

The information in this preliminary prospectus supplement and the accompanying prospectus is not complete and may be changed. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell nor do they seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED APRIL 10, 2013

PRELIMINARY PROSPECTUS SUPPLEMENT
(To prospectus dated April 5, 2013)



Shares

SUNSHINE HEART, INC.

Common Stock

We are offering _____ shares of our common stock.

Our common stock is listed on the NASDAQ Capital Market (“Nasdaq”) under the trading symbol “SSH,” and Chess Depository Instruments (“CDIs”) representing beneficial ownership of our common stock are listed on the Australian Securities Exchange (the “ASX”) under the trading symbol “SHC.” On April 9, 2013, the last reported sale price of our common stock on Nasdaq was \$6.07 per share.

We are an “emerging growth company” under the U.S. federal securities laws and are subject to reduced public company reporting requirements. Investing in our common stock involves a high degree of risk. See “Risk Factors” beginning on page S-8 of this prospectus supplement for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.

	Per Share (1)	Total
Public offering price	\$	\$
Underwriting discount (1)	\$	\$
Proceeds, before expenses, to us	\$	\$

Neither the Securities and Exchange Commission (the “SEC”) nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

We have granted the underwriter an option for a period of 30 days after the date of this prospectus supplement to purchase up to an additional _____ shares of our common stock on the same terms and conditions set forth above solely to cover over-allotments, if any.

The underwriter expects to deliver the shares of our common stock on or about _____, 2013.

Sole Book-Running Manager

Canaccord Genuity

The date of this prospectus supplement is _____, 2013

TABLE OF CONTENTS

PROSPECTUS SUPPLEMENT

About This Prospectus Supplement	S-1
Special Note Regarding Forward-Looking Statements	S-1
Prospectus Supplement Summary	S-3
The Offering	S-7
Risk Factors	S-8
Price Range of Common Stock	S-27
Dividend Policy	S-27

Use of Proceeds	S-28
Capitalization	S-29
Dilution	S-30
Underwriting	S-31
Legal Matters	S-34
Experts	S-34
Where You Can Find More Information	S-34
Incorporation of Certain Documents by Reference	S-34

PROSPECTUS

About This Prospectus	1
Summary	2
Risk Factors	10
Forward-Looking Statements	10
Ratios of Earnings to Fixed Charges	11
Use of Proceeds	11
Description of Common Stock	11
Description of Preferred Stock	16
Description of Warrants	18
Description of Debt Securities	20
Legal Ownership of Securities	27
Plan of Distribution	30
Legal Matters	33
Experts	33
Incorporation by Reference	33
Where You Can Find More Information	34

S-i

[Table of Contents](#)

ABOUT THIS PROSPECTUS SUPPLEMENT

We are providing information to you about this offering in two parts. The first part consists of this prospectus supplement, which provides the specific details regarding this offering of shares of our common stock. The second part consists of the base prospectus dated April 5, 2013, included in our shelf registration statement on Form S-3 (No. 333-187273), which we are supplementing with the information contained in this prospectus supplement. Generally, when we refer to this “prospectus,” we are referring to both parts combined. Some of the information in the base prospectus may not necessarily apply to this offering.

This prospectus supplement describes the specific details regarding this offering, including the price, the number of shares of our common stock being offered, certain risks of investing in our common stock and other items. You should read this entire prospectus, together with the additional information described in the section of this prospectus entitled “Where You Can Find More Information,” carefully before making an investment decision.

You should rely only on the information contained or incorporated by reference in this prospectus. We have not, and the underwriter has not, authorized any other person to provide you with different or inconsistent information. If anyone provides you with different or inconsistent information, you should not rely on it. For further information, see the section of this prospectus entitled “Where You Can Find More Information.” We and the underwriter are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted.

This prospectus supplement, the accompanying prospectus and the documents incorporated by reference are accurate only as of their respective dates, regardless of the time of delivery of this prospectus supplement, the accompanying prospectus or the sale of any security. The information in this prospectus supplement supersedes any inconsistent information included or incorporated by reference in the accompanying prospectus. Our business, financial condition, results of operations and prospects may have changed since such dates.

Unless otherwise indicated, the terms “we,” “us,” “our Company,” “the Company” and “Sunshine Heart” refer to Sunshine Heart, Inc., a Delaware corporation, together with its wholly owned subsidiary.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

- anticipated results of financing activities;
- anticipated agreements with marketing partners;
- anticipated clinical trial timelines or results;

- anticipated timing of marketing and commercialization of our products;
- anticipated research and product development results;

S-1

[Table of Contents](#)

- projected regulatory timelines;
- descriptions of plans or objectives of management for future operations, products or services;
- forecasts of future economic performance;
- estimates regarding our capital requirements and our need for additional financing;
- anticipated ability to utilize the equity line of credit facility with Aspire Capital Fund, LLC, an Illinois limited liability company (“Aspire”), pursuant to that certain Common Stock Purchase Agreement dated January 15, 2013 (the “Aspire Stock Purchase Agreement”); and
- descriptions or assumptions underlying or relating to any of the above items.

Please also see the discussions of risks and uncertainties under the heading “Risk Factors” beginning on page S-8 of this prospectus supplement and elsewhere herein.

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

S-2

[Table of Contents](#)

PROSPECTUS SUPPLEMENT SUMMARY

The following summary highlights selected information contained elsewhere in this prospectus and the documents incorporated herein by reference. This summary does not contain all the information you should consider before investing in shares of our common stock. Before deciding to invest in shares of our common stock, you should read this entire prospectus and the documents incorporated herein by reference, including the discussion of “Risk Factors” beginning on page S-8 of this prospectus supplement and our consolidated financial statements and the related notes incorporated herein by reference from our annual report on Form 10-K for the period ended December 31, 2012. Moreover, the information contained in this prospectus includes “forward-looking statements,” which are based on current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments actually affecting us will be those anticipated. Please see the previous page of this prospectus for cautionary information regarding forward-looking statements.

Overview

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 trial in the first half of 2011. In November 2011, we announced the preliminary results of the six-month follow-up period for the feasibility study and we submitted the clinical data to the United States Food and Drug Administration (the “FDA”). In March 2012, the FDA notified us that it completed its review of the C-Pulse System feasibility trial data, concluded we met the applicable agency requirements, and indicated that we can move forward with an investigational device exemption (“IDE”) application. In October 2012, we announced the results of the 12-month follow-up period for the feasibility study. In November 2012, the FDA provided us with unconditional approval to initiate a pivotal trial. We currently anticipate that enrollment of our pivotal trial will begin during the first half of 2013. We expect to complete enrollment of our pivotal trial by the end of 2015 and do not anticipate marketing our system in the United States before 2017.

We obtained CE Mark approval for the C-Pulse System in July 2012 and have taken initial steps to evaluate the market potential for our system in targeted countries that accept the CE Mark in anticipation of commencing commercial sales. In order to gain additional clinical data and support reimbursement in Europe, we also expect to initiate a post-market trial in Europe that will evaluate endpoints similar to those for our U.S. pivotal trial. We do not expect to receive reimbursement in Germany before 2014, if at all, and cannot be certain of when we will receive reimbursement in other targeted countries.

We incurred net losses of \$14.1 million and \$16.2 million in the years ended December 31, 2012 and 2011, respectively. Historically, we have generated our revenue solely from sales of the C-Pulse System to hospitals and clinics pursuant to research arrangements and with appropriate regulatory approvals for sales in conjunction with our feasibility clinical trial. We expect to continue to incur significant net losses as we continue to conduct clinical trials 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 heart's ability to pump blood to the various organs of the body. Patients with heart failure commonly experience shortness of breath, fatigue, difficulty

[Table of Contents](#)

exercising and swelling of the legs. The heart becomes weak or stiff and enlarges over time, making it harder to pump the blood needed for the body to function properly. The severity of heart failure depends on how well a person's heart is able to pump blood throughout the body. A common measure of heart failure severity is the New York Heart Association ("NYHA") Class guideline. Patients are classified in Classes I through IV based on their symptoms and functional limitations. Classes I and II include mild heart failure patients, Class III includes moderate heart failure patients, and Class IV includes severe heart failure patients.

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

Treatment alternatives currently available for Class III heart failure patients in the United States consist primarily of pharmacological therapies and pacing devices that are designed to address heart rhythm issues. Although these treatments may provide symptomatic relief and prolong the life of patients, they do not often halt the progression of congestive heart failure. Circulatory assist devices, specifically left ventricular assist devices ("LVADs") have been used to treat Class IV patients in the United States, and one product received FDA approval in the United States for Class IIIb patients. However, this device is not reimbursed by the Centers for Medicare and Medicaid Services for Class IIIb patients. These devices are designed to take over some or all of the pumping function of the heart by mechanically pumping blood into the aorta. Although such products are effective in increasing blood flow, these devices are designed to be in contact with the patient's bloodstream, increasing the risk of adverse events, including thrombosis, bleeding and neurologic events.

