or distributors may be ineffective, and violations of the FCPA and similar laws may result in severe criminal or civil sanctions, or other liabilities or proceedings against us, any of which would likely harm our reputation, business, results of operations and financial condition.

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 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 December 31, 2014, we owned 18 issued patents in the United States and eight patent applications in the United States, as well as 50 issued patents and 28 patent applications in foreign jurisdictions. We estimate that most of our 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 studies 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 were 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, results of operations and financial condition would be significantly harmed.

If we were 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.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we collect and store sensitive data, including legally protected health information, personally identifiable information, intellectual property and proprietary business information owned or controlled by ourselves or others. We manage and maintain our applications and data utilizing on-site systems. These applications and data encompass a wide variety of business-critical information including research and development information, commercial information, and business and financial information. We face four primary risks relative to protecting this critical information, including: loss of access risk; inappropriate disclosure risk; inappropriate modification risk; and the risk of our being unable to adequately monitor our controls over the first three risks.

The secure processing, storage, maintenance, and transmission of this critical information is vital to our operations and business strategy. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance, or other disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost, or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as HIPAA, and regulatory penalties. Although we believe we have implemented adequate security measures, there is no guarantee we can continue to protect our systems and data from unauthorized access, loss or dissemination that could also disrupt our operations, including our ability to conduct our analyses, bill payers or patients, conduct research and development activities, collect, process, and prepare company financial information, provide information about our products and other patient and physician education and outreach efforts through our website, manage the administrative aspects of our business, and damage our reputation, any of which could adversely affect our business.

In addition, the interpretation and application of consumer, health-related, and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory, and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations may differ from country to country, and may vary based on whether testing is performed in the United States or in the local country. Complying with these various laws could

cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

Risks 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 NASDAQ only since February 16, 2012 and has experienced limited trading volume. The average daily trading volume in our common stock on NASDAQ for the three-month period ended December 31, 2014 was approximately 89,000 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 traded on NASDAQ since February 16, 2012, and CDIs representing beneficial ownership of our common stock traded on the ASX from September 2004 until May 6, 2013. 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 price per share of our common stock traded on NASDAQ ranged from $4.85 to $8.13 from January 1, 2013 to June 30, 2013, and from $5.34 to $13.80 from July 1, 2013 to December 31, 2013, from $4.99 to $11.29 from January 1, 2014 to June 30, 2014, and from $3.56 to $6.40 from July 1, 2014 to December 31, 2014. 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 studies 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;
- 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 ability to use U.S. net operating loss carryforwards or Australian tax losses might be limited.

As of December 31, 2014, we had U.S. net operating loss (***"NOL"***) carryforwards of approximately $69.3 million for U.S. income tax purposes, which expire from 2022 through 2033. To the extent these NOL carryforwards are available, we intend to use them to reduce any corporate income tax liability associated with our operations that 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, 2014, we had tax losses in the Commonwealth of Australia of approximately AU$48.8 million. Continuing utilization of carryforward tax losses in Australia may also be affected by the issuance of our common stock 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 use of our NOL 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 NOL carryforwards and tax losses, which could result in lower profits.

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 will not realize a return on their investments unless the trading price of our common stock appreciates.

We will continue to incur increased costs as a result of being 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 were previously listed on the ASX and had 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, and will continue to cause 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 NASDAQ. We expect these rules and regulations will continue to increase our legal and financial compliance costs and make some activities more time-consuming and costly, and these activities may increase general and administrative expenses and divert management's time and attention away from revenue-generating activities. We also expect these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers.

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

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

We continue to evaluate our existing internal controls over financial reporting against the standards adopted by the Public Company Accounting Oversight Board. During the course of our ongoing evaluation of the internal controls, we may identify areas requiring improvement, and may have to design enhanced processes and controls to address issues identified through this review. Remediating any deficiencies, significant deficiencies or material weaknesses that we or our independent registered public accounting firm may identify may require us to incur significant costs and expend significant time and management resources. We cannot assure you that any of the measures we implement to remedy any such deficiencies will effectively mitigate or remedy such deficiencies. The existence of one or more material weaknesses could affect the accuracy and timing of our financial reporting. Investors could lose confidence in our financial reports, and the value of our common stock 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 to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, as amended (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.

Our certificate of incorporation, bylaws and stockholder rights plan, as well as certain provisions of the DGCL, may delay or deter a change in 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 in control of us, and could limit the price that investors might be willing to pay in the future for shares of our common stock.

Further, on June 14, 2013, our board of directors adopted a stockholder rights plan, which is designed to assure that all of our stockholders receive fair and equal treatment in the event of any proposed takeover of the Company and to guard against partial tender offers, open market accumulations and other abusive or coercive tactics without paying stockholders a control premium. The stockholder rights plan may have anti-takeover effects by discouraging potential proxy contests and other takeover attempts, particularly those that have not been negotiated with the board of directors, and the stockholder rights plan may also inhibit the acquisition of a controlling position in our common stock. Therefore, transactions may not occur that stockholders would otherwise support and/or from which they would receive a substantial premium for their shares over the current market price. The stockholder rights plan may also make it more difficult to remove members of the current board of directors or management.

It may be difficult to effect service of U.S. process and enforce U.S. legal process against one of our directors.

One of our seven directors resides outside of the United States, specifically in Australia. A substantial portion of the assets of this director is also located outside of the United States. Therefore, it may not be possible to effect service of process within the United States upon this director in order to enforce judgments of U.S. courts against this director 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 this director 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 external auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a non-binding 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 following our initial public offering, although we could lose that status sooner if our revenues exceed $1 billion, if we issue more than $1 billion in non-convertible debt in a three-year period, or if the market value of our common stock held by non-affiliates exceeds $700 million as of any June 30 before that time, in which case we would no longer be an emerging growth company as of the following December 31. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and 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.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

As of December 31, 2014, we had approximately 17.0 million shares of common stock outstanding. If our stockholders sell substantial amounts of our common stock in the public market, for example, liquidation of shares held by our principal stockholders, including shares issued upon the exercise of outstanding options, the market price of our common stock could decline. These sales also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

We have a large number of authorized but unissued shares of stock, which could negatively impact a potential investor if they purchased our common stock.

Our certificate of incorporation provides for 100,000,000 shares of authorized common stock, of which more than 80,000,000 shares are available for future issuance, and 40,000,000 shares of authorized preferred stock, 30,000 shares of which are designated as Series A Junior Participating Preferred Stock in connection with the stockholder rights plan and all of which are available for future issuance. The issuance of additional shares of common stock may have a dilutive effect on earnings per share and relative voting power and may cause a decline in the trading price of our common stock. We could use the shares of common stock that are available for future issuance in dilutive equity financing transactions, or to oppose a hostile takeover attempt or delay or prevent changes in control or changes in or removal of management, including transactions that are favored by a majority of the stockholders or in which the stockholders might otherwise receive a premium for their shares over then-current market prices or benefit in some other manner.

