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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the Fiscal Year Ended: December 31, 2014

o 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 o No x

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

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 x No o

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 x No o

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. o

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

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

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.

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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.

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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.**

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(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.

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(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.

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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

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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.

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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.

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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

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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.

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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

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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;

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- 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

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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.

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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;

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- 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.

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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.

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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.

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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.

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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.

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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.

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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.

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Item 3. Legal Proceedings.

We are not currently subject to any material pending legal proceedings.

Item 4. Mine Safety Disclosures.

Not applicable.

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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

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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.

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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

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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)%

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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.

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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

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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

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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

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SUNSHINE HEART, INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss

	Year ended	
In thousands, except per share amounts	Dec 31, 2014	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

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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

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SUNSHINE HEART, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

In thousands	Year ended Dec 31, 2014	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

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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

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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

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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

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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.

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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.

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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	$ —	$ —

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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.

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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.

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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."

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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.

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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

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EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
3.1	Certificate of Incorporation, as amended	10	001-35312	February 1, 2012	3.1	
3.2	Amended and Restated Bylaws	10	001-35312	September 30, 2011	3.2	
3.3	Form of Certificate of Designations of Series A Junior Participating Preferred Stock	8-K	001-35312	June 14, 2013	3.1	

4.1	Rights Agreement dated June 14, 2013 by and between the Company and American Stock Transfer & Trust Company, LLC, as Rights Agent	8-K	001-35312	June 14, 2013	4.1	
10.1	Amended and Restated 2002 Stock Plan†	10	001-35312	December 16, 2011	10.2	
10.2	Form of Notice of Stock Option Grant and Option Agreement for Amended and Restated 2002 Stock Plan†	10	001-35312	September 30, 2011	10.3	
10.3	Second Amended and Restated 2011 Equity Incentive Plan, as amended†	14A	001-35312	July 27, 2012	App. A	
10.4	Form of Stock Option Grant Notice and Option Agreement for 2011 Equity Incentive Plan †	10	001-35312	September 30, 2011	10.5	
10.5	Form of Stock Option Grant Notice and Option Agreement (Senior Management) for 2011 Equity Incentive Plan†	10	001-35312	September 30, 2011	10.6	
10.6	Form of Stock Option Grant Notice and Option Agreement (Director) for 2011 Equity Incentive Plan†	8-K	001-35312	September 18, 2012	10.1	
10.7	Form of Stock Grant Notice and Award Agreement for 2011 Equity Incentive Plan†	8-K	001-35312	September 10, 2013	10.1	
10.8	Form of Restricted Stock Unit Grant Notice and Agreement for 2011 Equity Incentive Plan†	8-K	001-35312	September 10, 2013	10.2	
10.9	2013 Non-Employee Directors' Equity Incentive Plan†	14A	001-35312	April 5, 2013	App. A	

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Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
10.10	Form of Stock Option Grant Notice and Option Agreement for 2013 Non-Employee Directors' Equity Incentive Plan†					X
10.11	Form of Restricted Stock Unit Award Grant Notice and Agreement for 2013 Non-Employee Directors' Equity Incentive Plan†					X
10.12	New-Hire Equity Incentive Plan†	10-Q	001-35312	August 8, 2013	10.1	
10.13	First Amendment to New-Hire Equity Incentive Plan†	10-Q	001-35312	November 12, 2013	10.1	
10.14	Form of Stock Option Grant Notice and Option Agreement for New-Hire Equity Incentive Plan†					X
10.15	Form of Indemnity Agreement for the Company's executive officers and directors†	10	001-35312	September 30, 2011	10.1	
10.16	Form of Change in Control Agreement for the Company's executive officers†					X
10.17	Non-Employee Director Compensation Policy†	10-Q	001-35312	August 8, 2013	10.2	

10.18	Executive Employment Agreement dated February 6, 2013 by and between the Company and David A. Rosa†	8-K	001-35312	February 6, 2013	10.1	
10.19	Separation and Release Agreement dated August 29, 2014 by and between the Company and Patrick Verta†					X
10.20	License, Supply & Manufacturing Agreement dated April 26, 2010 by and between the Company and DSM PTG, Inc.#	10	001-35312	February 14, 2012	10.17	
10.21	Lease Agreement dated October 21, 2011 by and between the Company and Silver Prairie Crossroads, LLC	10	001-35312	December 16, 2011	10.18	

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Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
10.22	Registration Rights Agreement dated January 15, 2013 by and between the Company and Aspire Capital Fund, LLC	8-K	001-35312	January 16, 2013	4.1	
10.23	Sales Agreement dated March 21, 2014 by and between the Company and Cowen and Company, LLC	S-3	333-194731	March 21, 2014	1.2	
21	List of subsidiaries of the Company					X
23	Consent of Ernst & Young LLP					X
31.1	Section 302 Certification — CEO					X
31.2	Section 302 Certification — CFO					X
32.1	Section 906 Certification — CEO					X
32.2	Section 906 Certification — CFO					X
101.INS	XBRL Instance Document.					X
101.SCH	XBRL Taxonomy Extension Schema Document.					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.					X

† Indicates management compensatory plan, contract or arrangement.

Confidential treatment has been granted with respect to certain portions of this exhibit, which portions have been omitted and filed separately with the Securities and Exchange Commission as part of an application for confidential treatment pursuant to the Securities and Exchange Act of 1934, as amended.

SUNSHINE HEART, INC.
FORM OF STOCK OPTION GRANT NOTICE
(2013 NON-EMPLOYEE DIRECTORS' EQUITY INCENTIVE PLAN)

Sunshine Heart, Inc. (the ***"Company"***), pursuant to its 2013 Non-Employee Directors' Equity Incentive Plan (the ***"Plan"***), hereby grants to the Participant an Option to purchase the number of shares of the Company's Common Stock set forth below (this ***"Option"***). This Option is subject to all of the terms and conditions set forth in this Stock Option Grant Notice (this ***"Grant Notice"***), the related Option Agreement and Notice of Exercise, and the Plan, all of which are attached hereto and incorporated herein in their entireties. Capitalized terms not explicitly defined herein but defined in the Plan or the related Option Agreement will have the same definitions as in the Plan or the related Option Agreement. If there is any conflict between the terms in this Grant Notice and the Plan, the terms of the Plan will control.

Participant: _____

Date of Grant: _____

Vesting Commencement Date: _____

Number of Shares Subject to Option: _____

Exercise Price (Per Share): _____

Expiration Date: _____

Type of Grant: Nonstatutory Stock Option o

Vesting Schedule: 1/48th of the shares will vest on the twelfth day of each month commencing the Vesting Commencement Date.

Payment: By one or a combination of the following items (in each case, as described in the related Option Agreement):

o By cash, check, bank draft or money order payable to the Company;

o By delivery of already-owned shares;

o By a "net exercise" arrangement; or

o Pursuant to a broker assisted cashless exercise.

Additional Terms/Acknowledgements: The Participant acknowledges receipt of, and understands and agrees to, the terms and conditions of this Grant Notice, the related Option Agreement and the Plan. The Participant acknowledges and agrees that this Grant Notice and the related Option Agreement may not be modified, amended or revised except as provided in the Plan. The Participant further acknowledges that as of the Date of Grant, this Grant Notice, the

related Option Agreement, and the Plan set forth the entire understanding between the Participant and the Company regarding this Option and supersede all prior oral and written agreements, promises and/or representations on that subject with the exception of (i) other Options previously granted and delivered to the Participant, (ii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law and (iii) any written service or severance arrangement that would provide for vesting acceleration of this Option upon the terms and conditions set forth therein.

By accepting this Option, the Participant consents to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

This Grant Notice may be executed in one or more counterparts, each of which will be deemed to be an original, and all of which will constitute one document.

SUNSHINE HEART, INC.		**PARTICIPANT**	
By:	_____	By:	_____
Name:	_____	Date:	_____
Title:	_____		
Date:	_____		

ATTACHMENTS: Option Agreement, including Notice of Exercise, and 2013 Non-Employee Directors' Equity Incentive Plan

ATTACHMENT I

SUNSHINE HEART, INC.
2013 NON-EMPLOYEE DIRECTORS' EQUITY INCENTIVE PLAN

FORM OF OPTION AGREEMENT FOR NON-EMPLOYEE DIRECTORS
(NONSTATUTORY STOCK OPTION)

Pursuant to your Stock Option Grant Notice (the ***"Grant Notice"***) and this Option Agreement (this ***"Agreement"***), Sunshine Heart, Inc. (the ***"Company"***) has granted you an Option (your ***"Option"***) under its 2013 Non-Employee Directors' Equity Incentive Plan (the ***"Plan"***) to purchase the number of shares of the Company's Common Stock indicated in the Grant Notice at the Exercise Price indicated in the Grant Notice. Capitalized terms not explicitly defined in this Agreement or in the Grant Notice but defined in the Plan will have the same definitions as in the Plan. If there is any conflict between the terms in this Agreement and the Plan, the terms of the Plan will control.

The details of your Option are as follows:

1. VESTING. Subject to the provisions contained herein, your Option will vest as provided in the Grant Notice. Vesting will cease upon the termination of your Continuous Service.

2. NUMBER OF SHARES AND EXERCISE PRICE. The number of shares of Common Stock subject to your Option and the Exercise Price per share set forth in the Grant Notice will be adjusted for Capitalization Adjustments.

3. EXERCISE.

(a) You may exercise the vested portion of your Option during its term by (i) delivering the Notice of Exercise attached hereto as EXHIBIT A and by completing such other documents and/or procedures designated by the Company for exercise and (ii) paying the Exercise Price per share set forth in the Grant Notice and any applicable withholding taxes to the Company's Secretary, stock plan administrator, or such other person as the Company may designate. You may exercise your Option only for whole shares of Common Stock; the Company will not be required to issue any fractional shares of Common Stock under any circumstances.

(b) By exercising your Option you agree that, as a condition to any exercise of your Option, the Company may require you to enter into an arrangement providing for the payment by you to the Company of any tax withholding obligation of the Company arising by reason of your Option.

(c) The exercise of your Option must comply with all applicable laws and regulations governing your Option, and you may not exercise your Option if the Company determines that such exercise would not be in material compliance with such laws and regulations. Notwithstanding anything to the contrary contained herein, the Committee may suspend your right to exercise your Option for any period of up to 180 days in any 365-day

period for which the Committee determines, in good faith, that such suspension is necessary or advisable in order to comply with the requirements of (i) any applicable federal securities law or rule or regulation thereunder; (ii) any rule of a national securities exchange, national securities association, or other self-regulatory organization; or (iii) any other federal or state law or regulation (each an ***"Option Exercise Suspension"***). Notwithstanding the foregoing, no Option Exercise Suspension will extend the term of your Option in a manner that would result in your Option becoming nonqualified deferred compensation subject to Section 409A of the Code.

4. METHOD OF PAYMENT. Payment of the Exercise Price set forth in the Grant Notice is due in full upon exercise of all or any part of your Option. You may elect to make payment of the Exercise Price by cash, check, bank draft or money order payable to the Company or in any one or more of the following manners unless otherwise provided in the Grant Notice:

(a) Provided that at the time of exercise the Common Stock is publicly traded, pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of Common Stock, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate Exercise Price set forth in the Grant Notice to the Company from the sales proceeds.