Our Strategy

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

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

Our System

The C-Pulse System utilizes the scientific principles of intra-aortic balloon counter-pulsation applied in an extra-aortic approach to assist the left ventricle by reducing the workload required to pump blood throughout the body, while increasing blood flow to the coronary arteries. Combined, these potential benefits may help sustain the patient's current condition or, in some cases, reverse the heart failure process, thereby potentially preventing the need for later-stage heart failure devices, such as LVADs, artificial hearts or transplants. It may also provide relief from the symptoms of Class III and ambulatory Class IV heart failure and improve quality of life and cardiac function. Based on the results from our feasibility trial, we also believe that some patients treated with our C-Pulse System will be able to stop using the device due to sustained improvement in their conditions as a result of the therapy.

Once implanted, the C-Pulse cuff is positioned on the outside of the patient's ascending aorta above the aortic valve. An electrocardiogram sensing lead is then attached to the heart to determine timing for cuff inflation and deflation in synchronization with the heartbeat. As the heart fills with blood, the C-Pulse cuff inflates to push blood from the aorta to the rest of the body and to the heart muscle via the coronary arteries. Just before the heart pumps, the C-Pulse cuff deflates to reduce the heart's workload through pressure changes, allowing the heart to pump with less effort. The C-Pulse cuff and electrical leads are connected to a single line that is run through the

[Table of Contents](#)

abdominal wall to connect to a power driver outside the body. The system's single unit driver and battery source are contained inside a carrying bag.

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

The C-Pulse System distinguishes itself from other mechanical heart failure therapies in two important respects, which we believe differentiate our system from other products addressing moderate to severe heart failure patients. First, the C-Pulse System is placed outside a patient's vascular system. The C-Pulse cuff is placed outside a patient's ascending aorta and assists the heart's normal pumping function, rather than being inserted into the vascular system and replacing heart function in a manner similar to other devices such as LVADs. Because the C-Pulse System remains outside the vascular system, there is potentially less risk of complications such as blood clots, stroke and thrombosis in comparison to other mechanical devices that reside or function inside the vascular system. Because it rests outside the vasculature, it also does not require blood thinning agents that are necessary for patients with devices that are in contact with the bloodstream. As with any implanted device, patients using our system have a risk of infection from the implantation procedure, and any untreated sternal infection arising from the implantation procedure or otherwise could result in erosion of the aortic wall or an aortic rupture in connection with using our system. Because our system has been implanted in a limited number of patients to date, the potential competitive disadvantages and risks associated with the use of our system are not fully known at this time.

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 allows patients intervals of freedom to perform certain activities such as showering. Patients are not required to visit a medical facility when turning our device on or off or using the device. However, 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

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

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

S-5

[Table of Contents](#)

Corporate Information

Sunshine Heart, Inc. was incorporated in Delaware on August 22, 2002. We began operating our business in November 1999 through Sunshine Heart Company Pty Ltd., which currently is a wholly owned Australian subsidiary of Sunshine Heart, Inc. Since September 2004, CDIs representing beneficial ownership of our common stock have been traded on the ASX under the symbol "SHC." Historically, each CDI represented one share of our common stock. In connection with the 1-for-200 reverse stock split we effected on January 27, 2012, we changed this ratio so that each CDI represents 1/200th of a share of our common stock.

On September 30, 2011, we filed a Form 10 registration statement with the SEC, which was declared effective on February 14, 2012. The Form 10 registered our common stock under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Our common stock began trading on 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 is expected to occur at the close of trading on May 6, 2013.

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

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

- a requirement to have only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations disclosure; and
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002.

We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We will cease to be an emerging growth company if we have more than \$1 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 burdens. 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.

Please see “Risk Factors” beginning on page S-8 of this prospectus supplement and in “Item 1A. Risk Factors” in our annual report on Form 10-K for the year ended December 31, 2012, and the other information contained or incorporated by reference in this prospectus for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.

[Table of Contents](#)

THE OFFERING

Issuer	Sunshine Heart, Inc.
Common stock offered	_____ shares of common stock. We have also granted the underwriter an option to purchase up to _____ additional shares of common stock solely to cover over-allotments, if any, within 30 days after the date of this prospectus supplement.
Offering price	\$ _____ per share.
Exchange listing	Our common stock currently trades on Nasdaq under the symbol “SSH.” CDIs representing beneficial ownership of our common stock also currently trade on the ASX under the symbol “SHC.”
Use of proceeds	We will receive net proceeds from this offering of approximately \$ _____ million, after deducting underwriting discounts and estimated offering expenses payable by us. We currently intend to use the net proceeds from the sale of shares of our common stock in this offering for general corporate purposes, including our ongoing clinical trial and product development activities. We will retain broad discretion over the use of the net proceeds from this offering. See “Use of Proceeds” on page S-28.
Risk factors	The shares of common stock offered hereby involve a high degree of risk. See “Risk Factors” beginning on page S-8.
Transfer agent	American Stock Transfer & Trust Company, LLC.

Except as otherwise noted, all information in this prospectus assumes no exercise of the underwriter’s option to purchase additional shares from us. The total number of shares of common stock outstanding after this offering is based on 9,509,867 shares of our common stock outstanding as of April 9, 2013, and excludes:

- 1,113,244 shares of our common stock issuable upon the exercise of stock options outstanding as of March 31, 2013, with a weighted-average exercise price of \$9.31 per share;
- 1,663,253 shares of our common stock issuable upon the exercise of warrants outstanding as of March 31, 2013, with a weighted-average exercise price of \$7.75 per share.

To the extent that shares represented by the stock options and warrants excluded are issued, there will be further dilution to new investors.

[Table of Contents](#)

RISK FACTORS

An investment in shares of our common stock involves a high degree of risk. In addition to the following risk factors, you should carefully consider the risks, uncertainties and assumptions described in “Item 1A. Risk Factors” in our annual report on Form 10-K for the year ended December 31, 2012, and in other documents that we subsequently file with the SEC that update, supplement or supersede such information, which documents are incorporated by reference into this prospectus. See “Where You Can Find More Information.” Additional risks not currently known to us or which we consider immaterial based on information currently available to us may also materially adversely affect us. If any of the events anticipated by the risks described occur, our business, results of operations and financial condition could be adversely affected, which could result in a decline in the market price of our common stock, causing you to lose all or part of your investment.

Risks Relating to Our Business

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

We are an early-stage company with a history of incurring net losses. We have incurred net losses since our inception, including net losses of \$14.1 million and \$16.2 million for the years ended December 31, 2012 and 2011, respectively. As of December 31, 2012, our accumulated deficit was \$79.3 million. We do not have any products that have been approved for marketing in the United States, we have not established any sales capability outside of the United States, and we continue to incur research and development and general and administrative expenses related to our operations. We expect to continue to incur significant and increasing operating losses for the foreseeable future as we incur costs associated with the conduct of clinical trials, continue our research and development programs, seek regulatory approvals, expand our sales and marketing capabilities, increase manufacturing of our system and comply with the requirements related to being a U.S. public company listed on 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

trials, obtaining regulatory approvals, manufacturing products and marketing and selling commercial products. There can be no assurance that we will succeed in these activities, and we may never generate revenues sufficient to achieve profitability. If we do achieve profitability, we may not be able to sustain it.

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, 2012 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 feasibility study. 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, 2012 expresses substantial doubt about our ability to continue as a going concern. After completion of this offering, we expect to continue to incur significant and increasing operating losses for the foreseeable future as we incur costs associated with the conduct of clinical trials, continue our research and development programs, seek regulatory approvals, expand our sales and marketing capabilities, increase manufacturing of our system and comply with the requirements related to being a U.S. public company listed on Nasdaq. Substantial additional funding will be needed after the completion of this offering 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.

S-8

[Table of Contents](#)

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

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

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

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

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

- we may not be able to attract and build an effective marketing or sales force;
- the cost of establishing, training and providing regulatory oversight for a marketing or sales force may be substantial; and
- there are significant legal and regulatory risks in medical device marketing and sales that we have never faced, and any failure to comply with applicable legal and regulatory requirements for sales, marketing and distribution could result in an enforcement action by the FDA, European regulators or other authorities that could jeopardize our ability to market the system or could subject us to substantial liability.

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

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

- costs of complying with varying regulatory requirements and potential, unexpected changes to those requirements;
- fluctuations in and management of currency exchange rates;
- 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;

S-9

- potentially adverse tax consequences, including the complexities of foreign value added tax systems and restrictions on the repatriation of earnings;
- government-imposed pricing controls on sales of our system;
- longer payment cycles and difficulties in collecting accounts receivable;
- difficulties in managing and staffing international operations;
- the burdens of complying with a wide variety of non-U.S. laws and legal standards;
- increased financial accounting and reporting burdens and complexities; and
- reduced or varied protection for intellectual property rights in some countries.