Our board of directors will be authorized, without further stockholder approval, to issue up to 39,970,000 shares of preferred stock with such rights, preferences and privileges as our board may determine. These rights, preferences and privileges may include dividend rights, conversion rights, voting rights and liquidation rights that may be greater than the rights of our common stock. As a result, the rights of holders of our common stock will be subject to, and could be adversely affected by, the rights of holders of any preferred stock that may be issued in the future.

On June 14, 2013, our board of directors authorized 30,000 shares of Series A Junior Participating Preferred Stock in connection with the Company's adoption of the stockholder rights plan.

If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our common stock, the price of our common stock could decline.

The trading market for our common stock relies in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts. The price of our common stock could decline if one or more equity analysts downgrade our common stock or if analysts issue other unfavorable commentary or cease publishing reports about us or our business.

Item 1B. Unresolved Staff Comments.

Not applicable.

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 $23,000. The lease includes several months abated rent and contains future rent escalation provisions based upon Consumer Price Indexes. Rent expense is being recorded across all periods covered by the lease.

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 pending 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 NASDAQ under the symbol "SSH."

The following table sets forth, for the periods indicated, the high and low trading prices for our common stock as reported on NASDAQ in U.S. Dollars.

Period	High	Low
Year Ended December 31, 2015		
First Quarter (through March 16, 2015)	5.77	3.90
Year Ended December 31, 2014		
First Quarter	11.49	5.45
Second Quarter	6.49	4.78
Third Quarter	6.54	4.15
Fourth Quarter	6.20	3.49
Year Ended December 31, 2013		
First Quarter	8.13	5.21
Second Quarter	6.40	4.85
Third Quarter	13.80	5.34
Fourth Quarter	12.04	7.71

Stockholders of Record. As of March 18, 2015, we had 18,231,091 shares of common stock issued and outstanding, and there were 249 holders of record of our common stock.

Dividends. We have not historically paid cash 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.

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 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 study 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 had completed its review of the C-Pulse System feasibility study data and concluded we met the applicable agency requirements, and further indicated that we could move forward with an investigational device exemption

application. In November 2012, the FDA provided us with unconditional approval to initiate a pivotal study. We commenced enrollment in our COUNTER HF™ pivotal study in September 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 have initiated a post-market study in Europe which may include data from other geographies (e.g., Canada) that will evaluate endpoints similar to those for our U.S. pivotal study and enrollment under this study commenced in the second quarter of 2013.

Recent Developments

On March 6, 2015, we announced that COUNTER HF, our US pivotal trial, had reached a pre-determined pausing point and we temporarily suspended enrollment in accordance with the study protocol. The FDA has responded to our pause notification and has advised that we submit an IDE supplement to discuss the reasons for the temporary suspension and a plan for study resumption. We submitted the document to the FDA on March 16, 2015. This supplement carries up to a 30-day review period by the FDA.

On February 25, 2015, we announced that we had received unconditional approval from the FDA to conduct an interim analysis of COUNTER HF. The COUNTER HF study is a prospective, randomized, multi-center, controlled study expected to randomize 388 patients in up to 40 clinical sites. This interim analysis could reduce the overall duration of the trial.

On February 18, 2015, we entered into a loan and security agreement with Silicon Valley Bank for a total loan amount of up to $10.0 million, with $6.0 million funded at closing, an additional $2.0 million available after notification that the FDA has granted us approval of a statistical interim analysis plan, and the remaining $2.0 million available subject to the Company enrolling its one hundredth patient in the COUNTER HF study in the United States on or before September 30, 2015. In connection with this transaction, we issued warrants to Silicon Valley Bank and affiliates to purchase 68,996 shares of common stock at $5.22 per share. As of March 16, 2015, total amounts outstanding under this loan agreement were $6.0 million.

In 2014, we entered into a sales agreement with Cowen and Company, LLC (***"Cowen"***), allowing Cowen to sell from time to time, shares of our common stock having an aggregate offering price of up to $40.0 million, through an "at the market" equity offering program (the ***"Sales Agreement"***). We pay Cowen a commission of up to 3.0% of the gross proceeds from the sale of any shares pursuant to the Sales Agreement. From November 17, 2014 to December 31, 2014, we sold 23,120 shares of common stock for net proceeds of $73,000 after issuance costs of $32,000. From January 1, 2015 to February 27, 2015, we sold 1,214,395 shares of common stock for net proceeds of $6.9 million after stock issuance costs of $0.2 million. There were no sales subsequent to February 27, 2015. We have a total of $32.8 million available for future sales under the Sales Agreement.

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. The C-Pulse System is not approved for commercial sale. However, the FDA has assigned the C-Pulse System to a Category B designation, making it eligible for reimbursement at certain U.S. sites during our clinical studies. Consequently, we are able to invoice hospitals and clinics that are eligible for reimbursement by Medicare, Medicaid or private insurance companies. Our revenue consists solely of sales of the C-Pulse System to hospitals and clinics who participate in our clinical studies per the terms of the clinical study contracts. For clinical study implant revenue, the product title generally transfers on the date the product is implanted. Product costs incurred for our clinical studies are deemed to be development costs and, accordingly, are expensed to research and development as incurred. Upon commercialization, product costs will be capitalized in inventory and recorded to cost of sales as the inventory is sold. We do not charge hospitals and clinics for shipping. We expense shipping costs at the time we report the related revenue and record such costs in cost of sales.

Stock-Based Compensation

We recognize all share-based payments to employees and directors, including grants of stock options, restricted stock units (RSUs), warrants and common stock awards in the income statement as an operating expense based on their fair values over the requisite service period.

We compute the estimated fair values of stock options and warrants using the Black-Scholes option pricing model. Market price at the date of grant is used to calculate the fair value of restricted stock units and common stock awards. We did not record a tax benefit in connection with these awards as we provided a full valuation allowance on our deferred tax assets.

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 include RSUs, warrants or options to purchase shares of our common stock. These RSUs, 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 fully vested awards at the time of grant, and of unvested awards over the period in which the related services are received. Unvested awards are remeasured to fair value until they vest.