(b) Provided that at the time of exercise the Common Stock is publicly traded, by delivery to the Company (either by actual delivery or attestation) of already-owned shares of Common Stock that are owned free and clear of any liens, claims, encumbrances or security interests, and that are valued at Fair Market Value on the date of exercise. "Delivery" for these purposes, in the sole discretion of the Company at the time you exercise your Option, will include delivery to the Company of your attestation of ownership of such shares of Common Stock in a form approved by the Company. Notwithstanding the foregoing, you may not exercise your Option by delivery to the Company of Common Stock if doing so would violate the provisions of the applicable listing rules, any law, regulation or agreement restricting the redemption of the Company's stock.

(c) Subject to the consent of the Company at the time of exercise, by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issued upon exercise of your Option by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate Exercise Price per share set forth in the Grant Notice. You must pay any remaining balance of the aggregate Exercise Price not satisfied by the "net exercise" in cash or other permitted form of payment. Shares of Common Stock will no longer be outstanding under your Option and will not be exercisable thereafter if those shares are (i) used to pay the Exercise Price pursuant to the "net exercise," (ii) delivered to you as a result of such exercise, and (iii) withheld to satisfy tax withholding obligations.

5. TERM. You may not exercise your Option before the Date of Grant or after the Expiration Date set forth in the Grant Notice. Subject to Section 7 below, the term of your Option commences on the Date of Grant and terminates upon the earliest of the following:

(a) immediately upon the termination of your Continuous Service for Cause;

(b) three months after the termination of your Continuous Service other than for Cause or upon your Disability or death or as of, or within 12 months following a Change in Control;

(c) 12 months after the termination of your Continuous Service due to your Disability;

(d) 18 months after your death if you die either during your Continuous Service or within three months after your Continuous Service terminates for any reason other than Cause;

(e) 12 months after the termination of your Continuous Service as of, or within 12 months following a Change in Control;

(f) the Expiration Date indicated in your Grant Notice; or

(g) the day before the tenth anniversary of the Date of Grant.

6. TRANSFERABILITY. Your Option is not transferable, except (a) by will or by the laws of descent and distribution, (b) pursuant to a domestic relations order and (c) with the prior written approval of the Company, by instrument to an inter vivos or testamentary trust, in a form accepted by the Company, in which your Option is to be passed to beneficiaries upon the death of the trust (or settlor).

7. INVOLUNTARY TERMINATION FOLLOWING A CHANGE IN CONTROL.

(a) If, as a condition of a Change in Control, you are required to resign your position as a Non-Employee Director, all of your outstanding Options will become fully vested and exercisable immediately prior to the effectiveness of such resignation (and contingent upon the effectiveness of such Change in Control). Additionally, upon a Change in Control event (other than due to a change in the Incumbent Board) and subject to your Continuous Service through the effective date of such Change in Control, all of your outstanding Options will automatically become fully vested and immediately exercisable in full.

(b) Any payment to which you may be entitled pursuant to the Grant Notice or this Agreement will be subject to Section 11(e) of the Plan, as if it were included herein.

8. OPTION NOT A SERVICE CONTRACT. Your Option is not a service contract, and nothing in your Option will be deemed to create in any way whatsoever any obligation on your part to continue in the service of the Company or an Affiliate, or of the Company or an Affiliate to continue your service. In addition, nothing in your Option will obligate the Company or an Affiliate, their respective stockholders, boards of directors, officers or Employees to continue any relationship that you might have as a director or Consultant for the Company or an Affiliate.

9. WITHHOLDING OBLIGATIONS.

(a) At the time you exercise your Option, in whole or in part, or at any time thereafter as requested by the Company, you hereby authorize withholding from payroll and any

other amounts payable to you, and otherwise agree to make adequate provision for, any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or an Affiliate, if any, which arise in connection with your Option.

(b) Upon your request and subject to approval by the Company, in its sole discretion, and in compliance with any applicable conditions or restrictions of law, the Company may withhold from fully vested shares of Common Stock otherwise issuable to you upon the exercise of your Option a number of whole shares of Common Stock having a Fair Market Value, determined by the Company as of the date of exercise, not in excess of the minimum amount of tax required to be withheld by law (or such lower amount as may be necessary to avoid classification of your Option as a liability for financial accounting purposes). Any adverse consequences to you arising in connection with such share withholding procedure will be your sole responsibility.

(c) You may not exercise your Option unless the tax withholding obligations of the Company and/or any Affiliate are satisfied. Accordingly, you may not be able to exercise your Option when desired even though your Option is vested, and the Company will have no obligation to issue a certificate for such shares of Common Stock unless such obligations are satisfied.

10. TAX CONSEQUENCES. You hereby agree that the Company does not have a duty to design or administer the Plan or its other compensation programs in a manner that minimizes your tax liabilities. You will not make any claim against the Company, or any of its officers, Directors, Employees or Affiliates related to tax liabilities arising from your Option or your other compensation. In particular, you acknowledge that your Option is exempt from Section 409A of the Code only if the Exercise Price per share specified in the Grant Notice is at least equal to the "fair market value" per share of the Common Stock on the Date of Grant and there is no other impermissible deferral of compensation associated with your Option.

11. NOTICES. Any notices provided for in your Option or the Plan must be given in writing and will be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five days after deposit in the U.S. mail, postage prepaid, addressed to you at the last address you provided to the Company. The Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and your Option by electronic means or to request your consent to participate in the Plan by electronic means. By accepting your Option, you consent to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

12. GOVERNING PLAN DOCUMENT. Your Option is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Option, and is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted

pursuant to the Plan. If there is any conflict between the provisions of your Option and those of the Plan, the provisions of the Plan will control. In addition, your Option (and any compensation paid, shares issued under your Option, or proceeds received upon the sale of such shares) is subject to recoupment in accordance with The Dodd—Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback or

compensation recovery policy adopted by the Company and any compensation recovery policy otherwise required by applicable law.

13. EFFECT ON OTHER EMPLOYEE BENEFIT PLANS. The value of your Option will not be included as compensation, earnings, salaries, or other similar terms used when calculating your benefits under any employee benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company's or any Affiliate's employee benefit plans.

14. VOTING RIGHTS. You will not have voting or any other rights as a stockholder of the Company with respect to the shares to be issued pursuant to your Option until such shares are issued to you. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in your Option, and no action taken pursuant to its provisions, will create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

15. SEVERABILITY. If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity will not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid will, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

16. CONSENT TO TRANSFER OF PERSONAL DATA. In administering the Plan, or to comply with applicable legal, regulatory, tax, or accounting requirements, it may be necessary for the Company to transfer certain Participant data to an Affiliate or to its outside service providers or governmental agencies. By accepting your Option, you consent, to the fullest extent permitted by law, to the use and transfer, electronically or otherwise, of your personal data to such entities for such purposes.

17. MISCELLANEOUS.

(a) The rights and obligations of the Company under your Option will be transferable by the Company to any one or more persons or entities, and all covenants and agreements hereunder will inure to the benefit of, and be enforceable by the Company's successors and assigns.

(b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your Option.

(c) You acknowledge and agree that you have reviewed your Option in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Option, and fully understand all provisions of your Option.

(d) This Agreement will be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(e) All obligations of the Company under the Plan and this Agreement will be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

* * *

This Agreement will be deemed to be signed by you upon the signing by you of the Grant Notice to which it is attached.

EXHIBIT A

NOTICE OF EXERCISE

SUNSHINE HEART, INC.
12988 Valley View Road
Eden Prairie, MN 55344

Date of exercise: _____

This constitutes notice to Sunshine Heart, Inc. (the ***"Company"***) under my Option that I elect to purchase the below number of shares of Common Stock of the Company (the ***"Shares"***) for the price set forth below.

Type of Option: Nonstatutory

Stock Option dated:

Number of Shares as to which Option is exercised:

Certificates to be issued in name of:

Total exercise price: $

Cash payment delivered herewith: $

[Value of Shares delivered herewith(1): $]

[Value of Shares pursuant to net exercise(2): $]

[Regulation T Program (cashless exercise)(3): $]

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(1) Shares must meet the public trading requirements set forth in the related Option Agreement. Shares must be valued in accordance with the terms of the Option being exercised, and must be owned free and clear of any liens, claims, encumbrances or security interests. Certificates must be endorsed or accompanied by an executed assignment separate from certificate.

(2) The Company must have established net exercise procedures at the time of exercise, in order to utilize this payment method.

(3) Shares must meet the public trading requirements set forth in the related Option Agreement.

EXHIBIT A

By this exercise, I agree (i) to provide such additional documents as you may require pursuant to the terms of the Sunshine Heart, Inc. 2013 Non-Employee Directors' Equity Incentive Plan, and (ii) to provide for the payment by me to you (in the manner designated by you) of your withholding obligation, if any, relating to the exercise of my Option.

Very truly yours,

ATTACHMENT II

2013 NON-EMPLOYEE DIRECTORS' EQUITY INCENTIVE PLAN

SUNSHINE HEART, INC.
FORM OF RESTRICTED STOCK UNIT AWARD GRANT NOTICE
(2013 NON-EMPLOYEE DIRECTORS' EQUITY INCENTIVE PLAN)

Sunshine Heart, Inc., a Delaware corporation (the ***"Company"***), pursuant to its 2013 Non-Employee Directors' Equity Incentive Plan (the ***"Plan"***), hereby grants to the Participant the number of restricted stock units (***"RSUs"***) set forth below (this ***"Award"***). This Award is subject to all of the terms and conditions set forth in this Restricted Stock Unit Award Grant Notice (this ***"Grant Notice"***), the related Restricted Stock Unit Award Agreement (the ***"Award Agreement"***) and the Plan, both of which are attached hereto and incorporated herein in their entireties. Capitalized terms not explicitly defined herein but defined in the Plan or the Award Agreement will have the same definitions as in the Plan or the Award Agreement. If there is any conflict between the terms in this Grant Notice and the Plan, the terms of the Plan will control.

Participant:

Date of Grant:

Vesting Commencement Date:

Number of RSUs:

Vesting Schedule: **[** (each, a ***"Vesting Date"***).]

Settlement of RSUs: Subject to Capitalization Adjustments, one share of Common Stock will be issued for each RSU that vests at the time set forth in Section 5 of the Award Agreement.

Additional Terms/Acknowledgements: The Participant acknowledges receipt of, and understands and agrees to, the terms and conditions of this Grant Notice, the Award Agreement and the Plan. The Participant acknowledges and agrees that this Grant Notice and the Award Agreement may not be modified, amended or revised except as provided in the Plan. The Participant further acknowledges that as of the Date of Grant, this Grant Notice, the Award Agreement and the Plan set forth the entire understanding between the Participant and the Company regarding this Award and supersede all prior oral and written agreements, promises and/or representations on that subject with the exception of (i) other Restricted Stock Unit Awards previously granted and delivered to the Participant, (ii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law and (iii) any written service or severance arrangement that would provide for vesting acceleration of this Award upon the terms and conditions set forth therein.