The occurrence of any one of these risks could negatively affect our international operations. Additionally, operating in international markets also requires significant management attention and financial resources. We cannot be certain that our operations in other countries will produce desired levels of revenues or profitability.

We depend on a limited number of manufacturers and suppliers of various critical components for our C-Pulse System. The loss of any of these manufacturer or supplier relationships could delay future clinical trials or prevent or delay commercialization of our C-Pulse System.

We rely entirely on third parties to manufacture our C-Pulse System and to supply us with all of the critical components of our C-Pulse System, including the balloon, driver, cuff and interface lead. We primarily purchase our components and products on a purchase order basis and do not “second source” any components of our system. If one or more of the suppliers of the components used in our system were unable or unwilling to meet our demand for such components or faced financial or business difficulties in general, or if the components or finished products provided by any of our suppliers do not meet quality and other specifications, clinical trials or commercialization of our system could be delayed and our expenses could increase. Moreover, if any of the suppliers were unable or unwilling to perform, we would be required to find alternative sources for the components provided by such supplier, and there can be no assurance that we would be able to find a replacement supplier on a timely basis, or at all. In particular, the balloon used in our system is highly specialized and is currently solely available from a single supplier. If the manufacturer of the balloon were unable or unwilling to supply this component for any reason, we would have to locate and qualify another supplier and such supplier and its balloon product would have to be qualified under FDA and European regulations and may require FDA and European submissions, such as Premarket Approval (“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 our C-Pulse System could be interrupted for an extended period of time and become significantly more expensive. This could delay completion of future clinical trials or commercialization of our C-Pulse System and adversely affect our 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 our C-Pulse System in the quantities that we anticipate will be required to meet market demand, we will need our manufacturers to increase, or scale-up, the production process by a significant factor over the current level of production. There are technical challenges to scaling-up manufacturing capacity and developing commercial-scale manufacturing facilities that may require the investment of substantial additional funds by our manufacturers and hiring and retaining additional management and technical personnel who have the necessary manufacturing experience. If our manufacturers are unable to do so, we may not be able to meet the requirements for

[Table of Contents](#)

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 our C-Pulse System following commercialization. If we develop and obtain regulatory approval for our system and are unable to obtain a sufficient supply of our system, our revenue, business, 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 develop, conduct clinical studies, obtain reimbursement and regulatory approvals for the products we develop;
- the expenses we incur for the research and development required to maintain and improve our system;
- the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation;
- the expenses we incur in connection with commercialization activities, including marketing, sales and distribution;
- our sales strategy and whether the revenues from sales of our system will be sufficient to offset our expenses;
- the costs to attract and retain personnel with the skills required for effective operations; and
- the costs associated with being a public company.

Our budgeted expense levels are based in part on our expectations concerning our ability to receive additional financing, as well as future revenues from sales of our C-Pulse System. We may be unable to reduce our expenditures in a timely manner to compensate for any unexpected shortfall in 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.

S-11

[Table of Contents](#)

We compete against many companies, some of which have longer operating histories, more established products and greater resources than we do, which may prevent us from achieving further market penetration or improving operating results.

Competition from medical device companies and medical device divisions of health care companies, as well as pharmaceutical companies and gene- and cell-based therapies is intense and is expected to increase. Our system will compete against therapies, including pharmacological therapies, as well as other medical device competitors that treat or may treat in the future Class III or ambulatory Class IV heart failure patients, including AbioMed, Inc., Berlin Heart GmbH, CardioKinetix, Inc., CircuLite, Inc., HeartWare International Inc., Jarvik Heart, Inc., MicroMed Technology, Inc., SynCardia Systems, Inc., Terumo Heart, Inc. and Thoratec Corporation, as well as a range of other specialized medical device companies with devices at varying stages of development. Some of these competitors have significantly greater financial and human resources than we do and have established reputations, as well as worldwide distribution channels and sales and marketing capabilities that are significantly larger and more established than ours. Additional competitors may enter the market, and we are likely to compete with new companies in the future. We also face competition from other medical therapies which may focus on our target market as well as competition from manufacturers of pharmaceutical and other devices that have not yet been developed. Competition from these companies could harm our business. In addition, because our system has been implanted in a limited number of patients to date, all of the material risks and potential competitive disadvantages of our system are not necessarily known at this time.

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

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

The competition for qualified personnel is particularly intense in our industry. If we are unable to retain or hire key personnel, we may not be able to sustain or grow our business.

Our ability to operate successfully and manage our potential future growth depends significantly upon our ability to attract, retain and motivate highly skilled and qualified research, technical, clinical, regulatory, sales, marketing, managerial and financial personnel. We face intense competition for such personnel, and we may not be able to attract, retain and motivate these individuals. We compete for talent with numerous companies, as well as universities and nonprofit research organizations. Our future success also depends on the personal efforts and abilities of the principal members of our senior management and scientific staff to provide strategic direction, manage our operations and maintain a cohesive and stable environment. We do not maintain key man life insurance

S-12

[Table of Contents](#)

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 \$10.0 million aggregate limit. However, if there are product liability claims against us, our insurance may be insufficient to cover the expense of defending against such claims, or may be insufficient to pay or settle such claims. Furthermore, we may be unable to obtain adequate product liability insurance coverage for commercial sales of any of our approved products. If such insurance is insufficient to protect us, our 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 trial participants, significant costs of related litigation, loss of revenue or the inability to commercialize the C-Pulse System.

Risks Relating to Regulation

We do not have FDA approval for our system and our success will depend heavily on the success of our pivotal trials for our C-Pulse System. Any failure or significant delay in successfully completing our pivotal trial 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 trial, we submitted the trial's clinical data to the FDA in November 2011. In November 2012, the FDA provided us with unconditional approval to initiate a pivotal trial. We currently anticipate that enrollment of our pivotal trial will begin during the first half of 2013. Completion of the pivotal trial could be delayed, and adverse events during the trial could cause us to modify the existing design, repeat or terminate the trial. If the trial is delayed, if it must be repeated or if it is terminated, our costs associated with the trial will increase, and it will take us longer to obtain regulatory approvals and commercialize the C-Pulse System, if we are able to do so at all. Our pivotal trial also may be suspended or

[Table of Contents](#)

terminated at any time by regulatory authorities or by us. FDA scrutiny of IDE applications has intensified in recent years, increasing the risk of delay or failure.

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

In addition to successfully completing our U.S. pivotal trial, we will need to receive approval from regulatory agencies in each country outside the 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 trial, or experience significant delays in the trial, or if the results of the trial do not meet its safety and efficacy endpoints, our ability to obtain regulatory approval to commercialize our system and to generate revenues will be significantly harmed.

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

Even if we obtain foreign regulatory approvals, we will need to obtain FDA approval to commercialize our system in the United States, which will require us to conduct clinical trials in the United States and to complete those trials successfully. If we fail to obtain approval from the FDA, we will not be able to market and sell our system in the United States, which we believe is the largest potential market for our C-Pulse System. We do not currently have the

necessary regulatory approvals to commercialize our C-Pulse System in the United States. We can offer no assurance that our clinical trials will be successful or that we will ever obtain FDA approval of the C-Pulse System or any future products.

In order to obtain FDA approval for our C-Pulse System, we will be required to receive a PMA from the FDA. A PMA must be supported by data from pre-clinical and clinical trials to demonstrate safety and efficacy. A clinical trial will be required to support an application for a PMA, and we received FDA approval of our IDE application in November 2012 that will allow us to commence a clinical trial in the United States. We intend to commence our U.S. pivotal trial in the first half of 2013, but there can be no assurance that our U.S. pivotal trial will begin or be completed on schedule or at all. Even if completed, we do not know if this trial will meet its objectives or end-points to show the safety and efficacy of our system so as to support an application for a PMA.

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

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

S-14

[Table of Contents](#)

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

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

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

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

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

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

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

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

If our pivotal trial is delayed, it will take us longer to ultimately commercialize a product or the delay could result in our being unable to do so. Our development costs will also increase if we have material delays in our

[Table of Contents](#)

pivotal trial or if we need to perform more or larger clinical trials than planned. Moreover, there can be no assurance that we will be able to successfully complete, or achieve the desired clinical end-points from, our pivotal trial at all, which could prevent us from receiving regulatory approval for the C-Pulse System altogether. Any of the foregoing could harm our 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 payors, there may be no commercially viable markets for our system or the markets may be much smaller than expected.