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, 2014 and 2013, 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 development, clinical and regulatory milestones as and when required. Our directors, after due consideration, believe that we will be able to raise new 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 the C-Pulse System. 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. However, management is subject to Section 404(a) of the Sarbanes-Oxley Act of 2002 and is required to report annually on effectiveness of our internal control over financial reporting.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, (the FASB) issued Accounting Standards Update No. 2014-09 *Revenue from Contracts with Customers* (Topic 606) (ASU 2014-09). ASU 2014-09 is a comprehensive new revenue recognition model that creates a single source of revenue guidance for all companies in all industries. The model is more principle-based than current guidance, and is primarily based on recognizing revenue in an amount that reflects the consideration to which the entity expects to be entitled in exchange for transferring goods or services to a customer. The guidance of ASU 2014-09 will be effective for our interim and annual reporting periods beginning January 1, 2017. The standard allows us to transition to the new model using either a full or modified retrospective approach, and early adoption is not permitted. We are currently evaluating the impact that this standard will have on our business practices, financial condition, results of operations and disclosures.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements - Going Concern* (Subtopic 205-40); *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, which explicitly requires management of a company to evaluate whether there is substantial doubt about a company's ability to continue as a going concern and to provide related footnote disclosure in certain circumstances. This guidance will be effective for interim and annual reporting periods beginning

January 1, 2017, with early adoption permitted. We are evaluating the impact that the adoption of this guidance will have, if any, on our financial statements and disclosures.

Financial Overview

We are an early-stage medical device company focused on developing, manufacturing and commercializing the 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 pre-clinical and clinical studies. At December 31, 2014, we had an accumulated deficit of $126.6 million and we expect to incur losses for the foreseeable future. To date, we have been funded primarily by various 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, 2014 to Year Ended December 31, 2013

Revenue

Year Ended December 31, 2014	Year Ended December 31, 2013	Increase (Decrease)	% Change
$ 295,000	$ 59,000	$ 236,000	400%

Sales of the C-Pulse System to hospitals and clinics under contract in conjunction with our North American FDA clinical studies historically have generated all of our revenue. The C-Pulse System is not approved for commercial sale, however, the FDA has assigned the C-Pulse System to a Category B designation, making it eligible for reimbursement at certain U.S. sites when implanted in connection with our clinical studies. Consequently, we are able to invoice hospitals and clinics that are eligible for reimbursement by Medicare, Medicaid or private insurance companies. As many private insurance companies and certain governmental institutions have a non-coverage policy for experimental or investigational procedures, however, we have not been successful in achieving reimbursement for some implant procedures. Five C-Pulse System devices were implanted in 2014 for which we recognized revenue, compared to one during 2013. We expect our revenue will be minimal until we begin enrolling patients in our North American pivotal clinical study at an increased rate and establish reimbursement in our post-marketing study in select countries in Europe. Product costs incurred for our clinical studies are deemed to be development costs and, accordingly, are expensed to research and development as incurred.

Selling, General and Administrative Expense

Year Ended December 31, 2014	Year Ended December 31, 2013	Increase (Decrease)	% Change
$ 9,208,000	$ 9,426,000	$ (218,000)	(2.3)%

Our decrease in selling, general and administrative expense in 2014 compared to 2013 is attributed to decreased stock compensation costs. We expect our selling, general and administrative expense will grow above comparable prior year period levels in future periods as we continue investments to support our growth.

Research and Development Expense

Year Ended December 31, 2014	Year Ended December 31, 2013	Increase (Decrease)	% Change
$ 16,874,000	$ 13,504,000	$ 3,370,000	25.0%

Our increase in research and development expense in 2014 compared to 2013 resulted primarily from increased personnel and clinical research infrastructure to support our clinical studies in North America and Europe. We expect our research and development expense will continue to be above prior year levels throughout 2015 as we add personnel to support our clinical studies and pursue our development efforts.

Other Expense, Net

Year Ended December 31, 2014	Year Ended December 31, 2013	Increase (Decrease)	% Change
$ (49,000)	$ (100,000)	$ (51,000)	(51.0)%

Interest income in 2014 and 2013 was offset by foreign currency exchange losses, primarily on the remeasurement of intercompany liabilities of our subsidiaries in Australia and Ireland that are denominated in their respective functional currencies.

Income Tax Benefit

Year Ended December 31, 2014	Year Ended December 31, 2013	Increase (Decrease)	% Change
$ 249,000	$ 1,213,000	$ (964,000)	(79.5)%

Our income tax benefit for 2014 resulted primarily from research and development tax credits in Australia. Our income tax benefits for 2013 resulted from research and development tax credits in Australia and Minnesota. We completed our Australian tax return for the 12-month period ended June 30, 2013 in 2014 and received a $265,000 research and development tax credit refund during the year. We completed our Australian tax return for the twelve month period ended June 30, 2012 in 2013 and received a $1,077,000 research and development tax credit refund during the year. We completed our Minnesota tax return for the 12-month period ended December 31, 2012 in 2013 and recognized a $136,000 research and development tax credit refund during the year. Assuming no further changes to the applicable Australian law for research and development tax credits, we expect to receive research and development tax credit refunds in the future in decreased amounts that vary based on reduced research and development expenditures in Australia. At this time, we are working to complete our analysis of the potential research and development tax credit refund that may be available for the period ended June 30, 2014. The Minnesota research and development tax credit is no longer refundable for tax years beyond 2012.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations primarily through cash on hand and a series of equity issuances, including the issuance of common shares for net cash proceeds of $0.1 million and $57.6 million in the years ended December 31, 2014 and 2013, respectively.

In 2014, we entered into a sales agreement with Cowen, allowing Cowen to sell from time to time, shares of our common stock having an aggregate offering price of up to $40.0 million, through the Sales Agreement. As of March 16, 2015, we had a total of $32.8 million available for future sales under the Sales Agreement. In addition, subsequent to year end, we entered into a loan agreement with Silicon Valley Bank for proceeds of up to $10 million. As of December 31, 2014 and 2013, cash and cash equivalents were $31.3 million and $54.1 million, respectively.

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 equity and debt financings 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 $22.6 million and $17.4 million in 2014 and 2013, respectively. The net cash used in each of these periods primarily reflects the net loss for those periods, offset in part by $2.7 million and $3.2 million, respectively, of stock-based compensation, $0.3 million and $0.2 million, respectively of depreciation, and the effects of changes in operating assets and liabilities.

Cash Flows from Investing Activities

Net cash used in investing activities was $0.4 million and $0.3 million in 2014 and 2013, respectively. Cash used in investing activities was for equipment to support our assembly, research and development and clinical study activities.

Cash Flows from Financing Activities

Net cash provided by financing activities was $0.1million and $57.6 million in 2014 and 2013, respectively. Net cash provided by financing activities was attributable to proceeds from sales of our common stock and exercise of warrants.