By accepting this Award, the Participant consents to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

This Grant Notice may be executed in one or more counterparts, each of which will be deemed to be an original, and all of which will constitute one document.

SUNSHINE HEART, INC.		**PARTICIPANT**	
By:	_____	By:	_____
Name:	_____	Date:	_____
Title:	_____		
Date:	_____		

ATTACHMENTS: Restricted Stock Unit Award Agreement and 2013 Non-Employee Directors' Equity Incentive Plan

ATTACHMENT I

SUNSHINE HEART, INC.
2013 NON-EMPLOYEE DIRECTORS' EQUITY INCENTIVE PLAN

FORM OF RESTRICTED STOCK UNIT AWARD AGREEMENT

Pursuant to your Restricted Stock Unit Award Grant Notice (the ***"Grant Notice"***) and this Restricted Stock Unit Award Agreement (this ***"Agreement"***), Sunshine Heart, Inc. (the ***"Company"***) has granted you a Restricted Stock Unit Award (your ***"Award"***) under its 2013 Non-Employee Directors' Equity Incentive Plan (the ***"Plan"***) for the number of restricted stock units (***"RSUs"***) indicated in the Grant Notice. Capitalized terms not explicitly defined in this Agreement or in the Grant Notice but defined in the Plan will have the same definitions as in the Plan. If there is any conflict between the terms in this Agreement and the Plan, the terms of the Plan will control.

The details of your Award are as follows.

1. VESTING. The RSUs subject to your Award will vest as provided in the Grant Notice. Vesting will cease upon termination of your Continuous Service for any reason. Any RSUs that have not yet vested will be forfeited upon termination of your Continuous Service for any reason.

2. NUMBER OF RSUS & SHARES OF COMMON STOCK.

(a) The RSUs subject to your Award will be adjusted for Capitalization Adjustments.

(b) Any additional restricted stock units and any shares, cash or other property that become subject to your Award pursuant to this Section 2 will be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the RSUs subject to your Award.

(c) No fractional shares or rights for fractional shares of Common Stock will be created pursuant to this Section 2. Any fraction of a share will be rounded down to the nearest whole share.

3. TERMINATION OF SERVICES; FORFEITURE. Notwithstanding any other provision of this Agreement:

(a) Termination for Any Reason. Any unvested RSUs subject to your Award will be immediately canceled and forfeited upon termination of your Continuous Service for any reason.

(b) Discretion to Accelerate. Notwithstanding the provisions of Section 3(a) hereof, the Board retains the right to accelerate the vesting of all or a portion of the RSUs subject to your Award.

4. CORPORATE TRANSACTION; CHANGE IN CONTROL. Upon a Corporation Transaction or Change in Control, the RSUs subject to your Award will fully vest, subject to your Continuous Service through the effective date of such Corporate Transaction or Change in Control.

5. SETTLEMENT. Subject to Section 11 below, following the occurrence of any Vesting Date, the Company shall deliver to you the number of shares of Common Stock equal to the number of RSUs subject to your Award that vested on such Vesting Date. The Company shall deliver such shares as soon as administratively practicable after such Vesting Date, but in no event later than 2-1/2 months following the end of the calendar year in which such Vesting Date occurs.

6. SECURITIES LAW COMPLIANCE. The Company will not issue you any shares of Common Stock upon settlement of your Award in accordance with Section 5 hereof unless either (a) the shares are registered under the Securities Act, or (b) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Your Award also must comply with other laws and regulations applicable to it, and you will not receive any shares of Common Stock upon settlement of your Award in accordance with Section 5 hereof if the Company determines that such receipt would not be in material compliance with such laws and regulations.

7. TRANSFERABILITY. Prior to the time that shares of Common Stock have been delivered to you, you may not transfer, pledge, sell or otherwise dispose of any portion of the RSUs subject to your Award or the shares that may be issued upon vesting of the RSUs. For example, you may not use shares that may be issued in respect of your RSUs as security for a loan, nor may you transfer, pledge, sell or otherwise dispose of such shares. This restriction on transfer will lapse upon delivery to you of shares of Common Stock in accordance with Section 5 hereof. Any attempt to sell, transfer, pledge, assign, or otherwise alienate or hypothecate, or dispose of in any manner any of the RSUs subject to your Award or the shares in respect of the RSUs contrary to the terms of this Agreement and/or the Plan shall be null and void and without legal effect.

(a) Death. The RSUs subject to your Award are not transferable other than by will and by the laws of descent and distribution. Upon receiving written permission from the Board or its duly authorized designee, you may, by delivering written notice to the Company, in a form provided by or otherwise satisfactory to the Company and any broker designated by the Company to effect transactions under the Plan, designate a third party who, in the event of your death, will thereafter be entitled to receive any distribution of Common Stock or other consideration to which you were entitled at the time of your death pursuant to this Agreement. In the absence of such a designation, the executor or administrator of your estate will be entitled to receive, on behalf of your estate, such Common Stock or other consideration.

(b) Domestic Relations Orders. Upon receiving written permission from the Board or its duly authorized designee, and provided that you and the designated transferee enter into transfer and other agreements required by the Company, you may transfer your right to receive the distribution of Common Stock or other consideration in respect of the RSUs subject to your Award, pursuant to the terms of a domestic relations order or official marital settlement

agreement that contains the information required by the Company to effectuate the transfer. You are encouraged to discuss with the Company's general counsel (if any) the proposed terms of any such transfer prior to finalizing the domestic relations order or marital settlement agreement to help ensure the required information is contained within the domestic relations order or marital settlement agreement. The Company is not obligated to allow you to transfer your Award in connection with your domestic relations order or marital settlement agreement.

8. DIVIDENDS; RIGHTS AS A STOCKHOLDER. You will receive no benefit or adjustment to the RSUs subject to your Award with respect to any cash dividend, stock dividend or other distribution, except as contemplated by the Plan with respect to Capitalization Adjustments. Except as otherwise provided herein, you will have no rights as a stockholder with respect to shares of Common Stock issuable upon settlement of the RSUs subject to your Award unless and until you have become the holder of record of such shares.

9. RESTRICTIVE LEGENDS. The certificates representing the shares of Common Stock issued upon settlement of the RSUs subject to your Award may be endorsed with appropriate legends as determined by the Company in its discretion.

10. AWARD NOT A SERVICE CONTRACT. Your Continuous Service is not for any specified term and may be terminated by you or by the Company or an Affiliate at any time, for any reason, with or without cause and with or without notice. Nothing in this Agreement (including, but not limited to, the vesting of the RSUs subject to your Award or the issuance of shares of Common Stock upon vesting of the RSUs subject to your Award), the Plan or any covenant of good faith and fair dealing that may be found implicit in this Agreement or the Plan will: (a) confer upon you any right to continue in the

service of, or affiliation with, the Company or an Affiliate; (b) constitute any promise or commitment by the Company or an Affiliate regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of service or affiliation; (c) confer any right or benefit under this Agreement or the Plan unless such right or benefit has specifically accrued under the terms of this Agreement or the Plan; or (d) deprive the Company of the right to terminate your Continuous Service at any time, for any reason, and without regard to any future vesting opportunity that you may have.

11. WITHHOLDING OBLIGATIONS.

(a) On each Vesting Date, and on or before the time the Company delivers the shares of Common Stock issuable upon vesting of the RSUs subject to your Award, and at any other time as reasonably requested by the Company in accordance with applicable tax laws, you agree to make adequate provision for any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or any Affiliate that arise in connection with your Award (the ***"Withholding Taxes"***). Specifically, the Company or an Affiliate may, in its sole discretion, satisfy all or any portion of the Withholding Taxes relating to your Award by any of the following means or by a combination of such means: (i) withholding from any compensation otherwise payable to you by the Company or an Affiliate; (ii) causing you to tender a cash payment; (iii) permitting or requiring you to enter into a "same day sale" commitment with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a ***"FINRA Dealer"***) whereby you irrevocably elect to sell a portion of the shares to

be delivered upon settlement of the RSUs subject to your Award to satisfy the Withholding Taxes and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Withholding Taxes directly to the Company and/or its Affiliates; or (iv) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to you in connection with the RSUs with a Fair Market Value (measured as of the date such shares of Common Stock are issued to you) equal to the amount of such Withholding Taxes; provided, however, that the number of such shares of Common Stock so withheld will not exceed the amount necessary to satisfy the Company's required tax withholding obligations using the minimum statutory withholding rates for federal, state, local and foreign tax purposes, including payroll taxes, that are applicable to supplemental taxable income.

(b) Unless the Withholding Taxes of the Company and/or any Affiliate are satisfied, the Company will have no obligation to deliver to you any Common Stock in connection with your Award.

(c) In the event the Company's obligation to withhold arises prior to the delivery to you of Common Stock or it is determined after the delivery of Common Stock to you that the amount of the Company's withholding obligation was greater than the amount withheld by the Company, you agree to indemnify and hold the Company harmless from any failure by the Company to withhold the proper amount.

12. NO OBLIGATION TO MINIMIZE TAXES. The Company has no duty or obligation to minimize the tax consequences to you of your Award and will not be liable to you for any adverse tax consequences to you arising in connection with your Award. You are hereby advised to consult with your own personal tax, financial and/or legal advisors regarding the tax consequences of your Award and by signing the Grant Notice, you have agreed that you have done so or knowingly and voluntarily declined to do so.

13. UNSECURED OBLIGATION. Your Award is unfunded, and as a holder of vested RSUs, you will be considered an unsecured creditor of the Company with respect to the Company's obligation, if any, to issue shares or other property pursuant to this Agreement. Nothing contained in this Agreement, and no action taken pursuant to its provisions, will create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

14. OTHER DOCUMENTS. You hereby acknowledge receipt of and the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act, which includes the Plan prospectus. In addition, you acknowledge receipt of the Company's policy permitting certain individuals to sell shares only during certain "window" periods and the Company's insider trading policy, in effect from time to time.

15. SECTION 409A OF THE CODE. Your Award and the RSUs subject thereto are intended to comply with the "short-term deferral" rule set forth in Treasury Regulation Section 1.409A-1(b)(4) and accordingly be exempt from Section 409A of the Code and will be construed consistently therewith. Each RSU subject to your Award will be represented by a separate payment for one share of Common Stock for purposes of Section 409A of the Code. Notwithstanding the foregoing, if any portion of the RSUs subject to your Award fail to satisfy

the requirements of the short-term deferral rule and are otherwise not exempt from, and therefore deemed to be deferred compensation subject to, Section 409A of the Code, and if you are a "Specified Employee" (within the meaning set forth Section 409A(a)(2)(B)(i) of the Code) as of the date of your separation from service (within the meaning of Treasury Regulation Section 1.409A-1(h)), then the issuance of any shares that would otherwise be made on account of the your separation from service and was scheduled to made on or within the first six months following such separation from service will not be made on the originally scheduled date, but will instead be issued in a lump sum on the date that is six months and one day after the date of your separation from service without interest, with the balance of the shares issued thereafter in accordance with the original vesting and issuance schedule set forth above, but if and only if such delay in the issuance of the shares is necessary to avoid the imposition of taxation on you in respect of the shares under Section 409A of the Code. The Company makes no representation or warranty and will have no liability to you or any other person, other than with respect to payments made by the Company in violation of the provisions of this Agreement, if any provisions of or payments under this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but not to satisfy the conditions of Section 409A of the Code.