The availability and levels of reimbursement by governmental and other third-party payors significantly affect the market for our system. Reimbursement by third-party payors in the United States typically is based on the device's perceived benefit and whether it is deemed medically reasonable and necessary. Reimbursement levels of third-party payors in the United States are also based on established payment formulas that take into account part or all of the cost associated with these devices and the related procedures performed. We cannot assure you the level of reimbursement we might obtain in the United States, if any, for our system. If we do not obtain adequate levels of reimbursement for our system by third-party payors in the United States, which we believe is the largest potential market for our system, our 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 trials, that compares the cost-effectiveness of our system to other available therapies. We may not obtain international reimbursement or pricing approvals in a timely manner, if at all. Our failure to receive international reimbursement or pricing approvals would significantly negatively impact market acceptance of our system in international markets.

We believe that future reimbursement may be subject to increased restrictions both in the United States and in international markets. Future legislation, regulation or reimbursement policies of third-party payors may adversely affect the demand for the C-Pulse System and limit our ability to sell the C-Pulse System or any future products on a profitable basis. In addition, third-party payors continually attempt to contain or reduce the costs of health care by challenging the prices charged for health care products and services. If reimbursement for our system is unavailable in any market or limited in scope or amount, or if pricing is set at unsatisfactory levels, market acceptance of our system would be significantly impaired and our future revenues, if any, would be significantly harmed.

We depend on clinical investigators and clinical sites to enroll patients in our clinical trials, and on other third parties to manage the trials and to perform related data collection and analysis, and, as a result, we may face costs and delays that are outside of our control.

We have and plan to continue to rely on clinical investigators and clinical sites to enroll patients in our clinical trials, including our planned U.S. pivotal trial, and other third parties to manage the related data collection and analysis. While we are obligated by regulation to monitor the sites for compliance, we have limited oversight over the clinical investigators and sites and cannot control the amount and timing of resources that clinical sites may devote to our clinical trials. If these clinical investigators and clinical sites fail to enroll a sufficient number of patients in our clinical trials, to ensure compliance by patients with clinical protocols or comply with regulatory requirements, we will be unable to complete these trials, which could prevent us from obtaining regulatory approvals for our system. Our agreements with clinical investigators and clinical trial sites for clinical testing place substantial responsibilities on these parties and, if these parties fail to perform as expected, our trials could be delayed or terminated. If sites fail to meet FDA requirements in conducting the trials, we can be held responsible. If these clinical investigators, clinical sites or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, or the clinical data may be rejected by the FDA, our costs will increase and we may be unable to obtain regulatory approval for, or successfully commercialize, our system.

[Table of Contents](#)

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

Even if our system receives marketing approval, product approvals by the FDA can be withdrawn due to failure to comply with regulatory standards. We rely entirely on third parties to manufacture our C-Pulse System. We are required to demonstrate and maintain compliance with applicable Quality System Regulations (“QSR”) by controlling our suppliers and requiring that they manufacture in conformance with the QSR. A contractor that manufactures a completed device for us is directly subject to the QSR but we also are held responsible by the FDA. A contractor that manufactures a component is not subject to the QSR. In those cases we are responsible to the FDA for requiring by contract that the component meet QSR standards. The QSR is a complex regulatory scheme that covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our system. The FDA enforces the QSR through periodic unannounced inspections. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA. A failure by our manufacturers to comply with the QSR or to take satisfactory corrective action in response to an adverse QSR inspection could cause a significant delay in our ability to have our system manufactured and to complete our clinical trials and could significantly increase our costs, which would harm our financial results and our prospects. In addition, suppliers of components of, and products used to manufacture, our system must also comply with FDA and foreign regulatory requirements, which often require significant time, money and record-keeping and quality assurance efforts and subject us and our suppliers to potential regulatory inspections and stoppages. We are also subject to the international standard ISO 13485 in other jurisdictions. Like the QSR, ISO 13485 holds us responsible under the Purchasing Controls section for obtaining compliance with the standard by all of our suppliers.

We plan to operate in multiple regulatory environments that require costly and time consuming approvals.

Even if we obtain regulatory approvals to commercialize the C-Pulse System or any other product that we may develop 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.

The C-Pulse System may never achieve market acceptance even if we obtain regulatory approvals.

Even if we obtain regulatory approvals to commercialize the C-Pulse System or any other product that we may develop, our products may not gain market acceptance among physicians, patients, third-party health care payors or the medical community. The degree of market acceptance of any of the devices that we may develop will depend on a number of factors, including:

- the perceived effectiveness and price of the product;
- the prevalence and severity of any side effects;
- potential advantages over alternative treatments;
- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

S-17

[Table of Contents](#)

If our C-Pulse System, or any other product that we may develop, is approved but does not achieve an adequate level of acceptance by physicians, patients, third-party health care payors and the medical community, we may not generate product revenue and we may not become profitable or be able to sustain profitability.

We may be subject, directly or indirectly, to U.S. federal and state health care fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to, or have not fully complied with such laws, we could face substantial penalties.

If we are successful in achieving regulatory approval to market our C-Pulse System, our operations will be directly, or indirectly through our customers and health care professionals, subject to various U.S. federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, federal False Claims Act, and federal Foreign Corrupt Practices Act (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 a False Claim Act action. The Patient Protection and Affordable Care Act, enacted in 2010 (the “Patient Protection and Affordable Care Act”), includes provisions expanding the ability of certain relators to bring actions that would have been previously dismissed under prior law. When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. The Deficit Reduction Act of 2005 encouraged states to enact or modify their state false claims act to be at least as effective as the federal False Claims Act by granting states a portion of any federal Medicaid funds recovered through Medicaid-related actions. Most states have enacted state false claims laws, and many of those states included laws with *qui tam* provisions. States have until March 31, 2013 to enact or amend their false claims laws modeled after the federal False Claims Act for review and approval to receive a greater portion of any recovery.

The Patient Protection and Affordable Care Act includes provisions known as the Physician Payments Sunshine Act, which requires manufacturers of drugs, biologics, devices and medical supplies covered under Medicare and Medicaid starting in 2012 to record any transfers of value to physicians and teaching hospitals beginning in August 2013 and to report to the Centers for Medicare and Medicaid Services starting in 2014 for subsequent public disclosure. Manufacturers must also disclose investment interests held by physicians and their family members. Failure to submit the required information may result in civil monetary penalties of up to \$1.0 million per year for knowing violations and may result in liability under other federal laws or regulations. Similar reporting requirements have also been enacted on the state level in the United States, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with health care professionals. In addition, some states such as Massachusetts and Vermont impose an

[Table of Contents](#)

outright ban on certain gifts to physicians. If we receive FDA clearance to market our system in the United States, these laws could affect our promotional activities by limiting the kinds of interactions we could have with hospitals, physicians or other potential purchasers or users of our system. Both the disclosure laws and gift bans will impose administrative, cost and compliance burdens on us.

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

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

The expanded regulations under the Health Information Technology for Economic and Clinical Health Act of 2009 have increased the possibility that device manufacturers might be considered business associates in the future, exposing us to penalties for potential breaches of the Health Insurance Portability and Accountability Act of 1996 Security Regulation.

Risks Relating to our Intellectual Property

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

Our success depends in part on our ability to obtain and maintain protection in the United States and other countries of the intellectual property relating to or incorporated into our technology and system. As of January 22, 2013, we owned 12 issued patents in the United States and 9 patent applications in the United States, as well as 37 issued patents and 21 patent applications in foreign jurisdictions. We estimate that most of 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 trials or delay or abandon commercialization of our system;

[Table of Contents](#)

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

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

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

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

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

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

In addition, some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications or that we were the first to invent the technology. Another party may have filed, and may in the future file, patent applications covering our system or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions.

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

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

S-20

[Table of Contents](#)

Risks Related to Ownership of our Common Stock and this Offering

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

Our common stock has been listed for trading on Nasdaq only since February 16, 2012 and has experienced limited trading volume. On February 5, 2013, we received conditional approval from the ASX to delist from the official list of the ASX. The delisting is expected to occur at the close of trading on May 6, 2013. The average daily trading volume in our common stock on Nasdaq for the three-month period ended March 31, 2013 was approximately 61,000 shares. The reported average daily trading volume in our CDIs on the ASX for the three-month period ended March 31, 2013, was approximately 937,000 CDIs (equivalent to approximately 5,000 shares of common stock). There can be no assurance that an active public market for our shares will continue to develop in the United States. If an active trading market does not continue to develop in the United States, the market price and liquidity of our common stock would be adversely affected.

The price of our common stock may fluctuate significantly.