Capital Resource Requirements

As of December 31, 2014, we did not have any material commitments for capital expenditures.

Off-Balance Sheet Arrangements

We have no off-balance sheet transactions, arrangements, obligations (including contingent obligations), or other relationships with unconsolidated entities or other persons that have, or may have, a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

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

The Board of Directors and Shareholders
Sunshine Heart, Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of Sunshine Heart, Inc. and Subsidiaries (the Company) as of December 31, 2014 and 2013, and the related consolidated statements of operations and comprehensive loss, shareholders' 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 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 consolidated financial position of Sunshine Heart, Inc. and Subsidiaries at December 31, 2014 and 2013, and the consolidated results of their operations and their cash flows for each of the years then ended, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 of the consolidated financial statements, the Company has recurring losses from operations and an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not contain any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young LLP
Minneapolis, Minnesota
March 20, 2015

SUNSHINE HEART, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

In thousands, except share and per share amounts	Dec 31, 2014	Dec 31, 2013
ASSETS		
Current assets		
Cash and cash equivalents	$ 31,293	$ 54,136
Accounts receivable	59	59
Other current assets	360	448
Total current assets	31,712	54,643
Property, plant and equipment, net	661	587
TOTAL ASSETS	$ 32,373	$ 55,230
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 2,079	$ 2,188
Accrued salaries, wages, and other compensation	1,079	1,315
Total current liabilities	3,158	3,503
Total liabilities	3,158	3,503
Commitments and contingencies (Note 6)	—	—
Stockholders' equity		
Series A junior participating preferred stock as of December 31, 2014 and December 31, 2013, $0.0001 par value per share; authorized 30,000 shares, none outstanding	—	—
Preferred stock as of December 31, 2014 and December 31, 2013, $0.0001 par value per share; authorized 39,970,000 shares, none outstanding	—	—
Common stock as of December 31, 2014 and December 31, 2013, par value $0.0001 per share; authorized 100,000,000 shares; issued and outstanding 16,982,642 and 16,825,284, respectively	2	2
Additional paid-in capital	154,540	151,530
Accumulated other comprehensive income:		
Foreign currency translation adjustment	1,272	1,207
Accumulated deficit	(126,599)	(101,012)
Total stockholders' equity	29,215	51,727
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$** 32,373	**$** 55,230

See notes to the consolidated financial statements

SUNSHINE HEART, INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss

In thousands, except per share amounts	Year ended Dec 31, 2014	Year ended Dec 31, 2013
Net sales	$ 295	$ 59
Operating expenses:		
Selling, general and administrative	9,208	9,426
Research and development	16,874	13,504
Total operating expenses	26,082	22,930
Loss from operations	(25,787)	(22,871)
Other expense, net	(49)	(100)
Loss before income taxes	(25,836)	(22,971)
Income tax benefit, net	249	1,213
Net loss	$ (25,587)	$ (21,758)
Basic and diluted loss per share	$ (1.51)	$ (1.71)
Weighted average shares outstanding—basic and diluted	16,899	12,723
Other comprehensive income:		
Foreign currency translation adjustment	$ 65	$ 22
Total comprehensive loss	$ (25,522)	$ (21,736)

See notes to the consolidated financial statements

SUNSHINE HEART, INC. AND SUBSIDIARIES

Consolidated Statements of Stockholders' Equity

In thousands	Outstanding Shares	Common Stock	Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Equity
Balance December 31, 2012	**9,283**	**$ 1**	**$ 91,017**	**$ 1,185**	**$ (79,254)**	**$ 12,949**
Net loss					(21,758)	(21,758)
Foreign currency translation adjustment				22		22
Stock based compensation, net	56		2,804			2,804
Reclassification of stock options as liability awards			(95)			(95)
Issuance of common stock, net	7,486	1	57,565			57,566
Issuance of warrants for service agreement			239			239
Balance December 31, 2013	**16,825**	**2**	**151,530**	**1,207**	**(101,012)**	**51,727**
Net loss					(25,587)	(25,587)
Foreign currency translation adjustment				65		65
Stock based compensation, net			2,678			2,678
Settlement of liability awards			243			243
Issuance of common stock, net	158		89			89
Balance December 31, 2014	**16,983**	**$ 2**	**$ 154,540**	**$ 1,272**	**$ (126,599)**	**$ 29,215**

See notes to the consolidated financial statements

SUNSHINE HEART, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

In thousands	Year ended Dec 31, 2014	Year ended Dec 31, 2013
Operating Activities		
Net loss	$ (25,587)	$ (21,758)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation	277	185
Stock based compensation expense, net	2,678	2,953
Amortization of warrants for service agreements	—	239
Changes in assets and liabilities:		
Accounts receivable	—	(59)
Other current assets	(5)	(22)
Accounts payable and accrued expenses	(7)	1,100
Net cash used in operations	(22,644)	(17,362)
Investing activities:		
Purchase of property and equipment	(351)	(293)
Net cash used in investing activities	(351)	(293)
Financing activities:		
Net proceeds from the sale of common stock	89	57,566
Net cash provided by financing activities	89	57,566
Effect of exchange rate changes on cash	63	1
Net increase (decrease) in cash and cash equivalents	(22,843)	39,912
Cash and cash equivalents—beginning of period	54,136	14,224
Cash and cash equivalents—end of period	$ 31,293	$ 54,136
Supplemental Schedule of non-cash activities		
Stock options and restricted stock units classified as liabilities, net	$ —	$ 206

See notes to the consolidated financial statements

SUNSHINE HEART, INC. AND SUBSIDIARIES

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. The Company is headquartered in Eden Prairie, Minnesota and has a wholly owned subsidiary, Sunshine Heart Company Pty Limited, located in Clontarf, New South Wales, Australia and a wholly owned subsidiary, Sunshine Heart Ireland Limited, located in Dublin, Ireland. The Company is a medical device company developing innovative technologies for cardiac and coronary disease. The Company's primary product, 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. The Company has received approval from the US Food and Drug Administration (***"FDA"***) to conduct a U.S. feasibility clinical study with the C-Pulse System. Commencing February 16, 2012, the Company's shares of common stock began trading on NASDAQ under the symbol "SSH." The Company's shares of common stock previously traded in the form of CDIs on the ASX under the symbol "SHC" from September 2004 until the Company's delisting from the ASX, which occurred at the close of trading on May 6, 2013.