16. NOTICES. Any notices provided for in this Agreement or the Plan must be given in writing (including electronically) and will be deemed effectively given upon receipt or, in the case of notices delivered by the Company to you, five days after deposit in the U.S. mail, postage prepaid, addressed to you at the last address you provided to the Company. The Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and your Award by electronic means or to request your consent to participate in the Plan by electronic means. By accepting your Award, you consent to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

17. GOVERNING PLAN DOCUMENT. Your Award is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Award, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. If there is any conflict between the provisions of your Award and those of the Plan, the provisions of the Plan will control. In addition, your Award (and any compensation paid or shares issued under your Award) is subject to recoupment in accordance with The Dodd—Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law.

18. EFFECT ON OTHER EMPLOYEE BENEFIT PLANS. The value of your Award will not be included as compensation, earnings, salaries, or other similar terms used when calculating your benefits under any employee benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company's or any Affiliate's employee benefit plans.

19. SEVERABILITY. If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity will not invalidate any portion of this Agreement or the Plan not declared to be unlawful or

invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid will, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

20. CONSENT TO TRANSFER OF PERSONAL DATA. In administering the Plan, or to comply with applicable legal, regulatory, tax, or accounting requirements, it may be necessary for the Company to transfer certain Participant data to an Affiliate or to its outside service providers or governmental agencies. By accepting your Award, you consent, to the fullest extent permitted by law, to the use and transfer, electronically or otherwise, of your personal data to such entities for such purposes.

21. MISCELLANEOUS.

(a) The rights and obligations of the Company under your Award will be transferable by the Company to any one or more persons or entities, and all covenants and agreements hereunder will inure to the benefit of, and be enforceable by the Company's successors and assigns.

(b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your Award.

(c) You acknowledge and agree that you have reviewed your Award in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Award, and fully understand all provisions of your Award.

(d) This Agreement will be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(e) All obligations of the Company under the Plan and this Agreement will be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

* * *

This Agreement will be deemed to be signed by you upon the signing by you of the Grant Notice to which it is attached.

ATTACHMENT II

2013 NON-EMPLOYEE DIRECTORS' EQUITY INCENTIVE PLAN

SUNSHINE HEART, INC.
FORM OF STOCK OPTION GRANT NOTICE
UNDER THE NEW-HIRE EQUITY INCENTIVE PLAN

Sunshine Heart, Inc. (the ***"Company"***), pursuant to its New-Hire Equity Incentive Plan (the ***"Plan"***), hereby grants to the Participant an Option to purchase the number of shares of the Company's Common Stock set forth below as an inducement material to the Participant entering into an employment relationship with the Company (this ***"Option"***). This Option is not intended to qualify as an incentive stock option within the meaning of Section 422 of the Code and shall therefore be treated as a non-qualified option. This Option is subject to all of the terms and conditions set forth in this Stock Option Grant Notice (this ***"Grant Notice"***), the related Option Agreement and Notice of Exercise, and the Plan, all of which are attached hereto and incorporated herein in their entireties. Capitalized terms not explicitly defined herein but defined in the Plan or the Option Agreement will have the same definitions as in the Plan or the Option Agreement. If there is any conflict between the terms in this Grant Notice and the Plan, the terms of the Plan will control.

Participant:	_____
Date of Grant:	_____
Vesting Commencement Date:	_____
Number of Shares Subject to Option:	_____
Exercise Price (Per Share):	_____
Expiration Date:	_____
Vesting Schedule:	25% of the shares will vest on the one-year anniversary of the Date of Grant; the remaining shares will vest in 36 equal consecutive monthly increments thereafter, so that all of the shares will be vested on the four-year anniversary of the Date of Grant.
Payment:	By one or a combination of the following items (in each case, as described in the Option Agreement): o By cash, check, bank draft or money order payable to the Company; o Pursuant to a Regulation T Program (cashless exercise); o By delivery of already-owned shares if the shares are publicly traded; or o By a "net exercise" arrangement.

Additional Terms/Acknowledgements: The Participant acknowledges receipt of, and understands and agrees to, the terms and conditions of this Grant Notice, the Option Agreement and the Plan. The Participant acknowledges and agrees that this Grant Notice and the Option Agreement may not be modified, amended or revised except as provided in the Plan. The Participant further acknowledges and agrees that this Option was granted to the Participant as an inducement material the Participant entering into an employment relationship with the Company. The Participant further acknowledges that as of the Date of Grant, this Grant Notice, the Option Agreement, and the Plan set forth the entire understanding between the Participant and the Company regarding this Option and supersede all prior oral and written agreements, promises and/or representations on that subject with the exception of (i) other Options previously granted and delivered to the Participant, (ii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law and (iii) any written employment or severance arrangement that would provide for vesting acceleration of this Option upon the terms and conditions set forth therein.

By accepting this Option, the Participant consents to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

This Grant Notice may be executed in one or more counterparts, each of which shall be deemed to be an original, and all of which shall constitute one document.

SUNSHINE HEART, INC.		**PARTICIPANT:**	
By:	_____	By:	_____
Name:	_____	Date:	_____
Title:	_____		
Date:	_____		

ATTACHMENTS: Option Agreement, including Notice of Exercise, and New-Hire Equity Incentive Plan

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ATTACHMENT I

SUNSHINE HEART, INC.
NEW-HIRE EQUITY INCENTIVE PLAN

FORM OF OPTION AGREEMENT FOR EMPLOYEES (NEW HIRES ONLY)
(NONSTATUTORY STOCK OPTION)

Pursuant to your Stock Option Grant Notice (the ***"Grant Notice"***) and this Option Agreement (this ***"Agreement"***), Sunshine Heart, Inc. (the ***"Company"***) has granted you an Option (your ***"Option"***) under its New-Hire Equity Incentive Plan (the ***"Plan"***) to purchase the number of shares of the Company's Common Stock indicated in the Grant Notice at the Exercise Price indicated in the Grant Notice. Capitalized terms not explicitly defined in this Agreement or in the Grant Notice but defined in the Plan will have the same definitions as in the Plan. If there is any conflict between the terms in this Agreement and the Plan, the terms of the Plan will control.

The details of your Option, in addition to those set forth in the Grant Notice and the Plan, are as follows:

1. VESTING. Subject to the provisions contained herein, your Option will vest as provided in the Grant Notice. Vesting will cease upon the termination of your Continuous Service.

2. NUMBER OF SHARES AND EXERCISE PRICE. The number of shares of Common Stock subject to your Option and the Exercise Price per share set forth in the Grant Notice will be adjusted for Capitalization Adjustments.

3. EXERCISE.

(a) You may exercise the vested portion of your Option during its term by (i) delivering the Notice of Exercise attached hereto as EXHIBIT A and by completing such other documents and/or procedures designated by the Company for exercise and (ii) paying the Exercise Price per share set forth in the Grant Notice and any applicable withholding taxes to the Company's Secretary, stock plan administrator, or such other person as the Company may designate. You may exercise your Option only for whole shares of Common Stock; the Company shall not be required to issue any fractional shares of Common Stock under any circumstances.

(b) By exercising your Option you agree that, as a condition to any exercise of your Option, the Company may require you to enter into an arrangement providing for the payment by you to the Company of any tax withholding obligation of the Company arising by reason of your Option.

(c) The exercise of your Option must comply with all applicable laws and regulations governing your Option, and you may not exercise your Option if the Company determines that such exercise would not be in material compliance with such laws and regulations. Notwithstanding anything to the contrary contained herein, the Committee may

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suspend your right to exercise your Option for any period of up to 180 days in any 365-day period for which the Committee determines, in good faith, that such suspension is necessary or advisable in order to comply with the requirements of (i) any applicable federal securities law or rule or regulation thereunder; (ii) any rule of a national securities exchange, national securities association, or other self-regulatory organization; or (iii) any other federal or state law or regulation (each, an ***"Option Exercise Suspension"***). Notwithstanding the foregoing, no Option Exercise Suspension shall extend the term of your Option in a manner that would result in your Option becoming nonqualified deferred compensation subject to Section 409A of the Code.

4. METHOD OF PAYMENT. Payment of the exercise price is due in full upon exercise of all or any part of your Option. You may elect to make payment of the exercise price in cash or by check, bank draft or money order payable to the Company, or in any one or more of the following manners unless otherwise provided in the Grant Notice:

(a) Provided that at the time of exercise the Common Stock is publicly traded, pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of Common Stock, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds.

(b) Provided that at the time of exercise the Common Stock is publicly traded, by delivery to the Company (either by actual delivery or attestation) of already-owned shares of Common Stock that are owned free and clear of any liens, claims, encumbrances or security interests, and that are valued at Fair Market Value on the date of exercise. "Delivery" for these purposes, in the sole discretion of the Company at the time you exercise your Option, will include delivery to the Company of your attestation of ownership of such shares of Common Stock in a form approved by the Company. Notwithstanding the foregoing, you may not exercise your Option by delivery to the Company of Common Stock if doing so would violate the provisions of the applicable listing rules, or any law, regulation or agreement restricting the redemption of the Company's stock.

(c) Subject to the consent of the Company at the time of exercise, by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issued upon exercise of your Option by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate Exercise Price per share set forth in the Grant Notice. You must pay any remaining balance of the aggregate Exercise Price not satisfied by the "net exercise" in cash or other permitted form of payment. Shares of Common Stock will no longer be outstanding under your Option and will not be exercisable thereafter if those shares are (i) used to pay the Exercise Price pursuant to the "net exercise," (ii) delivered to you as a result of such exercise, and (iii) withheld to satisfy your tax withholding obligations.

5. TERM. You may not exercise your Option before the Date of Grant or after the Expiration Date set forth in the Grant Notice. Subject to Section 6 below, the term of your Option commences on the Date of Grant and terminates upon the earliest of the following:

(a) three months after the termination of your Continuous Service for any reason other than your death or Disability;

(b) 12 months after the termination of your Continuous Service due to your death or Disability;

(c) the Expiration Date indicated in the Grant Notice; or

(d) the day before the tenth anniversary of the Date of Grant.

6. CORPORATE TRANSACTION; CHANGE IN CONTROL. In the event of a Corporate Transaction or Change in Control, your Option shall be subject to the provisions of Sections 9(c) and (d) of the Plan, respectively, including any forfeiture provisions described therein.

7. TRANSFERABILITY. Your Option is not transferable, except (i) by will or by the laws of descent and distribution, (ii) pursuant to a domestic relations order and (iii) with the prior written approval of the Company, by instrument to an inter vivos or testamentary trust, in a form accepted by the Company, in which your Option is to be passed to beneficiaries upon the death of the trust or (settlor).

8. WITHHOLDING OBLIGATIONS.

(a) At the time you exercise your Option, in whole or in part, or at any time thereafter as requested by the Company, you hereby authorize withholding from payroll and any other amounts payable to you, and otherwise agree to make adequate provision for, any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or an Affiliate, if any, which arise in connection with your Option.