Our common stock has been traded on Nasdaq since February 16, 2012, and CDIs representing beneficial ownership of our common stock have been listed on the ASX since 2004. The price of our common stock has been, and is likely to continue to be, volatile, which means that it could decline substantially within a short period of time. For example, the price per share of our common stock traded on Nasdaq ranged from \$2.50 to \$22.90 from February 16, 2012 to June 30, 2012, and from \$3.01 to \$13.30 from July 1, 2012 to March 31, 2013. Our CDI closing price on the ASX ranged from A\$0.020 (equivalent to approximately \$4.09 per share using a conversion rate of A\$1 to \$1.0231) to A\$0.055 (equivalent to approximately \$11.25 per share using a conversion rate of A\$1 to \$1.0231) for the six months ended June 30, 2012, and from A\$0.021 (equivalent to approximately \$4.37 per share using a conversion rate of A\$1 to \$1.0416) to A\$0.058 (equivalent to approximately \$12.08 per share using a conversion rate of A\$1 to \$1.0416) from July 1, 2012 to March 31, 2013. The price of our common stock could fluctuate significantly for many reasons, including the following:

- future announcements concerning us or our competitors;
- regulatory developments, disclosure regarding completed, ongoing or future clinical trials and enforcement actions bearing on advertising, marketing or sales;
- reports and recommendations of analysts and whether or not we meet the milestones and metrics set forth in such reports;
- introduction of new products;
- acquisition or loss of significant manufacturers, distributors or suppliers or an inability to obtain sufficient quantities of materials needed to manufacture our system;
- quarterly variations in operating results, which we have experienced in the past and expect to experience in the future;
- business acquisitions or divestitures;
- changes in governmental or third-party reimbursement practices;
- potential temporary downward pressure on the market price of our common stock that may result from the ASX delisting, related to the inflow of shares on Nasdaq resulting from the transmutation of CDIs to common shares, as well as from the forced liquidation of CDIs at the end of the delisting period;
- 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

[Table of Contents](#)

market price of our common stock. The market price of our common stock could decline below its current price and the market price of our shares may fluctuate significantly in the future. These fluctuations may be unrelated to our performance.

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

As of March 31, 2013, our executive officers and directors and entities affiliated with them beneficially owned, in the aggregate (including options or warrants exercisable currently or within 60 days of March 31, 2013), approximately 36.6% of our outstanding common stock. Our executive officers, directors and affiliated entities, if acting together, would be able to control all matters requiring approval by our stockholders, including the election of directors and the approval of mergers, financings or other significant corporate transactions. The concentration of ownership of our common stock may delay, prevent or deter a change of control of our Company, could deprive our stockholders and CDI holders of an opportunity to receive a premium for their common stock and CDIs as part of a sale of our Company and may affect the market price of our common stock and CDIs. This significant concentration of stock ownership may adversely affect the trading price of our common stock and CDIs due to investors' perception that conflicts of interest may exist or arise.

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

As of December 31, 2012, we had U.S. net operating loss ("NOL") carryforwards of approximately \$26.6 million for U.S. income tax purposes, which expire from 2022 through 2032. To the extent these NOL carryforwards are available, we intend to use them to reduce any corporate income tax liability associated with our operations 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, including due to this offering or due to our transaction with Aspire, could put limitations on the availability of our NOL carryforwards. In addition, our ability to utilize the current NOL carryforwards might be further limited by future issuances of our common stock.

As of December 31, 2012, we had tax losses in the Commonwealth of Australia of approximately \$55.5 million. Continuing utilization of carry forward tax losses in Australia may also be affected by the issuance of our common stock in this offering and in the future. This is because one test for carrying forward tax losses in Australia from year to year requires continuity of ultimate ownership (subject to the relevant tests in Australian tax law) of more than 50% between the loss year and the income year in which the loss is claimed.

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

We may be subject to arbitrage risks.

While we are delisting from the ASX on May 6, 2013, through such date investors may seek to profit by exploiting the difference, if any, between the price of our CDIs on the ASX and the price of shares of our common stock on Nasdaq. Such arbitrage activities could cause our share price in the market with the higher value to decrease to the price set by the market with the lower value and could also lead to significant volatility in the price of our common stock.

We do not intend to pay cash dividends on our common stock in the foreseeable future.

We have never declared or paid any cash dividends on our common stock, and we currently do not anticipate paying any cash dividends in the foreseeable future. We intend to retain any earnings to finance the development and expansion of our products and business. Accordingly, our stockholders and CDI holders will not realize a return on their investment unless the trading price of our common stock and CDIs appreciates.

[Table of Contents](#)

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

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

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

existing or potential material weaknesses in those controls.

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

We continue to evaluate our existing internal controls over financial reporting against the standards adopted by the Public Company Accounting Oversight Board. During the course of our ongoing evaluation of the internal controls, we may identify areas requiring improvement, and may have to design enhanced processes and controls to address issues identified through this review. Remediating any deficiencies, significant deficiencies or material weaknesses that we or our independent registered public accounting firm may identify may require us to incur significant costs and expend significant time and management resources. We cannot assure you that any of the measures we implement to remedy any such deficiencies will effectively mitigate or remedy such deficiencies. The existence of one or more material weaknesses could affect the accuracy and timing of our financial reporting. Investors could lose confidence in our financial reports, and the value of our common stock and CDIs may be harmed, if our internal controls over financial reporting are found not to be effective by management or by an independent registered public accounting firm or if we make disclosure of existing or potential material weaknesses in those controls.

Our certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with the Company.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, 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 or stockholders.

S-23

[Table of Contents](#)

Our certificate of incorporation, bylaws and the DGCL may delay or deter a change of control transaction.

Certain provisions of our certificate of incorporation and bylaws may have the effect of deterring takeovers, such as those provisions authorizing our board of directors to issue, from time to time, any series of preferred stock and fix the designation, powers, preferences and rights of the shares of such series of preferred stock; prohibiting stockholders from acting by written consent in lieu of a meeting; requiring advance notice of stockholder intention to put forth director nominees or bring up other business at a stockholders’ meeting; prohibiting stockholders from calling a special meeting of stockholders; requiring a 66 2/3% majority stockholder approval in order for stockholders to amend certain provisions of our certificate of incorporation or bylaws or adopt new bylaws; providing that, subject to the rights of preferred shares, the directors will be divided into three classes and the number of directors is to be fixed exclusively by our board of directors; and providing that none of our directors may be removed without cause. Section 203 of the DGCL, from which we did not elect to opt out, provides that if a holder acquires 15% or more of our stock without prior approval of our board of directors, that holder will be subject to certain restrictions on its ability to acquire us within three years. These provisions may delay or deter a change of control of us, and could limit the price that investors might be willing to pay in the future for shares of our common stock.

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

Two of our eight directors reside outside of the United States, principally in Australia. A substantial portion of the assets of these directors also are located outside of the United States. Therefore, it may not be possible to effect service of process within the United States upon these persons in order to enforce judgments of U.S. courts against these persons based on the civil liability provisions of the U.S. federal securities laws. In addition, there is doubt as to the enforceability in Australia, in original actions or in actions to enforce judgments of U.S. courts, of claims predicated solely upon U.S. federal securities laws. This could make it more difficult or impossible for investors to litigate or recover damages from certain of our directors in securities litigation or other claims.

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

We are an “emerging growth company,” as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of SOX, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. The JOBS Act also permits emerging growth companies to take advantage of an extended transition period to comply with new or revised accounting standards applicable to U.S. public companies. We could be an emerging growth company for up to five years, although we could lose that status sooner if our revenues exceed \$1 billion, if we issue more than \$1.0 billion in non-convertible debt in a three-year period, or if the market value of our common stock held by non-affiliates exceeds \$700.0 million as of any June 30 before that time, in which case we would no longer be an emerging growth company as of the following December 31. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and CDIs and our stock price may decline or be more volatile.

As explained above, Section 102(b)(1) of the JOBS Act also provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended (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.

[Table of Contents](#)

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

Since 2004, CDIs representing beneficial ownership of our common stock have been traded on the ASX. On January 29, 2013, we announced our intention to delist from the official list of the ASX during the first half of the 2013 calendar year. On February 5, 2013, we received conditional approval from the ASX to delist from the official list of the ASX. The delisting is expected to occur at the close of trading on May 6, 2013. Until such date, we will be subject to the Listing Rules of the ASX, which regulate certain actions we can take, such as limiting the circumstances under which we may issue shares of our common stock or CDIs without stockholder approval and require us to disregard votes cast by certain stockholders potentially interested in matters to be voted on at annual or special meetings of stockholders when such stockholders are permitted to vote at the meeting in accordance with the DGCL and Nasdaq Listing Rules. Most other companies listed on Nasdaq are not subject to the additional regulatory requirements imposed by the ASX Listing Rules, which increase our operating costs relative to other Nasdaq-listed companies, may make it more difficult to effect certain corporate actions, and might make an investment in our common stock less attractive to potential purchasers.

The number of shares of common stock registered in this offering and registered for resale in connection with the Aspire Stock Purchase Agreement and upon exercise of our outstanding warrants, is significant in relation to our currently outstanding common stock and could cause downward pressure on the market price for our common stock.