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, 2014 and 2013, the Company incurred losses from operations and net cash outflows from operating activities as disclosed in the consolidated statements of operations and comprehensive loss and cash flows, respectively. At December 31, 2014, the Company had an accumulated deficit of $126.6 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 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 subsidiaries, Sunshine Heart Company Pty Limited and Sunshine Heart Ireland Limited. 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

The Company's financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities. The Company believes 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 Financial Accounting Standards Board (the ***"FASB"***) Accounting Standards Codification (the ***"ASC"***) Topic 820 *"Fair Value Measurement,"* 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 equivalents are considered Level 1 measurements for all periods presented. The Company does not have any financial instruments classified as Level 2 or Level 3 and there were no movements between these categories during the years ended December 31, 2014 and 2013.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and term deposits with original maturities of three months or less. The carrying value of these instruments approximate fair value. The balances, at times, may exceed federally insured limits. The Company has not experienced any losses on its cash and cash equivalents.

Accounts Receivable

Accounts receivable are unsecured, are recorded at net realizable value, and do not bear interest. The Company makes judgments as to its ability to collect outstanding receivables based upon significant patterns of uncollectiblity, historical experience, and managements' evaluation of specific accounts and will provide an allowance for credit losses when collection becomes doubtful. The Company performs credit evaluations of its customers' financial condition on an as-needed basis. Payment is generally due 30 days from the invoice date and accounts past 30 days are individually analyzed for collectability. When all collection efforts have been exhausted, the account is written off against the related allowance. No allowance for doubtful accounts was considered necessary as of December 31, 2014 and 2013.

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. 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 to expense. 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	3-7 years

Depreciation expense was $277 and $185 for the years ended December 31, 2014 and 2013, respectively.

Property and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. If the impairment tests indicate that the carrying value of the asset, or asset group is greater than the expected undiscounted cash flows to be generated by such asset or asset group further analysis is performed to determine the fair value of the asset or asset group. To the extent the fair value of the asset or asset group is less than its carrying value, an impairment loss is recognized equal to the amount the fair value of the asset or asset group exceeds its carrying amount. The Company generally measures fair value by considering sale prices for similar assets or asset groups, or by discounting estimated

future cash flows from such assets or asset groups 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 or asset groups, and accordingly, actual results could vary significantly from such estimates. There have been no impairment losses recognized for the years ended December 31, 2014 or 2013.

Revenue Recognition

The Company recognizes 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. The C-Pulse System is not approved for commercial sale. However, the FDA has assigned the C-Pulse System to a Category B designation, making it eligible for reimbursement at certain U.S. sites during the Company's clinical studies. Consequently, the Company is able to invoice hospitals and clinics that are eligible for reimbursement by Medicare, Medicaid or private insurance companies. The Company's revenue consists solely of sales of the C-Pulse System to hospitals and clinics who participate in the Company's clinical studies per the terms of the clinical study contracts. For clinical study implant revenue, the product title generally transfers on the date the product is implanted. Product costs incurred for the Company's clinical studies are deemed to be development costs and are expensed to research and development as incurred. Upon commercialization, product costs will be capitalized in inventory and recorded to cost of sales as the inventory is sold. The Company does not charge hospitals and clinics for shipping. The Company expenses shipping costs at the time of shipment.

Foreign Currency Translation

Sales and expenses denominated in foreign currencies are translated at average exchange rates in effect throughout the year. Assets and liabilities of foreign operations are translated at period-end exchange rates with the impacts of foreign currency translation recognized to cumulative translation adjustment, a component of *accumulated other comprehensive income*. Foreign currency transactions gains and losses are included in *other expense, net* in the consolidated statements of operations and other comprehensive loss.

Stock-Based Compensation

The Company recognizes all share-based payments to employees and directors, including grants of stock options, restricted stock units (RSUs) and common stock awards in the income statement as an operating expense, based on their fair value. The Company's stock awards use a graded vesting schedule. The Company recognizes the option expense over the requisite service period, which is generally the vesting period.

The Company computes the estimated fair values of stock options and warrants using the Black-Scholes option pricing model. The closing market price of the Company's common stock at the date of grant is used to calculate the fair value of restricted stock units and common stock awards. No tax benefit has been recorded in connection with these awards as the Company has provided a full valuation allowance on its deferred tax assets.

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 include RSUs, warrants or options to purchase shares of the Company's common stock. These RSUs, 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 fully vested awards at the time of grant, and of unvested awards over the period in which the related services are received. Unvested awards are remeasured to fair value until they vest.

See Note 4 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 carryforwards. Deferred tax liabilities are recognized for taxable temporary differences, which are the differences between the reported amounts of assets and liabilities and their tax bases. 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 and restricted stock units totaling 2,832,194 and 3,623,806 for the years ended December 31, 2014 and 2013, 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 $16,874 and $13,504 for the years ended December 31, 2014 and 2013, respectively.

Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (Topic 606) (ASU 2014-09). This standard is a comprehensive new revenue recognition model that creates a single source of revenue guidance for all companies in all industries. The model is more principle-based than current guidance, and is primarily based on recognizing revenue in an amount that reflects the consideration to which the entity expects to be entitled in exchange for transferring goods or services to a customer. The guidance of ASU 2014-09 will be effective for the Company's interim and annual reporting periods beginning January 1, 2017. The standard allows the Company to transition to the new model using either a full or modified retrospective approach, and early adoption is not permitted. The Company is currently evaluating the impact that this standard will have on its business practices, financial condition, results of operations and disclosures.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements - Going Concern* (Subtopic 205-40); *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, which explicitly requires management of a company to evaluate whether there is substantial doubt about a company's ability to continue as a going concern and to provide related footnote disclosure in certain circumstances. This guidance is effective for the Company's interim and annual reporting periods beginning January 1, 2017, with early adoption permitted. The Company is evaluating the impact that the adoption of this standard will have, if any, on its financial statements and disclosures.

The Company evaluates events through the date the financial statements are filed for events requiring adjustment to or disclosure in the financial statements.

Note 2—Balance Sheet Information

Property, Plant and Equipment

Property, plant and equipment were as follows:

	December 31, 2014	December 31, 2013
Office Furniture & Fixtures	$ 229	$ 111
Leasehold Improvements	145	145
Software	65	61
Production Equipment	786	574
Computer Equipment	221	204
Total	1,446	1,095
Accumulated Depreciation	(785)	(508)
	$ 661	$ 587

Note 3—Shareholder's Equity

Stockholder Rights Plan

On June 14, 2013, the Company adopted a stockholder rights plan (the ***"Rights Plan"***), which entitles the holders of the rights to purchase from the Company 1/1,000th of a share of Series A Junior Participating Preferred Stock, par value $0.0001 per share, at a purchase price of $35.00 per share, as adjusted (a ***"Right"***), upon certain trigger events. In connection therewith, on June 14, 2013, the Company's board of directors authorized 30,000 shares of Series A Junior Participating Preferred Stock and it declared a dividend of one Right per each share of common stock of the Company outstanding as of June 24, 2013. Each 1/1,000th of a share of Series A Junior Participating Preferred Stock has terms that are substantially the economic and voting equivalent of one share of the Company's common stock. However, until a Right is exercised or exchanged in accordance with the provisions of the Rights Plan, the holder thereof will have no rights as a stockholder of the Company, including, but not limited to, the right to vote for the election of directors or upon any matter submitted to stockholders of the Company. The Rights Plan has a three-year term and the board of directors may terminate the Rights Plan at any time (subject to the redemption of the Rights for a nominal value). The Rights may cause substantial dilution to a person or group (together with all affiliates and associates of such person or group and any person or group of persons acting in concert therewith) that acquires beneficial ownership of 15% or more of the Company's stock on terms not approved by the board of directors or takes other specified actions.