(b) Upon your request and subject to approval by the Company, in its sole discretion, and in compliance with any applicable conditions or restrictions of law, the Company may withhold from fully vested shares of Common Stock otherwise issuable to you upon the exercise of your Option a number of whole shares of Common Stock having a Fair Market Value, determined by the Company as of the date of exercise, not in excess of the minimum amount of tax required to be withheld by law (or such lower amount as may be necessary to avoid classification of your Option as a liability for financial accounting purposes). Any adverse consequences to you arising in connection with such share withholding procedure shall be your sole responsibility.

(c) You may not exercise your Option unless the tax withholding obligations of the Company and/or any Affiliate are satisfied. Accordingly, you may not be able to exercise your Option when desired even though your Option is vested, and the Company will have no obligation to issue a certificate for such shares of Common Stock unless such obligations are satisfied.

9. TAX CONSEQUENCES. You hereby agree that the Company does not have a duty to design or administer the Plan or its other compensation programs in a manner that minimizes your tax liabilities. You will not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates related to tax liabilities arising from your Option or your other compensation. In particular, you acknowledge that your Option is exempt from Section 409A of the Code only if the Exercise Price per share specified in the Grant Notice is at least equal to the

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"fair market value" per share of the Common Stock on the Date of Grant indicated in the Grant Notice and there is no other impermissible deferral of compensation associated with your Option.

10. NOTICES. Any notices provided for in your Option or the Plan will be given in writing and will be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five days after deposit in the U.S. mail, postage prepaid, addressed to you at the last address you provided to the Company. The Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and your Option by electronic means or to request your consent to participate in the Plan by electronic means. By accepting your Option, you consent to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

11. GOVERNING PLAN DOCUMENT. Your Option is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Option, and is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. If there is any conflict between the provisions of your Option and those of the Plan, the provisions of the Plan will control. In addition, your Option (and any compensation paid, shares issued under your Option, or proceeds received upon the sale of such shares) is subject to recoupment in accordance with The Dodd—Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback or compensation recovery policy adopted by the Company and any compensation recovery policy otherwise required by applicable law.

12. EFFECT ON OTHER EMPLOYEE BENEFIT PLANS. The value of your Option will not be included as compensation, earnings, salaries, or other similar terms used when calculating your benefits under any employee benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company's or any Affiliate's employee benefit plans.

13. VOTING RIGHTS. You will not have voting or any other rights as a stockholder of the Company with respect to the shares to be issued pursuant to your Option until such shares are issued to you. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in your Option, and no action taken pursuant to its provisions, will create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

14. SEVERABILITY. If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity will not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

15. CONSENT TO TRANSFER OF PERSONAL DATA. In administering the Plan, or to comply with applicable legal, regulatory, tax, or accounting requirements, it may be necessary for the Company to transfer certain Participant data to an Affiliate or to its outside service

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providers or governmental agencies. By accepting your Option, you consent, to the fullest extent permitted by law, to the use and transfer, electronically or otherwise, of your personal data to such entities for such purposes.

16. MISCELLANEOUS.

(a) The rights and obligations of the Company under your Option will be transferable by the Company to any one or more persons or entities, and all covenants and agreements hereunder will inure to the benefit of, and be enforceable by the Company's successors and assigns.

(b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your Option.

(c) You acknowledge and agree that you have reviewed your Option in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Option, and fully understand all provisions of your Option.

(d) This Agreement will be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(e) All obligations of the Company under the Plan and this Agreement will be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

* * *

This Agreement will be deemed to be signed by you upon the signing by you of the Grant Notice to which it is attached.

EXHIBIT A

NOTICE OF EXERCISE

SUNSHINE HEART, INC.
12988 Valley View Road
Eden Prairie, MN 55344

Date of Exercise: _____

This constitutes notice to Sunshine Heart, Inc. (the ***"Company"***) under my Option that I elect to purchase the below number of shares of Common Stock of the Company (the ***"Shares"***) for the price set forth below.

Type of Option (check one): Nonstatutory

Stock Option dated:

Number of shares as to which Option is exercised:

Certificates to be issued in name of:

Total exercise price: $

Cash payment delivered herewith: $

[Value of shares delivered herewith(1): $]

[Value of shares pursuant to net exercise(2): $]

[[Regulation T Program (cashless exercise)(3): $]

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(1) Shares must meet the public trading requirements set forth in the Option Agreement. Shares must be valued in accordance with the terms of the Option being exercised, and must be owned free and clear of any liens, claims, encumbrances or security interests. Certificates must be endorsed or accompanied by an executed assignment separate from certificate.
(2) The Company must have established net exercise procedures at the time of exercise, in order to utilize this payment method.
(3) Shares must meet the public trading requirements set forth in the Option Agreement.

EXHIBIT A

By this exercise, I agree (i) to provide such additional documents as you may require pursuant to the terms of the Sunshine Heart, Inc. New-Hire Equity Incentive Plan, and (ii) to provide for the payment by me to you (in the manner designated by you) of your withholding obligation, if any, relating to the exercise of my Option.

Very truly yours,

_____

ATTACHMENT II

NEW-HIRE EQUITY INCENTIVE PLAN

FORM OF CHANGE IN CONTROL AGREEMENT

This Change in Control Agreement (this "Agreement") is entered into as of , 20 (the "Effective Date"), by and between Sunshine Heart, Inc., a Delaware corporation (the "Company"), and , a resident of ("Executive").

Background

WHEREAS, Executive is a key member of the management of the Company and has heretofore devoted substantial skill and effort to the affairs of the Company; and

WHEREAS, it is desirable and in the best interests of the Company and its stockholders to continue to obtain the benefits of Executive's services and attention to the affairs of the Company; and

WHEREAS, it is desirable and in the best interests of the Company and its stockholders to provide inducement for Executive (A) to remain in the service of the Company in the event of any proposed or anticipated Change in Control (as defined below) and (B) to remain in the service of the Company in order to facilitate an orderly transition if a Change in Control occurs, without regard to the effect such Change in Control may have on Executive's employment with the Company; and

WHEREAS, it is desirable and in the best interests of the Company and its stockholders that Executive be in a position to make judgments and advise the Company with respect to any proposed Change in Control; and

WHEREAS, for the reasons set forth above, the Company and Executive desire to enter into this Agreement.

Agreement

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants and agreements contained herein, the Company and Executive agree as follows:

1. Definitions. Capitalized terms used in the Agreement shall have their defined meaning throughout the Agreement. The following terms shall have the meanings set forth below.

(a) **"Board"** means the Board of Directors of the Company.

(b) **"Cause"** shall have the meaning ascribed to such term in any written agreement between the Participant and the Company defining such term and, in the absence of such agreement, such term shall mean with respect to Executive, the occurrence of any of the following events, if such event results in a demonstrably harmful impact on the Company's business or reputation, or that of any of its subsidiaries: (i) Executive's commission of any felony or any crime involving fraud, dishonesty or moral turpitude under the laws of the United States

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or any state thereof; (ii) Executive's attempted commission of, or participation in, a fraud or act of dishonesty against the Company; (iii) Executive's intentional, material violation of any contract or agreement between Executive and the Company or of any statutory duty owed to the Company; (iv) Executive's unauthorized use or disclosure of the Company's confidential information or trade secrets; or (v) Executive's gross misconduct. The determination that a termination of Executive's employment is either for Cause or without Cause shall be made by the Company in its sole discretion.

(c) **"Code"** means the Internal Revenue Code of 1986, as amended. Any reference to a specific provision of the Code includes a reference to such provision as it may be amended from time to time and to any successor provision.

(d) **"Change in Control"** shall have the meaning ascribed to that term under Section 13(d) of the Equity Incentive Plan.

(e) **"Disability"** shall have the meaning ascribed to that term under Section 13(m) of the Equity Incentive Plan, replacing "Participant" with "Executive" for purposes of this Agreement.

(f) **"Equity Incentive Plan"** means the Sunshine Heart, Inc. New-Hire Equity Incentive Plan, as amended from time to time and any other equity incentive plan of the Company that Executive participates in after the date of this Agreement.

(g) **"Health Benefits"** means if Executive (and/or Executive's covered dependents) is eligible for and properly elects to continue group medical and/or dental insurance coverage, as in place immediately prior to the Termination Date, the Company's continued payment of the Company's portion of any premiums or costs of such coverage until the earlier of (i) twelve (12) months after the Termination Date, or (ii) the date Executive (and/or Executive's covered dependents, as applicable) is eligible to receive group medical and/or dental insurance coverage by a subsequent employer, in either case provided Executive remains eligible for continuation coverage and timely pays Executive's portion, if any, of such coverage. All such Company-provided medical and/or dental insurance premiums, or costs of coverage, will be paid directly to the insurance carrier or other provider by the Company and Executive will make arrangements with the Company to pay Executive's portion of such coverage in an amount equal to such portion that Executive would pay if Executive was actively employed by the Company during such period.

(h) **"Letter Agreement"** means the Employment Terms letter from the Company to Executive dated , 20 , and countersigned by Executive on , 20 .

(i) **"Monthly Base Salary"** means Executive's monthly base salary as of the Termination Date, provided, however, if Executive's monthly base salary has been reduced and such reduction has triggered Executive's Resignation for Good Reason, then "Monthly Base Salary" shall mean Executive's monthly base salary immediately prior to such reduction.

(j) **"Notice of Termination"** means a written notice which shall indicate the specific termination provisions in this Agreement relied upon and shall set forth in reasonable detail the facts and circumstances claimed to provide the basis for such termination.

(k) **"Preliminary Event"** shall mean an involuntary termination of the Executive's employment by the Company without Cause prior to a Change in Control and the expiration of the Term; provided that Executive reasonably demonstrates that such termination (i) was requested by a party other than the Board that has taken other steps reasonably calculated to result in a Change in Control or (ii) otherwise arose in connection with or in anticipation of a Change in Control.

(l) **"Proprietary Information Agreement"** means the Employee Proprietary Information, Inventions, Assignment and Non-Competition Agreement between Executive and the Company dated , 20 .

(m) **"Resignation for Good Reason"** means a termination of Executive's employment by the Executive within thirty (30) days of the Company's failure to cure, in accordance with the procedures set forth below, any of the following events without Executive's consent: (i) a reduction in any of the Executive's compensation rights under the Letter Agreement; (ii) a material reduction in the Executive's duties and responsibilities as in effect immediately prior to such reduction; (iii) the relocation of the Executive's principal office to a location that is more than 75 miles outside of Eden Prairie, Minnesota; or (iv) a material breach of any material provision of the Letter Agreement by the Company. Notwithstanding the foregoing, a termination shall not be treated as a Termination for Good Reason (A) if Executive shall have consented in writing to the occurrence of the event giving rise to the claim of Termination for Good Reason, (B) unless Executive shall have delivered a written notice to the Board within forty-five (45) days of Executive's having actual knowledge of the occurrence of one of such events stating that Executive intends to terminate Executive's employment for Good Reason and specifying the factual basis for such termination, and such event, if capable of being cured, shall not have been cured within twenty-one (21) days of the receipt of such notice or (C) if Executive's date of termination as a result of such event occurs within 180 days after the initial occurrence of such event alleged to constitute Resignation for Good Reason.