The number of shares of common stock registered on our registration statement on Form S-3, sold in this offering and registered for resale in connection with the Aspire Stock Purchase Agreement and upon exercise of our outstanding warrants, is significant in relation to the number of shares of common stock currently outstanding. If any security holder, including purchasers in this offering or Aspire, determines to sell a substantial number of shares into the market at any given time, there may not be sufficient demand in the market to purchase the shares without a decline in the market price for our common stock. Moreover, continuous sales into the market of a number of shares in excess of the typical trading volume for our common stock, or even the availability of such a large number of shares, could depress the trading market for our common stock over an extended period of time.

Investors in this offering will pay a much higher price than the book value of our stock.

If you purchase shares of our common stock in this offering, you will incur immediate and substantial dilution of \$ per share, representing the difference between the amount per share paid by you in this offering and the net tangible book value per share of our common stock after giving effect to this offering at a public offering price of \$ per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. In the past, we issued certain stock options and warrants to purchase common stock at prices below the offering price. To the extent these outstanding stock options and warrants are ultimately exercised, you will incur further dilution. See the section entitled "Dilution" in this prospectus for a discussion of the dilution you will incur if you purchase shares of our common stock in this offering.

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

As of April 9, 2013, we had 9,509,867 shares of our 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 90,000,000 shares are available for future issuance, and 40,000,000 shares of authorized preferred stock,

[Table of Contents](#)

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 40,000,000 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.

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.

We will have broad discretion as to the use of the proceeds from this offering, and we may not use the proceeds effectively.

We cannot specify with certainty the particular uses of the net proceeds we will receive from this offering, and these uses may vary substantially from our current plans. Our management will have broad discretion in the application of the net proceeds. Accordingly, you will have to rely upon the judgment of our management with respect to the use of the proceeds. Our stockholders may not agree with the manner in which our management chooses to allocate and spend the net proceeds. Moreover, our management could use the net proceeds for corporate purposes that may not necessarily increase our market value or improve our results of operations. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may also invest the net proceeds from this offering in a manner that does not produce income or that loses value.

S-26

[Table of Contents](#)

PRICE RANGE OF COMMON STOCK

Commencing February 16, 2012, our shares of common stock began trading on Nasdaq under the symbol “SSH.” CDIs representing beneficial ownership of our common stock have also traded on the ASX under the symbol “SHC” since September 2004. On January 29, 2013, we announced our intention to delist from the official list of the ASX during the first half of the 2013 calendar year. On February 5, 2013, we received conditional approval from the ASX to delist from the official list of the ASX. The delisting is expected to occur upon the close of trading on May 6, 2013. 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 and as converted into Australian Dollars, and for our CDIs as reported on the ASX, in Australian Dollars and as converted into U.S. Dollars. All currency conversions are based on the prevailing Australian Dollar to the U.S. Dollar rate on the last day of each respective quarter.

Period	High (A\$)	Low (A\$)	High (US\$)	Low (US\$)
Nasdaq Capital Market				
Year Ended December 31, 2013				
Second Quarter (through April 9, 2013)	n/a	n/a	6.30	5.83
First Quarter	n/a	n/a	8.13	5.21
Year Ended December 31, 2012				
First Quarter (from February 16, 2012)	n/a	n/a	22.90	8.50
Second Quarter	n/a	n/a	8.85	2.50
Third Quarter	n/a	n/a	13.30	3.01
Fourth Quarter	n/a	n/a	8.54	6.08
ASX				
Year Ended December 31, 2011:				
First Quarter	9.00	6.00	9.40	6.20
Second Quarter	12.60	7.80	13.60	8.40
Third Quarter	11.00	7.00	10.80	6.80
Fourth Quarter	9.40	6.40	9.20	6.60

These quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions, and may not represent actual transactions.

On April 9, 2013, the last reported sale price of our common stock on Nasdaq was \$6.07 per share.

As of February 28, 2013, we had 44 holders of record of our common stock. One stockholder of record, CHESSE Depository Nominees Pty Ltd, held shares of our common stock on behalf of approximately 1,059 CDI holders.

DIVIDEND POLICY

We have never paid dividends to holders of our common stock and we do not anticipate paying any cash dividends in the foreseeable future as we intend to retain any earnings for use in our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon our results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

S-27

[Table of Contents](#)

USE OF PROCEEDS

We estimate the net proceeds to us from the sale of our common stock in this offering will be approximately \$, or \$ million if the underwriter fully exercises its over-allotment option, based on the public offering price of \$ per share, after deducting underwriting discounts and estimated offering expenses payable by us. We currently intend to use the net proceeds from the sale of shares of our common stock under this prospectus for general corporate purposes and our ongoing clinical trial and product development activities. We will retain broad discretion over the use of the net proceeds from this offering.

S-28

[Table of Contents](#)

CAPITALIZATION

The following table summarizes our cash and cash equivalents and our capitalization as of December 31, 2012, (i) on an actual basis, and (ii) on an as-adjusted basis to give effect to the sale by us of _____ shares of our common stock in this offering at a public offering price of \$ _____ per share, after deducting underwriting discounts and estimated offering expenses payable by us. The information presented below is based on our audited financial statements as of December 31, 2012.

This table should be read with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and related notes incorporated by reference in this prospectus.

	As of December 31, 2012	
	Actual	As Adjusted (unaudited)
	(in thousands except share data)	
Cash and cash equivalents	\$ 14,224	\$ _____
Stockholders’ equity:		
Preferred stock, \$0.0001 par value, 40,000,000 shares authorized; none issued and outstanding	—	—
Common stock, \$0.0001 par value, authorized 100,000,000 shares; issued and outstanding, actual, 9,282,724; issued and outstanding, as adjusted for this offering, _____ shares (1)	1	1
Additional paid-in capital	91,017	_____
Accumulated other comprehensive income:		
Foreign currency translation adjustment	1,185	1,185
Accumulated deficit	(79,254)	(79,254)
Total stockholders’ equity	12,949	_____
Total capitalization	\$ 12,949	\$ _____

- (1) The table and calculations above are based on the number of shares of common stock outstanding as of December 31, 2012, and exclude:
- 1,113,244 shares of our common stock issuable upon the exercise of stock options outstanding as of December 31, 2012, with a weighted-average exercise price of \$9.47 per share;
 - 1,663,253 shares of our common stock issuable upon the exercise of warrants outstanding as of December 31, 2012, with a weighted-average exercise price of \$7.75 per share; and
 - The _____ shares of common stock subject to the underwriter’s over-allotment option.

S-29

[Table of Contents](#)

DILUTION

As of December 31, 2012, our audited net tangible book value was approximately \$12.9 million, or \$1.39 per share based on 9,282,724 shares outstanding as of December 31, 2012. Our historical net tangible book value per share is calculated by subtracting our total liabilities, goodwill and intangible assets from our total assets and dividing this amount by the number of shares of our common stock outstanding on December 31, 2012.

Dilution per share to new investors in this offering represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the net tangible book value per share of our common stock after giving effect to this offering. After giving effect to the sale of _____ shares of our common stock in this offering at a public offering price of \$ _____ per share and deducting underwriting discounts and estimated offering expenses payable by us, our pro forma net tangible book value as of December 31, 2012 would have been approximately \$(_____) or \$(_____) per share of our common stock. This amount represents an immediate increase in net tangible book value of \$ _____ per share to our existing stockholders and an immediate dilution in net tangible book value of \$ _____ per share to purchasers of common stock in this offering without giving effect to the over-allotment option granted to the underwriter. Dilution per share to new investors is determined by subtracting pro forma net tangible book value per share after this offering from the public offering price per share paid by a new investor. The following table illustrates this per share dilution:

Public offering price per share of common stock		\$ _____
Historical net tangible book value per share as of December 31, 2012	\$ _____	
Increase per share attributable to new investors in this offering		
Pro forma net tangible book value per share as of December 31, 2012, after giving effect to this offering (1)		
Dilution per share to new investors in this offering		\$ _____

- (1) Based on net proceeds of \$ _____.

The above number of shares of our common stock outstanding excludes, as of December 31, 2012:

- 1,113,244 shares of our common stock issuable upon the exercise of stock options outstanding as of December 31, 2012, with a weighted-average exercise price of \$9.47 per share; and
- 1,663,253 shares of our common stock issuable upon the exercise of warrants outstanding as of December 31, 2012, with a weighted-average exercise price of \$7.75 per share.

To the extent that shares represented by the stock options and warrants excluded from the table above are issued, there will be further dilution to new investors.

S-30

UNDERWRITING

Subject to the terms and conditions of the underwriting agreement between us and Canaccord Genuity Inc., as the underwriter, we have agreed to sell to the underwriter, and the underwriter has agreed to purchase, the number of shares indicated in the following table:

Underwriter	Number of Shares
Canaccord Genuity Inc.	
Total	

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

The underwriter has advised us that it proposes to offer the shares of common stock directly to the public at the public offering price set forth on the cover page of this prospectus, and to selected dealers at the public offering price less a selling concession not in excess of \$ _____ per share. After the public offering of the shares, the underwriter may change the offering price and other selling terms.