Common Stock Purchase Agreement

On January 15, 2013, the Company entered into a Common Stock Purchase Agreement (the ***"Purchase Agreement"***) with Aspire Capital Fund, LLC (***"Aspire Capital"***), which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $25 million in shares of the Company's common stock (the ***"Purchase Shares"***) over an approximately two-year period, terminating February 19, 2015, at purchase prices determined in accordance with the Purchase Agreement. Pursuant to the terms of the Purchase Agreement, the Company has filed and maintains a registration statement on Form S-1 with the SEC under which the Company has registered 3,000,000 shares of its common stock for resale by Aspire Capital.

The Purchase Agreement contains customary representations, warranties, covenants, closing conditions and indemnification and termination provisions by, among and for the benefit of the parties to the Purchase Agreement. The Purchase Agreement may be terminated by the Company at any time, at the Company's discretion, without any cost or penalty to the Company. Aspire Capital has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of the Company's shares. The Company 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, and restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement.

In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, the Company issued to Aspire Capital 80,257 shares of the Company's common stock as a commitment fee (the ***"Commitment Shares"***). The Purchase Agreement provides that the Company may not issue and sell more than 1,856,616 shares, or 19.99% of the Company's outstanding shares as of January 15, 2013.

As of December 31, 2014, the Company had sold 146,886 shares of common stock to Aspire Capital pursuant to the Purchase Agreement. Including the Commitment Shares, an aggregate of 227,143 shares of common stock were issued to Aspire Capital pursuant to the Purchase Agreement. There were no further issuances under the Purchase Agreement subsequent to December 31, 2014. The Purchase Agreement expired on February 19, 2015.

Public Offerings

On April 16, 2013, the Company sold 2,875,000 shares of common stock in a public offering at $5.25 per share, including 375,000 shares of common stock pursuant to the exercise of the over-allotment option by the Company's underwriters. Proceeds in the public offering and exercise of the over-allotment option, net of transaction costs were $14,036 in the aggregate.

On September 24, 2013, the Company sold 4,381,500 shares of common stock in a public offering at $10.50 per share, including 571,500 shares of common stock pursuant to the exercise of the over-allotment option by the Company's underwriters. Proceeds in the public offering and exercise of the over-allotment option, net of transaction costs were $42,674 in the aggregate.

ATM Sales

On March 21, 2014, the Company entered into a sales agreement (the "Sales Agreement") with Cowen and Company LLC ("***Cowen***"). Under the Sales Agreement, the Company may sell from time to time, in "at the market" offerings, shares of its common

stock registered under its currently effective registration statement on Form S-3. On March 21, 2014, the Company filed a prospectus supplement with the SEC in connection with the offering, relating to shares of its common stock having an aggregate offering price of up to $40.0 million. The Company pays Cowen a commission of up to 3.0% of the gross proceeds from the sale of any shares pursuant to the Sales Agreement.

From November 17, 2014 to December 31, 2014, the Company sold 23,120 shares of common stock for net proceeds of $73, after stock issuance costs of $32. As of December 31, 2014, the Company has a total of $39.9 million available for future sales under the Sales Agreement. Subsequent to year end, from January 1, 2015 to February 27, 2015, the Company sold 1,214,395 shares of common stock for net proceeds of $6.9 million after stock issuance costs of $0.2 million.

Note 4— Stock-Based Compensation

Stock Options and Restricted Stock Awards

The Company has various share-based compensation plans, including the Amended and Restated 2002 Stock Plan, the Second Amended and Restated 2011 Equity Incentive Plan, the 2013 Non-Employee Directors' Equity Incentive Plan and the New-Hire Equity Incentive Plan (collectively, the ***"Plans"***). The Plans are designed to assist in attracting, motivating and retaining employees and directors 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 non-employees outside of the Plans.

The Company recognized share-based compensation expense related to grants of stock options, RSUs and common stock awards to employees, directors and consultants of $3,085 and $3,604 during the years ended December 31, 2014 and 2013, 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, 2014	December 31, 2013
Selling, general and administrative	$ 2,241	$ 2,722
Research and development	844	882
Total	$ 3,085	$ 3,604

The majority of the RSUs and options to purchase common stock vest on the anniversary of the date of grant, which ranges from one to four years. Share-based compensation expense related to these awards is recognized on a straight-line basis over the related vesting term in most cases, which generally is the service period. It is the Company's policy to issue new shares upon the exercise of options.

Stock Options: The following is a summary of the Plan's stock option activity during the years ended December 31, 2014 and 2013.

	2014		2013	
	Options Outstanding	Weighted Average Exercise Price	Options Outstanding	Weighted Average Exercise Price
Beginning Balance	1,886,579	$ 8.80	1,113,244	$ 9.47
Granted	776,348	5.37	905,900	8.17
Exercised	(16,580)	5.88	—	—
Forfeited/expired	(475,854)	10.98	(132,565)	10.06
Outstanding at December 31	2,170,493	$ 6.51	1,886,579	$ 8.80
Exercisable at December 31	995,351	$ 7.18	801,480	$ 8.95

For options outstanding and exercisable at December 31, 2014, the weighted average remaining contractual life was 8.07 years and 7.05 years, respectively. The total intrinsic value, calculated as the closing stock price at year-end less the option exercise price, of options exercised during 2014 was $56. There were no option exercises in 2013.

Valuation Assumptions: The fair value of each stock option is estimated at the grant date using the Black-Scholes option pricing model. The fair value of stock options under the Black-Scholes model requires management to make assumptions regarding projected employee stock option exercise behaviors, risk-free interest rates, volatility of the Company's stock price, and expected dividends.

The Company has not historically paid cash 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 risk free interest rate is based upon the rates of U.S. Treasury bills with a term that approximates the expected life of the option. Since the Company has limited historical exercise data to reasonably estimate the expected life of its option awards, the expected life is calculated using a simplified method. Expected volatility is based on historical volatility of the Company's stock.