(n) **"Successor"** means any successor to all or substantially all of the Company's business by merger, consolidation, purchase of assets or otherwise.

(o) **"Term"** means the period from the Effective Date through the later of (i) the five-year anniversary of the Effective Date, provided that such period shall be automatically extended for successive two-year periods thereafter until notice of non-renewal is given by the Company or Executive to the other party hereto at least sixty (60) days prior to the five-year anniversary of the Effective Date or the end of the two-year extension period then in effect, as the case may be, or (ii) if a Change in Control occurs on or prior to the five-year anniversary of the Effective Date (or prior to the end of the two-year extension period then in effect as provided for in clause (i) hereof), the one-year anniversary of the effective date of the Change in Control.

(p) **"Termination Date"** means the date of Executive's "separation from service" with the Company within the meaning of Section 409A(a)(2)(A)(i) of the Code.

(q) **"Termination Payments"** means the Company's payment to Executive of (i) an amount equal to twelve (12) months of Executive's Monthly Base Salary, less applicable withholdings, plus (ii) an amount equal to the incentive bonus payment received by Executive for the fiscal year immediately preceding the fiscal year in which the Termination Date occurs, less applicable withholdings, both payable in a lump sum on the Company's first regular payroll date after expiration of the release described in Section 7.

(r) **"Transition Period"** means the period commencing on the effective date of the Change in Control and ending on the date that is one year thereafter.

2. **Award Acceleration Upon a Change in Control.** Subject to Section 8, a Change in Control while Executive is actively employed by the Company during the Term shall cause the immediate acceleration of the vesting of 100% of any unvested portion of any stock option or other equity based awards held by Executive on the effective date of such Change in Control, including without limitation any options granted under the Equity Incentive Plan, which acceleration shall be in addition to any other rights Executive may have under the terms of any such stock option or restricted stock award. Any such acceleration shall not, however, detract from the authority of the Board or any committee thereof under the Equity Incentive Plan or otherwise to cancel any such stock option award, to the extent not exercised prior to the effective time of the Change in Control, in exchange for consideration, in such form as may be determined by the Board or such committee, in an amount equal to the excess, if any, of (A) the fair market value (as determined in good faith by the Board or such committee) immediately prior to the effective time of the Change in Control of the number of shares of the Company's common stock remaining subject to the stock option award, over (B) the aggregate exercise price of such number of shares remaining subject to the stock option award.

3. **Termination of Employment.** Executive shall at all times be an employee at will, and the Company may terminate Executive's employment with or without Cause at any time or Executive may resign (whether through a Resignation for Good Reason or otherwise) at any time, subject to any notice requirements or other obligations of the parties under this Agreement.

4. **Payments Upon Termination of Employment After a Change in Control.** If a Change in Control occurs during the Term, and if Executive's employment terminates such that the Termination Date occurs during or after the Transition Period, then Executive shall be entitled to payments and benefits on the terms and conditions specified in this Section 4.

(a) Payment Upon Involuntary Termination Without Cause or Voluntary Resignation for Good Reason During the Transition Period. If Executive's Termination Date occurs during the Transition Period, and if such termination is involuntary at the initiative of the Company without Cause or due to a voluntary Resignation for Good Reason, then, in addition to such base salary and other compensation that has been earned but not paid to Executive as of the

Termination Date (which shall be payable in accordance with the Company's regular payroll practices and applicable plans and programs), the Company shall provide to Executive the Termination Payments and the Health Benefits, subject to the conditions in Section 7.

(b) Other Termination Following a Change in Control. If Executive's Termination Date occurs during the Transition Period or otherwise following a Change in Control, and such termination is:

(i) by reason of Executive's abandonment of or resignation from employment for any reason (other than, during the Transition Period, a Resignation for Good Reason);

(ii) by reason of termination of Executive's employment by the Company for Cause;

(iii) because of Executive's death or Disability; or

(iv) upon or following expiration of the Term,

then the Company will pay to Executive, or Executive's beneficiary or Executive's estate, as the case may be, such base salary and other compensation that has been earned but not paid to Executive as of the Termination Date (which shall be payable pursuant to the Company's regular payroll practices and applicable plans and programs), and Executive shall not be entitled to any additional compensation or benefits provided under this Section 4.

5. Payments Upon a Change in Control. If Executive's employment terminates during the Term due to a voluntary Resignation for Good Reason and a Change in Control occurs within ninety (90) days after the Termination Date and during the Term or a Preliminary Event occurs and a Change in Control occurs within ninety (90) days after the Termination Date and during the Term, then, in addition to such base salary and other compensation that has been earned but not paid to Executive as of the Termination Date (which shall be payable in accordance with the Company's regular payroll practices and applicable plans and programs), the Company shall provide to Executive the Termination Payments and the Health Benefits, subject to the conditions in Section 7. Except as provided in the preceding sentence and Section 2, Executive shall not be entitled to any payments, benefits or accelerated vesting of equity upon a Change in Control.

6. Payments Upon Termination of Employment Prior to a Change in Control or Upon or Following Expiration of the Term. If Executive's employment is terminated for any reason, whether at the initiative of the Company or Executive or due to Executive's death or Disability, and the Termination Date occurs prior to a Change in Control or upon or following expiration of the Term, then, except as provided in Section 5, the Company will pay to Executive, or Executive's beneficiary or Executive's estate, as the case may be, such base salary and other compensation that has been earned but not paid to Executive as of the Termination Date (which shall be payable pursuant to the Company's regular payroll practices and applicable

plans and programs), and Executive shall not be entitled to any additional compensation or benefits under this Section 6.

7. Release and Other Conditions. Notwithstanding any other provisions of this Agreement, neither the Company nor any Successor shall be obligated to provide the Termination Payments or Health Benefits under Sections 4 or 5 unless (a) Executive shall have signed a full release of any and all claims in favor of the Company (and any Successor), pursuant to a form of release acceptable to counsel to the Company, (b) all applicable consideration periods and rescission periods provided by law shall have expired, and (c) Executive is in strict compliance with the terms of this Agreement and the Proprietary Information Agreement as of the dates the Company provides any Termination Payments or Health Benefits.

8. "Parachute Payment" Adjustment.

(a) Possible Reduction. In the event Executive becomes entitled to any benefits or payments in the nature of compensation (within the meaning of section 280G(b)(2) of the Code) under this Agreement, or any other plan, arrangement, or agreement with the Company (the "Payments"), and such benefits or payments would (in the absence of this Section 8) be subject to the excise tax imposed by section 4999 of the Code (the "Excise Tax"), the aggregate present value of the Payments under this Agreement shall be reduced (but not below zero) to the Reduced Amount (as defined below), if reducing the Payments under this Agreement will provide Executive with a greater net after-tax amount than would be the case if no reduction was made. The "Reduced Amount" shall be an amount expressed in present value which maximizes the aggregate present value of Payments without causing any Payment under this Agreement to be subject to the Excise Tax, determined in accordance with section 280G(d)(4) of the Code. If Payments are to be reduced, the Company shall reduce the Payments under this Agreement by first reducing Payments that are payable in cash and then by reducing non-cash Payments. Only amounts payable under this Agreement shall be reduced pursuant to this Section 8.

(b) Determinations. All determinations to be made under this Section 8 shall be made by the Company's independent public accounting firm as in effect immediately prior to the event that constitutes a change in control under section 280G of the Code or another independent firm selected by the Company before such event (the "Accounting Firm"), which firm shall provide its determinations and any supporting calculations to the Company and Chief Executive Officer within ten (10) business days after such event. Any such determination by the Accounting Firm shall be binding upon the Company and Executive.

(c) Fees and Expenses. All of the fees and expenses of the Accounting Firm in performing the determinations referred to in this Section 8 shall be borne solely by the Company. The Company agrees to indemnify and hold harmless the Accounting Firm of and from any and all claims, damages and expenses resulting from or relating to its determinations pursuant to this Section 8, except for claims, damages or expenses resulting from the gross negligence or willful misconduct of the Accounting Firm.

9. Notice of Termination. Any purported termination of employment by the Company or by Executive (other than a termination by mutual agreement or Executive's death) shall be communicated by written Notice of Termination to the other party hereto.

10. Acknowledgment of Letter Agreement or the Proprietary Information Agreement. Executive acknowledges and agrees that nothing in this Agreement limits or supersedes any of the provisions contained in the Letter Agreement or the Proprietary Information Agreement, all of which remain in full force and effect between Executive and the Company and are hereby reaffirmed in all respects.

11. Miscellaneous.

(a) Tax Withholding. The Company may withhold from any amounts payable under this Agreement such federal, state and local income and employment taxes as the Company shall determine are required to be withheld pursuant to any applicable law or regulation.

(b) Section 409A. This Agreement is intended to satisfy, or be exempt from, the requirements of Section 409A(a)(2), (3) and (4) of the Code, including current and future guidance and regulations interpreting such provisions, and should be interpreted accordingly.

(c) Assignment; Successors. This Agreement is personal to Executive and without the prior written consent of the Company shall not be assignable by Executive otherwise than by will or the laws of descent and distribution. This Agreement shall inure to the benefit of and be enforceable by Executive's legal representatives. The Company may, without further consent of Executive, assign this Agreement to any Successor, and this Agreement shall be binding upon and inure to the benefit of any Successor of the Company.

(d) Notices. All notices and other communications required or permitted to be given hereunder shall be in writing and shall be deemed to have been duly given if delivered personally, mailed by certified mail (return receipt requested) or sent by overnight delivery service, cable, telegram, facsimile transmission or telex to the Company at the Company's address or to Executive at the last address of Executive contained in the Company's records. Either party may, by notice hereunder, designate a changed address. Notice so given shall, in the case of notice so given by mail, be deemed to be given and received on the registered date or the date stamped on the certified mail receipt, in the case of notice so given by overnight delivery service, on the date of actual delivery and, in the case of notice so given by cable, telegram, facsimile transmission, telex or personal delivery, on the date of actual transmission or, as the case may be, personal delivery.

(e) Governing Law; Consent to Jurisdiction, Waiver of Jury Trial. This Agreement shall be governed by and construed in accordance with the internal laws of the State of Minnesota, without regard to its principles of conflicts of laws. Each of the parties hereto irrevocably submits to the exclusive jurisdiction of the courts of the State of Minnesota and the United States District Court for the District of Minnesota for the purpose of any suit, action,

proceeding or judgment relating to or arising out of this Agreement and the transactions contemplated hereby. Service of process in connection with any such suit, action or proceeding may be served on each party hereto anywhere in the world by the same methods as are specified for the giving of notices under this Agreement. Each of the parties hereto irrevocably consents to the jurisdiction of any such court in any such suit, action or proceeding and to the laying of venue in such court. Each party hereto irrevocably waives any objection to the laying of venue of any such suit, action or proceeding brought in such courts and irrevocably waives any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum.

(f) Construction. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement shall be prohibited by or invalid under applicable law, such provision shall be ineffective only to the extent of such prohibition or invalidity without invalidating the remainder of such provision or the remaining provisions of this Agreement.

(g) Waivers. No failure on the part of either party to exercise, and no delay in exercising, any right or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise or any right or remedy hereunder preclude any other or further exercise thereof or the exercise of any other right or remedy granted hereby or by any related document or by law.