Over-allotment Option

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

Discounts and Expenses

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

	Per Share	Total	
		Without Over-allotment Exercise	With Over-allotment Exercise
Public offering price	\$	\$	\$
Underwriting discounts paid by us			
Proceeds, before expenses, to us			

We estimate expenses payable by us in connection with the offering of common stock, other than the underwriting discounts referred to above, will be approximately \$ _____, which amount includes our agreement to reimburse the underwriter for certain expenses up to an aggregate amount of \$80,000.

Indemnification

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

Lock-up Agreements

We and our executive officers and directors have entered into lock-up agreements with the underwriter. Under these agreements, we and each of these persons may not, without the prior written approval of Canaccord Genuity Inc., subject to limited exceptions, offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock or enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of our common stock. These restrictions will be in effect for a period of 90 days after the date of this prospectus. At any time, the underwriter may in its sole discretion release all or some of the securities from these lock-up agreements.

Price Stabilization, Short Positions and Penalty Bids

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

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

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

Electronic Distribution

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

Other Relationships

The underwriter and its affiliates have provided in the past to us and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, the underwriter and its affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

S-32

[Table of Contents](#)

In association with our announced delisting from the ASX, the underwriter may be appointed as our Australian broker for a share sale facility. The share sale facility would be voluntary and would be established and administered by us. If the underwriter is retained for this service, we will pay the underwriter a management fee of \$15,000, a brokerage fee of 1.5% of the gross proceeds of the sale of shares pursuant to the facility and any out-of-pocket expenses reasonably incurred in the provision of the service, provided that such expenses may not exceed \$1,500 without our prior written approval.

European Economic Area

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

- (i) to any legal entity which is a “qualified investor” as defined in the Prospectus Directive;
- (ii) to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives of the underwriter for any such offer; or
- (iii) in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of securities shall require us or the underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

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

United Kingdom

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

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

S-33

LEGAL MATTERS

Honigman Miller Schwartz and Cohn LLP, Kalamazoo, Michigan, will issue an opinion about certain legal matters with respect to the securities. Jones Day will pass upon certain matters for the underwriter.

EXPERTS

The consolidated financial statements of Sunshine Heart, Inc. appearing in Sunshine Heart, Inc.'s Annual Report (Form 10-K) for the year ended December 31, 2012, have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 1 to the consolidated financial statements), incorporated by reference therein, and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-3 (No. 333-187273) under the Securities Act with respect to the common stock, preferred stock, warrants and debt securities offered by us in this offering. This prospectus does not contain all of the information set forth in the registration statement and the exhibits to the registration statement. For further information regarding our Company and the common stock offered by this prospectus, please refer to the registration statement and the exhibits filed as part of the registration statement.

In addition, we file periodic reports with the SEC, including quarterly reports and annual reports, which include our audited financial statements. The registration statement, including exhibits thereto, and all of our periodic reports may be inspected without charge at the Public Reference Room maintained by the SEC at 100 F Street, N.E., Washington, D.C. 20549. You may obtain copies of the registration statement, including the exhibits thereto, and all of our periodic reports after payment of the fees prescribed by the SEC. For additional information regarding the operation of the Public Reference Room, you may call the SEC at 1-800-SEC-0330. The SEC also maintains a website which provides on-line access to reports and other information regarding registrants that file electronically with the SEC at the address: <http://www.sec.gov>.

Our Internet address is www.sunshineheart.com. The information on our Internet website is not incorporated by reference in this prospectus.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate" into this prospectus information that we file with the SEC in other documents. This means that we can disclose important information to you by referring to other documents that contain that information. Any information that we incorporate by reference is considered part of this prospectus. The documents and reports that we list below are incorporated by reference into this prospectus. In addition, all documents and reports which we file pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus are incorporated by reference in this prospectus as of the respective filing dates of these documents and reports. Statements contained in documents that we file with the SEC and that are incorporated by reference in this prospectus will automatically update and supersede information contained in this prospectus, including information in previously filed documents or reports that have been incorporated by reference in this prospectus, to the extent the new information differs from or is inconsistent with the old information.

We have filed the following documents with the SEC. These documents are incorporated herein by reference as of their respective dates of filing:

- annual report on Form 10-K for the year ended December 31, 2012 filed with the SEC on March 12, 2013;

S-34

- current reports on Form 8-K filed with the SEC on January 16, 2013, February 4, 2013, February 6, 2013, March 13, 2013 and April 2, 2013, respectively (other than the portions of these reports furnished but not filed pursuant to SEC rules and the exhibits filed on such form that relate to such portions);
- the information specifically incorporated by reference into our Annual Report on Form 10-K for the year ended December 31, 2012 from our definitive Proxy Statement for the Annual Meeting of Stockholders to be held on May 23, 2013, filed with the SEC on April 5, 2013;
- the description of our common stock in our Registration Statement on Form 10 filed with the SEC on September 30, 2011, including any amendment or report filed for the purpose of updating such description; and
- any and all filings we make with the SEC pursuant to Sections 13(a), 13(c), 14 or 15 of the Exchange Act after the effective date of the registration statement of which this prospectus is a part.

You may request a copy of these documents, which will be provided to you at no cost, by contacting:

Sunshine Heart, Inc.
Attention: David A. Rosa, Chief Executive Officer
12988 Valley View Road
Eden Prairie, MN 55344
Tel: (952) 345-4200

S-35

PROSPECTUS

\$75,000,000



**Common Stock
Preferred Stock
Warrants to Purchase Common Stock, Preferred Stock or Debt Securities
Debt Securities**

SUNSHINE HEART, INC.

This prospectus covers the primary offering by us of any combination of common stock; preferred stock; warrants to purchase common stock, preferred stock or debt securities; and debt securities, each as described herein, in one or more offerings from time to time. The aggregate initial offering price of all securities sold by us under this prospectus will not exceed \$75 million.

This prospectus provides a general description of the securities we may offer. Each time we sell securities, we will provide specific terms of the securities offered in a supplement to this prospectus. The prospectus supplement may also add, update or change information contained in this prospectus. You should read this prospectus and the applicable prospectus supplement carefully before you invest in any securities. This prospectus may not be used to consummate a sale of securities unless accompanied by the applicable prospectus supplement.

The securities may be sold directly by us to investors, through agents designated from time to time or to or through underwriters or dealers, on a continuous or delayed basis. For additional information on the methods of sale, you should refer to the section entitled "Plan of Distribution" in this prospectus. If any agents or underwriters are involved in the sale of any securities with respect to which this prospectus is being delivered, the names of such agents or underwriters and any applicable fees, commissions, discounts and over-allotment options will be set forth in a prospectus supplement. The price to the public of such securities and the net proceeds that we expect to receive from such sale will also be set forth in a prospectus supplement.

Our common stock is listed on the NASDAQ Capital Market ("*Nasdaq*") under the symbol "SSH," and Chess Depository Instruments ("*CDIs*") representing beneficial ownership of our common stock are listed on the Australian Securities Exchange (the "*ASX*") under the symbol "SHC." On April 1, 2013, the closing price of our common stock on Nasdaq was \$6.17.

The number of outstanding shares of our common stock, par value \$0.0001 per share, as of April 1, 2013 was 9,509,867.

Investing in our securities involves risks. See "Risk Factors" on page 10 of this prospectus and in the applicable prospectus supplement.

As of April 1, 2013, the aggregate market value of our outstanding common stock held by non-affiliates was approximately \$41.2 million, which was calculated based on approximately 6.67 million shares of outstanding common stock held by non-affiliates as of such date at a price per share of \$6.17, the closing sale price of our common stock on April 1, 2013. We have not sold any securities pursuant to General Instruction I.B.6. of Form S-3 during the 12 calendar months prior to, and including, the date of this Registration Statement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is April 5, 2013.

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS	1
SUMMARY	2
RISK FACTORS	10
FORWARD-LOOKING STATEMENTS	10
RATIOS OF EARNINGS TO FIXED CHARGES	11
USE OF PROCEEDS	11
DESCRIPTION OF COMMON STOCK	11
DESCRIPTION OF PREFERRED STOCK	16
DESCRIPTION OF WARRANTS	18
DESCRIPTION OF DEBT SECURITIES	20
LEGAL OWNERSHIP OF SECURITIES	27
PLAN OF DISTRIBUTION	30
LEGAL MATTERS	33
EXPERTS	33
INCORPORATION BY REFERENCE	33

[Table of Contents](#)**ABOUT THIS PROSPECTUS**

This prospectus is a part of a registration statement that we filed with the Securities and Exchange Commission (the “SEC”), utilizing a “shelf” registration process. Under this shelf registration process, we may offer to sell any combination of the securities described in this prospectus in one or more offerings from time to time up to a total dollar amount of \$75 million. This prospectus provides you with a general description of the securities we may offer and sell. Each time we offer and sell securities under this prospectus, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus. To the extent that any statement that we make in a prospectus supplement is inconsistent with statements made in this prospectus, the statements made in this prospectus will be deemed modified or superseded by those made in the prospectus supplement, as appropriate. You should read both this prospectus and any prospectus supplement, including all documents incorporated herein or therein by reference, together with additional information described under “Where You Can Find More Information.” **THIS PROSPECTUS MAY NOT BE USED TO CONSUMMATE A SALE OF SECURITIES UNLESS IT IS ACCOMPANIED BY A PROSPECTUS SUPPLEMENT.**

We have filed or incorporated by reference exhibits to the registration statement of which this prospectus forms a part. You should read the exhibits carefully for provisions that may be important to you.