The following table provides the assumptions used in the Black-Scholes model:

	Year ended December 31	
	2014	2013
Expected dividend yield	0%	0%
Risk-free interest rate	2.12%	1.31%
Expected volatility	91%	96%
Expected life (in years)	6.25	5.5

The weighted-average fair value of stock options granted in 2014 and 2013 was $4.05 and $5.54, respectively. As of December 31, 2014, the total compensation cost related to all non-vested stock option awards not yet recognized was $4,668 and is expected to be recognized over the remaining weighted-average period of 2.8 years.

Effective September 23, 2014, the Company redenominated certain outstanding stock options totaling 539,869 shares originally granted to non-Australia-based employees with an AU$ exercise price to the equivalent US$ exercise price, the Company's functional currency. The redenomination was computed using the quoted currency exchange rate on September 23, 2014 and did not result in the recognition of any incremental stock option expense as a result of the modification.

Restricted Stock Awards: The following table summarizes restricted stock award activity during 2014 and 2013:

	2014		2013	
	RSUs	Weighted Average Grant Price	RSUs	Weighted Average Grant Price
Nonvested, beginning balance	84,128	$ 11.32	—	$ —
Granted	244,225	5.07	116,202	10.97
Vested	(168,682)	8.11	(32,074)	10.01
Forfeited	(3,136)	10.90	—	—
Nonvested at December 31	156,535	$ 5.06	84,128	$ 11.32

During 2014 and 2013, employees tendered restricted stock units totaling 70,161 and 9,779, respectively, to cover related payroll tax withholdings.

Common Stock Issuances: Fully vested common stock awards totaling 105,605 shares at a weighted average value of $11.32 per share were issued in the year ended December 31, 2013. Of these shares awarded, 49,137 shares were tendered to the Company to cover related employee payroll tax withholdings. There were no awards of fully vested common stock in 2014.

Warrants

During the year ended December 31, 2014, 2,798 warrants were exercised at a price of AU$6.40 per share for total proceeds of $16 and 15,000 warrants were exercised at a price of AU$6.40 per share resulting in the net issuance of 5,397 shares of common stock. During the year ended December 31, 2013, 2,449 warrants were exercised at a price of AU$6.40 per share for total proceeds of $15.

Warrants to purchase 505,166 and 1,630,804 shares of common stock were outstanding at December 31, 2014 and 2013, respectively.

Note 5—Income Taxes

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

	Year Ended	
	December 31, 2014	December 31, 2013
Domestic	$ (25,773)	$ (22,149)
Foreign	(63)	(822)
Loss before income taxes	$ (25,836)	$ (22,971)

The components of income tax benefit consist of the following:

	Year Ended	
	December 31, 2014	December 31, 2013
Income tax benefit:		
Current:		
United States and state	$ —	$ 136
Foreign, net	249	1,077
Deferred:		
United States and state	—	—
Foreign	—	—
Total income tax benefit	$ 249	$ 1,213

Actual income tax benefit differs from statutory federal income tax benefit as follows:

	Year Ended	
	December 31, 2014	December 31, 2013
Statutory federal income tax benefit	$ 8,784	$ 7,810
State tax benefit, net of federal taxes	—	1,363
Foreign tax	23	(33)
R&D tax credit	265	1,213
Nondeductible/nontaxable items	(283)	(367)
Other	—	(119)
Valuation allowance increase	(8,540)	(8,654)
Total income tax benefit	$ 249	$ 1,213

Deferred taxes consist of the following:

	As of	
	December 31, 2014	December 31, 2013
Deferred tax assets:		
Current:		
Accrued leave	$ 84	$ 76
Other accrued expenses	97	114
Total current deferred tax asset	181	190
Noncurrent:		
Stock based compensation	1,287	1,476
Net operating loss carryforward	37,248	31,958
Deferred rent	29	76
Other	54	46
R&D credit carryforward	531	531
Total noncurrent deferred tax assets	39,149	34,087
Total deferred tax assets	$ 39,330	$ 34,277
Deferred tax liabilities:		
Current:	$ —	$ —
Noncurrent:		
Fixed assets	(31)	(37)
Total deferred tax liabilities	$ (31)	$ (37)
Net deferred tax asset	39,299	34,240
Less: valuation allowance	(39,299)	(34,240)
Total	$ —	$ —

As of December 31, 2014, the Company had net operating loss ***("NOLs")*** carryforwards of approximately $69.3 million for U.S. federal income tax purposes, which expire between 2024 and 2034, and NOLs in the Commonwealth of Australia of approximately AU$48.8 million which the Company can carry forward indefinitely. U.S. NOLs cannot be used to offset taxable income in foreign jurisdictions. In addition, future utilization of NOL carryforwards in the U.S. may be subject to certain limitations under Section 382 of the Internal Revenue Code.

The Company received a $265 and $1.1 million fully refundable research and development tax credits in 2014 and 2013, respectively, related to qualified research and development expenditures of its Australian subsidiary for its tax years ended June 30, 2013 and 2012, respectively. Additionally, in 2013, the Company received $136 research and development tax credit refund from the State of Minnesota for the tax year ended December 31, 2012. The Company has not completed its Australian tax return for its Australian subsidiaries tax year ended June 30, 2014. As the Company cannot be reasonably assured of the amount or eligibility of the refundable research and development credit resulting from its Australian research and development activities, the Company has not reflected a benefit related to the research and development credit in its income tax provision for the year ended December 31, 2014. The Minnesota research and development credit is no longer refundable for tax years beyond 2012.

The Company provides for a valuation allowance when it is more likely than not that it will not realize a portion of the deferred tax assets. The Company has 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, the Company has not reflected any benefit of such deferred tax assets in the accompanying financial statements. For the years ended December 31, 2014 and 2013, the valuation allowance increased by $5.1 million and $5.8 million, respectively.

The accounting guidance related to uncertain tax positions 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 Company had no material uncertain tax positions as of December 31, 2014 or December 31, 2013.

The Company recognizes interest and penalties on unrecognized tax benefits as well as interest received from favorable tax settlements within income tax expense. During the years ended December 31, 2014 and 2013, the Company recorded no accrued interest or penalties related to uncertain tax positions.

The fiscal tax years ended June 30, 2011 through December 31, 2014 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, 2011 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, 2010 through June 30, 2014.

Note 6—Commitments and Contingencies

Leases

The Company leases office space under a non-cancelable operating lease that expires in March 2016. The lease includes several months abated rent and contains future rent escalation provisions based upon Consumer Price Indexes. Rent expense is being recorded across all periods covered by the lease. The Company leases office equipment under non-cancelable operating leases that expire at various times through May 2016.