(h) Amendment. No modification of or amendment to this Agreement nor any waiver of any rights under this Agreement shall be effective unless in a writing signed by the Company and Executive.

(i) Entire Agreement. This Agreement sets forth the entire agreement and understanding between the Company and Executive relating to payments and benefits upon a Change in Control or termination of Executive's employment or other separation from service with the Company. This Agreement supersedes all prior discussions, agreements or understandings between Executive and the Company related to such subject matter.

(j) Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original but all of which together will constitute one and the same instrument.

EXECUTIVE HAS READ THIS AGREEMENT CAREFULLY AND UNDERSTANDS AND ACCEPTS THE OBLIGATIONS WHICH IT IMPOSES UPON EXECUTIVE WITHOUT RESERVATION. NO PROMISES OR REPRESENTATIONS HAVE BEEN MADE TO EXECUTIVE TO INDUCE EXECUTIVE TO SIGN THIS AGREEMENT. EXECUTIVE SIGNS THIS AGREEMENT VOLUNTARILY AND FREELY.

THE COMPANY:

SUNSHINE HEART, INC.

By: _____
Name: _____
Title: _____

Date: _____

EXECUTIVE:

_____

SEPARATION AND RELEASE AGREEMENT

THIS SEPARATION AND RELEASE AGREEMENT (this ***"Agreement"***) is made as of August 29, 2014 by and between **SUNSHINE HEART, INC.**, a Delaware corporation, whose address is 12988 Valley View Road, Eden Prairie, Minnesota 55344 (the ***"Company"***) and **PATRICK VERTA** whose address is 5282 E. Lomita Avenue, Orange, California 92869 (***"Employee"***). The parties agree as follows:

ARTICLE 1
EMPLOYMENT TERMINATION, CONSIDERATION AND RESIGNATION

1.1 TERMINATION OF EMPLOYMENT. Employee's employment with the Company shall terminate as of August 29, 2014 (the ***"Termination Date"***). Effective as of the Termination Date, Employee resigns from every office of the Company held by Employee and/or its related entities. The Company shall pay Employee's compensation for hours worked through the end of August 2014, subject to withholding and payable in accordance with the Company's payroll practices. The Company agrees to pay Employee in full and final settlement of all vacation pay entitlement on the Company's books as of the Termination Date, the aggregate sum of One Thousand Four Hundred Sixteen dollars and Twenty-three cents ($1,416.23), subject to payroll deductions and all required withholdings. In addition, the Company will reimburse Employee for his outstanding travel and entertainment expenses remaining on the Company's books, which are properly reviewed and approved according to firm policy on the Termination Date. Employee will receive the foregoing payments regardless of whether he signs this Agreement.

1.2 SEPARATION CONSIDERATION. As consideration for Employee's agreements and releases set forth herein, following the later to occur of the (A) execution of this Agreement and expiration of the Revocation Period (as defined below) and (B) the Termination Date, and recognizing that without execution of this Agreement, Employee would not be entitled to any additional compensation beyond wages due, the Company agrees to provide Employee with the following benefits after the Termination Date, provided this Agreement becomes effective in accordance with Section 2.2:

A. the Company agrees to provide Employee payments equal to two (2) months of Employee's annual base salary which shall be paid in accordance with the Company's standard payroll practices and policies during the two (2) months following the Termination Date subject to payroll deductions and all required withholdings;

B. upon the Termination Date, Employee will be credited with an additional two (2) months of vesting on all issued and outstanding stock options held by Employee as of the Termination Date; and

C. provided that Employee timely elects continued health insurance coverage under the federal COBRA law, the Company will pay one-hundred percent of the cost of premiums for such health and dental insurance continuation coverage until October 31, 2014. Notwithstanding anything to the contrary in this Section 1.2.B., Employee's entitlement to any benefits or payments under this Section 1.2 B. shall cease on such date that Employee becomes eligible to receive health insurance coverage from another employer group health plan due to Employee's employment with a future employer.

1.3 CONFLICT WITH OTHER AGREEMENTS. In the event of any conflict of the provisions between this Agreement and that certain offer letter agreement describing Employee's employment terms dated as of August 18, 2013, by and between the Company and Employee (the ***"Employment Terms Letter"***), and the Change in Control Agreement dated as of August 18, 2013, by and between the Company and Employee (the ***"Change in Control Agreement"***), the provisions set forth in this Agreement shall control. In the event of any conflict between this Agreement and the provisions of that certain Employee Proprietary Information, Inventions Assignment Agreement dated as of August 19, 2013, by and between the Company and Employee (the ***"Invention Assignment Agreement"***), the terms and conditions of the Invention Assignment Agreement shall control over the terms of this Agreement. Effective as of the Termination Date, the Change in Control Agreement shall terminate in its entirety.

1.4 ACKNOWLEDGEMENT. Except as contemplated by Section 1.2 above, the parties acknowledge and agree that Employee is not, and shall not after the Termination Date, be eligible for any additional payment by the Company of any bonus, salary, vacation pay, retirement pension, severance pay, back pay, or other remuneration or compensation of any kind in respect of employment by the Company. Employee hereby confirms to the Company that the Invention Assignment Agreement contains a complete list of all inventions or improvements, if any, to which Employee claims ownership and desires to remove from the operation of the Invention Assignment Agreement. Employee further agrees that the Invention Assignment Agreement remains in full force and effect, and Employee hereby reaffirms his obligations arising under the terms of the Invention Assignment Agreement. Employee agrees to return to the Company all Company documents and materials, apparatus, equipment and other physical property in Employee's possession on the Termination Date and in the manner directed by the CEO of the Company.

1.5 COOPERATION AND ASSISTANCE. Following the Termination Date, Employee agrees to furnish such information and assistance to the Company as may be reasonably required by the Company in connection with any issues or matters of which Employee had knowledge during his employment with the Company. In addition, Employee shall make himself reasonably available to assist the Company in matters relating to the transition of his prior duties to other employees of the Company (including his successor), as may be reasonably requested by the Company. The Company shall reimburse Employee for the reasonable documented out-of-pocket expenses incurred by him in providing such cooperation and assistance; provided that any such expense exceeding Five Hundred Dollars ($500) shall require the advance consent of the Chairman of the Board. Any services rendered by Employee pursuant to this Section 1.5 shall be compensated at Employee's effective hourly rate as of the Termination Date, unless a different rate is negotiated by the Parties.

1.6 CLAIMS AGAINST THE COMPANY. At the Company's cost, Employee agrees to cooperate with the Company in any internal investigation, any administrative, regulatory or judicial proceeding or any dispute with a third party. Further, to the fullest extent permitted by law, Employee will not cooperate with or assist any person or entity asserting or investigating a claim against the Company unless required to do so by a lawfully issued subpoena, by court order or as expressly provided by regulation or statute. If Employee is served with a subpoena or is required by court order or otherwise to testify or produce documents in any type of proceeding involving the Company, he shall immediately advise the Company of same and cooperate with the Company, at the Company's cost, in objecting to such request and/or seeking confidentiality protections.

ARTICLE 2
RELEASE AND NON-DISPARAGEMENT

2.1 EMPLOYEE RELEASE OF CLAIMS. In consideration for the separation consideration set forth in this Agreement, Employee, on behalf of himself, his heirs, executors, legal representatives, spouse and assigns (***"Employee Releasing Parties"***), hereby fully and forever releases the Company and its respective past and present officers, directors, employees, investors, stockholders, administrators, subsidiaries, affiliates, predecessor and successor corporations and assigns, attorneys and insurers (the ***"Company's Released Parties"***) of and from any and all claims, duties, liabilities, demands, obligations, actions, causes of action, and losses of every kind and nature whatsoever, whether presently known or unknown, suspected or unsuspected, that any of them may possess arising from any omissions, acts or facts that have occurred through the date that Employee signs this Agreement, including, without limitation, any and all claims:

A. which arise out of, result from, or occurred in connection with Employee's employment by or consulting to the Company or any of its affiliated entities, the termination of that employment or consulting relationship, any events occurring in the course of that employment or consultancy, or any events occurring prior to the execution of this Agreement;

B. for wrongful discharge, discrimination, harassment and/or retaliation; breach of contract, both express and implied; breach of a covenant of good faith and fair dealing, both express and implied; negligent or intentional infliction of emotional distress; negligent or intentional misrepresentation; negligent or intentional interference with contract or prospective economic advantage; slander, libel or invasion of privacy; constructive

termination of employment; violation of public policy; fraud, misrepresentation or conspiracy; and false imprisonment;

C. for a violation of any federal, state or municipal statute, regulation or ordinance relating to employment, all as amended, including, without limitation, (1) Title VII of the Civil Rights Act of 1964, (2) 42 U.S.C. § 1981, (3) the Civil Rights Act of 1991, (4) the Employee Retirement and Income Security Act of 1974, (5) the Age Discrimination in Employment Act of 1967 (the ***"ADEA"***), (6) the Older Workers' Benefit Protection Act (***"OWBPA"***), (7) the Americans with Disabilities Act of 1990, (8) the Family Medical Leave Act, (9) the Equal Pay Act), (10) the Minnesota Human Rights Act (the ***"MHRA"***), (11) the Minnesota Equal Pay for Equal Work Law, (12) the Minnesota healthcare worker whistleblower protection laws, (13) the Minnesota family leave law, (14) the Minnesota personnel record access statutes, (15) the California Fair Employment and Housing Act, (16) the Rehabilitation Act of 1973, (17) the California and United States Constitutions, (18) the California Labor Code, (19) the California Business and Professions Code, (20) the California Family Rights Act, (21) the California Government Code, and (22) the California Wage Orders;

D. for back pay or other unpaid compensation;

E. relating to equity of the Company; and/or

F. for attorneys' fees, penalties and costs.

Employee represents that he has not filed any lawsuit, arbitration, or other claim against any of the Company's Released Parties. Employee states that he knows of no violation of state, federal, or municipal law or regulation by any of the Company's Released Parties, and knows of no ongoing or pending investigation, charge, or complaint by any agency charged with enforcement of state, federal, or municipal law or regulation. Employee further agrees he shall not receive any monetary damages, recovery and/or relief of any type related to any released claim(s), whether pursued by Employee or any governmental agency, other person or group based on the released claims.

This release in all respects has been voluntarily and knowingly executed with the express intention of effecting the legal consequences provided in the California Civil Code § 1541, that is, the extinguishment of obligations herein designated. The parties agree, with the advice of counsel, that this is a general release and that Civil Code section 1542 is waived by Employee. Section 1542 provides:

> A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor.