Rent expense related to operating leases was approximately $179 and $196 for the years ended December 31, 2014 and 2013, respectively. Future minimum lease payments under non-cancelable operating leases as of December 31, 2014, were approximately $289, $85, $9, $0 and $0 for each of the years ended December 31, 2015, through 2019, respectively.

Employee Retirement Plan

The Company has a 401(k) profit sharing plan that provides retirement benefit to substantially all full-time U.S. employees. Eligible employees may contribute a percentage of their annual compensation, subject to IRS limitations, with the Company matching a portion of the employee's contributions at the discretion of the Company. Matching contributions totaled $146 and $14 for the years ended December 31, 2014, and 2013, respectively.

Note 7—Segment and Geographic Information

The Company has one reportable segment, cardiac and coronary disease products.

At December 31, 2014, long-lived assets were located primarily in the United States.

Note 8—Subsequent Events

On February 18, 2015, the Company entered into a loan and security agreement with Silicon Valley Bank for proceeds of up to $10.0 million. Under this agreement, the Company received $6.0 million at closing and has available an additional $2.0 million after the notification that the FDA had accepted its statistical interim analysis plan. The remaining $2.0 million will become available upon the Company enrolling its one hundredth patient in the COUNTER HF trial on or before September 30, 2015.

The proceeds from the loan will be used for general corporate and working capital purposes. The Company is entitled to make interest only payments until January 1, 2016. Commencing on January 1, 2016, and continuing on the first day of each calendar month thereafter, the Company is required to repay the advances made in twenty-four (24) consecutive equal monthly installments of principal and interest, based upon: (i) the amount of the advances made under the loan, and (ii) interest at a fixed per annum rate equal to 7.0%,

In connection with the loan and security agreement, the Company issued 68,996 warrants at an exercise price of $5.22 per share to Silicon Valley Bank and one of its affiliates. The warrants have a life of ten years and were fully vested at the date of grant. The Company is in the process of completing the valuation of these warrants. The value of these warrants will be reflected as a charge to expense in the Company's first quarter statement of operations for the year ending December 31, 2015.

On February 25, 2015, the Company announced that it had received unconditional approval from the FDA to conduct an interim analysis of COUNTER HF, its US pivotal trial. The COUNTER HF study is a prospective, randomized, multi-center, controlled study expected to randomize 388 patients in up to 40 clinical sites. This interim analysis could reduce the overall duration of the trial.

On March 6, 2015, the Company announced that COUNTER HF had reached a pre-determined pausing point and temporarily suspended enrollment in accordance with the study protocol. The FDA has responded to the Company's pause notification and has advised that it submit an IDE supplement to discuss the reasons for the temporary suspension and a plan for study resumption. The Company submitted the document to the FDA on March 16, 2015. This supplement carries up to a 30-day review period by the FDA.

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 maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer (together, the ***"Certifying Officers"***), as appropriate, to allow for timely decisions regarding required disclosure.

In designing and evaluating disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired objectives. Also, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. The design of any system of controls is based, in part, upon certain assumptions about the likelihood of future events and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

As of December 31, 2014, the end of the period covered by this report, we conducted an evaluation, under the supervision and with the participation of management, including the Certifying Officers, of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their stated objectives. Based on their evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2014.

Management Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. Internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and Board; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Our management, including our Certifying Officers, recognizes that our internal control over financial reporting cannot prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Management, with the participation of the Certifying Officers, assessed our internal control over financial reporting as of December 31, 2014, the end of our fiscal year. Management based its assessment on criteria established in *Internal Control—Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2014.

This 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 that occurred during our most recent fiscal quarter ended December 31, 2014 that has materially affected, or is 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 is set forth under the following captions in our proxy statement to be filed with respect to the 2015 annual meeting of stockholders (the ***"Proxy Statement"***), all of which is incorporated herein by reference: "Proposal 1 — Election of Directors," "Board Matters — Committees of the Board," "Board Matters — Corporate Governance," "Executive Officers" and "Additional Matters — Section 16(a) Beneficial Ownership Reporting Compliance."

Item 11. Executive Compensation.

The information required by this item is set forth under the following captions in the Proxy Statement, all of which is incorporated herein by reference: "Board Matters — Director Compensation," "Named Executive Officer Compensation Tables" and "Certain Relationships and Related Transactions — Compensation Committee Interlocks and Insider Participation."

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

The information required by this item is set forth under the following captions in the Proxy Statement, all of which is incorporated herein by reference: "Security Ownership of Certain Beneficial Owners and Management" and "Additional Matters — Equity Compensation Plan Information."

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

The information required by this item is set forth under the following captions in the Proxy Statement, all of which is incorporated herein by reference: “Proposal 1 — Election of Directors — Director Independence” and “Certain Relationships and Related Transactions — Related Party Transactions.”

Item 14. Principal Accounting Fees and Services.

The information required by this item is set forth under the following captions in the Proxy Statement, all of which is incorporated herein by reference: “Audit Committee Matters.”

PART IV

Item 15. Exhibits, 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 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 part of this Annual Report on Form 10-K are listed in the attached Index to Exhibits.

POWER OF ATTORNEY

Each individual person whose signature appears below hereby appoints David A. Rosa and Claudia Drayton as attorneys-in-fact with full power of substitution, severally, to execute in the name and on behalf of each such person, individually and in each capacity stated below, one or more amendments to this annual report which amendments may make such changes in the report as the attorney-in-fact acting in the premises deems appropriate, to file any such amendment to the report with the SEC, and to take all other actions either of them deem necessary or advisable to enable the Company to comply with the rules, regulations and requirements of the SEC.

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.

Date: March 20, 2015

SUNSHINE HEART, INC.

By: /S/ DAVID A. ROSA
David A. 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 A. ROSA David A. Rosa	President, Chief Executive Officer and Director (principal executive officer)	March 20, 2015
/S/ CLAUDIA DRAYTON Claudia Drayton	Chief Financial Officer (principal financial and accounting officer)	March 20, 2015
/S/ PAUL R. BUCKMAN Paul R. Buckman	Director	March 20, 2015
/S/ GEOFFREY E. BROOKE Geoffrey E. Brooke	Director	March 20, 2015
/S/ JOHN L. ERB John L. Erb	Director	March 20, 2015
/S/ JON W. SALVESON Jon W. Salveson	Director	March 20, 2015
/S/ GREGORY D. WALLER Gregory D. Waller	Director	March 20, 2015
/S/ WARREN S. WATSON Warren S. Watson	Director	March 20, 2015