2.2 ACKNOWLEDGMENT OF WAIVER OF CLAIMS UNDER ADEA AND MHRA. Employee acknowledges that he is waiving and releasing any rights he may have under the OWBPA, the ADEA and the MHRA, and that this waiver and release is knowing and voluntary. Employee acknowledges that the consideration given for this waiver and release is in addition to anything of value to which Employee was already entitled. Employee further acknowledges that he has been advised by this writing that: (a) he should consult with an attorney prior to executing this Agreement; (b) he has at least twenty-one (21) days within which to consider this Agreement and that if he signed this Agreement before expiration of that twenty-one (21) calendar day period, he did so knowingly and voluntarily and with the intent of waiving his right to utilize the full twenty-one (21) calendar day consideration period; (c) he has the right to revoke his release of claims, insofar as it extends to potential claims arising under the ADEA, by informing the Company of such revocation within seven (7) calendar days following his execution of this Agreement; and (d) he has the right to rescind his release of claims, insofar as it extends to potential claims arising under the MHRA, by informing the Company of such rescission within fifteen (15) calendar days following Employee's execution of this Agreement. Employee further understands that these revocation and rescission periods shall run concurrently, and that this Agreement is not effective until the fifteen (15) day rescission period (the ***"Revocation Period"***) has expired. Communication of any such revocation by Employee to

the Company shall be provided in writing and mailed by certified or registered mail with return receipt requested and addressed to the Company at its principal corporate offices to the attention of its Chairman of the Board.

2.3 NO ADMISSION OF LIABILITY. Neither this Agreement nor any statement contained herein shall be deemed to constitute an admission of liability on the part of the parties herein released. This Agreement's execution and implementation may not be used as evidence, and shall not be admissible in a subsequent proceeding of any kind, except one alleging a breach of this Agreement.

2.4 NON-DISPARAGEMENT. The parties covenant and agree that they shall not make or cause to be made any statements, observations, or opinions, or communicate any information (whether in written or oral form), that defame, slander or are likely in any way to harm the reputation of the the other Party or that Party's Released Parties or tortiously interfere with any of the other Party's business relationships. The Parties acknowledge and agree that

any violation of the covenants contained in this Section will result in irreparable damage to the other Party and that the other Party shall be entitled to injunctive and other equitable relief. This provision with respect to injunctive relief shall not, however, diminish the right to claim and recover damages or other remedies in addition to equitable relief.

ARTICLE 3
REPRESENTATIONS AND WARRANTIES

3.1 REPRESENTATIONS AND WARRANTIES OF EMPLOYEE. Employee warrants and represents to the Company that he:

A. has been advised to consult with legal counsel and has had the opportunity to consult with legal counsel prior to entering into this Agreement;

B. has carefully read and understands all the terms and conditions of this Agreement;

C. has voluntarily executed this Agreement without any duress or undue influence and with the full intent of releasing all claims;

D. has received no promise, inducement or agreement not herein expressed with respect to this Agreement or the terms of this Agreement;

E. is the only person who is or may be entitled to receive or share in any damages or compensation on account of or arising out of his relationship with, or providing services to, the Company or any of its affiliated entities, the termination of that relationship or services, any actions taken in the course of that relationship or services, and any events related to that relationship or services or occurring prior to the execution of this Agreement;

F. understands and agrees that in the event any injury, loss, or damage has been sustained by him which is not now known or suspected, or in the event that the losses or damage now known or suspected have present or future consequences not now known or suspected, this Agreement shall nevertheless constitute a full and final release as to the parties herein released, and that this Agreement shall apply to all such unknown or unsuspected injuries, losses, damages or consequences; and

G. expressly acknowledges that his entry into this Agreement is in exchange for consideration in addition to anything of value to which he is already entitled.

3.2 AUTHORITY. Employee represents and warrants that he has the capacity to act on his own behalf and on behalf of all who might claim through him to bind them to the terms and conditions of this Agreement. Each Party warrants and represents that he has not assigned any claim released under this Agreement, and there are no liens or claims of lien or assignments in law or equity or otherwise of or against any of the claims or causes of action released herein.

3.3 NO OTHER REPRESENTATIONS. Neither party has relied upon any representations or statements made by other party hereto which are not specifically set forth in this Agreement.

ARTICLE 4
MISCELLANEOUS

4.1 CONFIDENTIALITY. Employee agrees to maintain in confidence the existence of this Agreement, the contents and terms of this Agreement, and the consideration for this Agreement (collectively, the ***"Separation Information"***), provided that Employee may share the Separation Information with his accountant or financial advisor to the limited extent needed for that person to prepare his tax returns, his spouse, and his attorney. In addition, Employee may reveal to potential employers only those Sections of this Agreement that would restrict his activities or ability to disclose information with respect to any such future employer.

4.2 REMEDIES. In addition to any other legal, contractual and/or equitable remedies, the Company's obligation to provide the payment identified in Section 1.2 shall immediately cease if the Company, in reasonable and good faith, believes Employee has breached one or more obligations of this Agreement, the Invention Assignment Agreement, and/or any other contractual or legal obligation Employee owes to the Company.

4.3 SEVERABILITY. Should any provision of this Agreement be declared or be determined by any arbitrator or court of competent jurisdiction to be illegal or invalid, the validity of the remaining parts, terms or provisions shall not be affected thereby and said illegal or invalid part, term, or provision shall be deemed not to be a part of this Agreement.

4.4 ENTIRE AGREEMENT. This Agreement represents the entire agreement and understanding between the Company and Employee concerning Employee's separation from the Company, and supersedes and replaces any and all prior agreements and understandings concerning Employee's relationship with the Company and his compensation by the Company, provided, however, that this Agreement does not supersede or modify the Invention Assignment Agreement, which shall remain in full force and effect. This Agreement may only be amended by a writing signed by Employee and the Company.

4.5 ASSIGNMENT. This Agreement may not be assigned by Employee without the prior written consent of the other party. The Company may assign this Agreement without Employee's consent in connection with a merger or sale of its assets and/or to a corporation controlling, controlled by or under common control with the Company. This Agreement shall inure to the benefit of, and be binding upon, each Party's respective heirs, legal representatives, successors and assigns.

4.6 GOVERNING LAW; CONSENT TO JURISDICTION, WAIVER OF JURY TRIAL. This Agreement shall be governed by and construed in accordance with the laws of the State of Minnesota. Each of the Parties hereto irrevocably submits to the exclusive jurisdiction of the state and federal courts of the State of Minnesota for the purpose of any suit, action, proceeding or judgment relating to or arising out of this Agreement, and consents to the laying of venue in such courts. EACH OF THE PARTIES KNOWINGLY AND VOLUNTARILY WAIVES ANY RIGHT TO REQUEST A TRIAL BY JURY IN ANY LITIGATION WITH RESPECT TO THIS AGREEMENT AND REPRESENTS THAT COUNSEL HAS BEEN CONSULTED

SPECIFICALLY AS TO THIS WAIVER. In addition, should it become necessary for either Party to seek to enforce any of the covenants contained in this Agreement through any legal, administrative or alternative dispute resolution proceeding, the prevailing Party in such enforcement action shall be entitled to reimbursement of its reasonable fees and expenses (legal costs, attorney's fees and otherwise) related thereto by the other Party.

4.7 COUNTERPARTS/ FACSIMILE SIGNATURE. This Agreement may be executed in one or more counterparts and by facsimile, each of which shall constitute an original and all of which together shall constitute one and the same instrument. Signatures of the parties transmitted by facsimile or via .pdf format shall be deemed to be their original signatures for all purposes.

4.8 EMPLOYMENT STATUS; NO APPLICATION FOR FUTURE EMPLOYMENT. Employee acknowledges

that his employment with the Company has ceased. Employee agrees that he will not attempt to procure employment or seek reinstatement with the Company or its affiliates at any time, nor or in the future, either as an employee, an independent contractor or in any other capacity.

SIGNATURES ON THE FOLLOWING PAGE

The Parties have executed this Separation and Release Agreement as of the date set forth below.

SUNSHINE HEART, INC.

By:	/S/ DAVE ROSA	/S/ PATRICK VERTA	
Name:	Dave Rosa	**PATRICK VERTA**	
Title:	CEO	Date:	30 Aug 2014

ELECTION TO EXECUTE PRIOR TO EXPIRATION OF TWENTY-ONE DAY CONSIDERATION PERIOD
(To be signed only if Separation and Release Agreement is signed prior to expiration of 21 days after it is presented to employee)

I understand that I have up to twenty-one (21) days within which to consider and execute the foregoing Separation and Release Agreement. However, after having had sufficient time to consider the matter and to consult with counsel, I have freely and voluntarily elected to execute the Separation and Release Agreement before the twenty-one (21) day period has expired.

/S/ PATRICK VERTA
PATRICK VERTA

Date: 30 Aug 2014

SIGNATURE PAGE TO SEPARATION AND RELEASE AGREEMENT

EXHIBIT 21

Subsidiaries

Entity	Jurisdiction of Formation
Sunshine Heart Company Pty Limited	Australia
Sunshine Heart Ireland Limited	Ireland

Exhibit 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-183924) pertaining to the Sunshine Heart, Inc. Amended and Restated 2002 Stock Plan;

(2) Registration Statement (Form S-8 No. 333-183925) pertaining to the Sunshine Heart, Inc. Second Amended and Restated 2011 Equity Incentive Plan;

(3) Registration Statement (Form S-8 No. 333-188935) pertaining to the Sunshine Heart, Inc. 2013 Non-Employee Directors' Equity Incentive Plan;

(4) Registration Statement (Form S-8 No. 333-190499) pertaining to the Sunshine Heart, Inc. New-Hire Equity Incentive Plan;

(5) Registration Statement (Form S-8 No. 333-194642) pertaining to the Sunshine Heart, Inc. Second Amended and Restated 2011 Equity Incentive Plan, the Sunshine Heart, Inc. 2013 Non-Employee Directors' Equity Plan, and the Sunshine Heart, Inc. New-Hire Equity Incentive Plan, as amended; and

(6) Registration Statement (Form S-3 No. 333-194731) of Sunshine Heart, Inc. and in the related base prospectus and sales agreement prospectus,

of our report dated March 20, 2015, with respect to the consolidated financial statements of Sunshine Heart, Inc. and Subsidiaries included in this Annual Report (Form 10-K) of Sunshine Heart, Inc. for the year ended December 31, 2014.

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

EXHIBIT 31.1

SUNSHINE HEART, INC.
CEO SECTION 302 CERTIFICATION

I, David A. Rosa, certify that:

1. I have reviewed this Annual Report on Form 10-K of Sunshine Heart, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 20, 2015

/S/ DAVID A. ROSA
David A. Rosa
Chief Executive Officer

EXHIBIT 31.2

SUNSHINE HEART, INC.
CFO SECTION 302 CERTIFICATION

I, Claudia Drayton, certify that:

1. I have reviewed this Annual Report on Form 10-K of Sunshine Heart, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 20, 2015

/S/ CLAUDIA DRAYTON
Claudia Drayton
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Sunshine Heart, Inc. (the ***"Company"***) on Form 10-K for the 12 months ended December 31, 2014 as filed with the Securities and Exchange Commission on the date hereof (the ***"Report"***), I, David A. Rosa, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 20, 2015

/S/ DAVID A. ROSA
David A. Rosa
Chief Executive Officer

EXHIBIT 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Sunshine Heart, Inc. (the ***"Company"***) on Form 10-K for the 12 months ended December 31, 2014 as filed with the Securities and Exchange Commission on the date hereof (the ***"Report"***), I, Claudia Drayton, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 20, 2015

/S/ CLAUDIA DRAYTON
Claudia Drayton
Chief Financial Officer