You should rely only on the information that we have provided or incorporated by reference in this prospectus, any prospectus supplement, any free writing prospectus or other written communication we may authorize to be delivered to you. We have not, and have not authorized anyone else, to provide you with different or additional information. This prospectus, any prospectus supplement, any free writing prospectus and any other written communication do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they specifically relate, nor does this prospectus, any prospectus supplement, any free writing prospectus or any other written communication constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus, any applicable prospectus supplement or any related free writing prospectus is accurate as of any date other than the date on the front cover of this prospectus, the prospectus supplement or any related free writing prospectus, as applicable, or that the information contained in any document incorporated by reference is accurate as of any date other than the date of the document incorporated by reference, regardless of the time of delivery of this prospectus, any applicable prospectus supplement or any related free writing prospectus, or any sale of a security. You should not consider any information in this prospectus or in the documents incorporated by reference herein, any prospectus supplement, any free writing prospectus or other written communication to be investment, legal or tax advice. We encourage you to consult your own counsel, accountant and other advisors for legal, tax, business, financial and related advice regarding an investment in our securities.

[Table of Contents](#)**SUMMARY**

Because this is only a summary, it does not contain all of the information that may be important to you. Before you invest, you should carefully read the more detailed information contained in this prospectus and the information incorporated in this prospectus by reference. Our business involves significant risks. You should carefully consider the information under the heading “Risk Factors” beginning on page 10.

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

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

C-Pulse®, Sunshine®, Sunshine Heart™, C-Patch™ and other trademarks or service marks of Sunshine Heart appearing in this prospectus are the property of Sunshine Heart. Trade names, trademarks and service marks of other companies appearing in this registration statement are the property of the respective owners.

We obtained industry and market data used throughout this prospectus through our research, surveys and studies conducted by third parties and industry and general publications. We have not independently verified market and industry data from third-party sources.

Our Company**Overview**

We are an early-stage medical device company focused on developing, manufacturing and commercializing our C-Pulse Heart Assist System (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 trial in the first half of 2011. In November 2011, we announced the preliminary results of the six-month follow-up period for the feasibility study and we submitted the clinical data to the United States Food and Drug Administration (the “FDA”). In March 2012, the FDA notified us that it completed its review of the C-Pulse System feasibility trial data, concluded we met the applicable agency requirements, and indicated that we can move forward with an investigational device exemption (“IDE”) application. In October 2012, we announced the results of the twelve-month follow-up period for the feasibility study. In November 2012, the FDA provided us with unconditional approval to initiate a pivotal trial. We currently anticipate that enrollment of our pivotal trial will begin during the first half of 2013. We expect to complete enrollment of our pivotal trial by the end of 2015 and do not anticipate marketing our system in the United States before 2017.

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

[Table of Contents](#)

endpoints similar to those for our U.S. pivotal trial. We do not expect to receive reimbursement in Germany before 2014 and cannot be certain of when we will receive reimbursement in other targeted countries.

We incurred net losses of \$14.1 million and \$16.2 million in the years ended December 31, 2012 and 2011, respectively. Historically, we have generated our revenue solely from sales of the C-Pulse System to hospitals and clinics pursuant to research arrangements and with appropriate regulatory approvals for sales in conjunction with our feasibility clinical trial. We expect to continue to incur significant net losses as we continue to conduct clinical trials 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 heart's ability to pump blood to the various organs of the body. Patients with heart failure commonly experience shortness of breath, fatigue, difficulty exercising and swelling of the legs. The heart becomes weak or stiff and enlarges over time, making it harder to pump the blood needed for the body to function properly. The severity of heart failure depends on how well a person's heart is able to pump blood throughout the body. A common measure of heart failure severity is the New York Heart Association ("**NYHA**") Class guideline. Patients are classified in Classes I through IV based on their symptoms and functional limitations. Classes I and II include mild heart failure patients, Class III includes moderate heart failure patients, and Class IV includes severe heart failure patients.

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

Treatment alternatives currently available for Class III heart failure patients in the United States consist primarily of pharmacological therapies and pacing devices that are designed to address heart rhythm issues. Although these treatments may provide symptomatic relief and prolong the life of patients, they do not often halt the progression of congestive heart failure. Circulatory assist devices, specifically left ventricular assist devices ("**LVADs**") have been used to treat Class IV patients in the United States, and one product received FDA approval in the United States for Class IIIb patients although the device is not reimbursed by the Centers for Medicare and Medicaid Services for Class IIIb patients. These devices are designed to take over some or all of the pumping function of the heart by mechanically pumping blood into the aorta. Although such products are effective in increasing blood flow, by design these devices are in contact with the patient's bloodstream, increasing the risk of adverse events, including thrombosis, bleeding and neurologic events.

Our Strategy

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

[Table of Contents](#)

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

Our System

The C-Pulse System utilizes the scientific principles of intra-aortic balloon counter-pulsation applied in an extra-aortic approach to assist the left ventricle by reducing the workload required to pump blood throughout the body, while increasing blood flow to the coronary arteries. Combined, these potential benefits may help sustain the patient's current condition or, in some cases, reverse the heart failure process, thereby potentially preventing the need for later-stage heart failure devices, such as LVADs, artificial hearts or transplants. It may also provide relief from the symptoms of Class III and ambulatory Class IV heart failure and improve quality of life and cardiac function. Based on the patient results from our feasibility trial, we also believe that some patients treated with our C-Pulse System will be able to stop using the device due to sustained improvement in their conditions as a result of the therapy.

Once implanted, the C-Pulse cuff is positioned on the outside of the patient's ascending aorta above the aortic valve. An electrocardiogram sensing lead is then attached to the heart to determine timing for cuff inflation and deflation in synchronization with the heartbeat. As the heart fills with blood, the C-Pulse cuff inflates to push blood from the aorta to the rest of the body and to the heart muscle via the coronary arteries. Just before the heart pumps, the C-Pulse cuff deflates to reduce the heart's workload through pressure changes, allowing the heart to pump with less effort. The C-Pulse cuff and electrical leads are connected to a single line that is run through the abdominal wall to connect to a power driver outside the body. The system's single unit driver and battery source are contained inside a carrying bag.

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

The C-Pulse System distinguishes itself from other mechanical heart failure therapies in two important respects, which we believe differentiate our system from other products addressing moderate to severe heart failure patients. First, the C-Pulse System is placed outside a patient's vascular system. The C-Pulse cuff is placed outside a patient's ascending aorta and assists the heart's normal pumping function, rather than being inserted into the vascular system and replacing heart function in a manner similar to other devices such as LVADs. Because the C-Pulse System remains outside the vascular system, there is potentially less risk of complications such as blood clots, stroke and thrombosis in comparison to other mechanical devices that reside or function inside the vascular system. Because it rests outside the

[Table of Contents](#)

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

Second, the C-Pulse System can be safely turned on or off at any time. 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 allows patients intervals of freedom to perform certain activities such as showering. Patients are not required to visit a medical facility when turning our device on or off or using the device. However, 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

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

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

Corporate Information

Sunshine Heart, Inc. was incorporated in Delaware on August 22, 2002. We began operating our business in November 1999 through Sunshine Heart Company Pty Ltd., which currently is a wholly owned Australian subsidiary of Sunshine Heart, Inc. Since September 2004, CDIs representing beneficial ownership of our common stock have been traded on the Australian Securities Exchange under the symbol "SHC." Historically, each CDI represented one share of our common stock. In connection with the 1-for-200 reverse stock split we effected on January 27, 2012, we changed this ratio so that each CDI represents 1/200th of a share of our common stock.

On September 30, 2011, we filed a Form 10 registration statement with the SEC, which was declared effective on February 14, 2012. The Form 10 registered our common stock under the Securities

[Table of Contents](#)

Exchange Act of 1934, as amended (the "**Exchange Act**"). Our common stock began trading on 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 is expected to occur at the close of trading on May 6, 2013.

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

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

- a requirement to have only two years of audited financial statements and only two years of related Management’s Discussion and Analysis of Financial Condition and Results of Operations disclosure; and
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002.

We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We will cease to be an emerging growth company if we have more than \$1 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 burdens. The JOBS Act permits emerging growth companies to take advantage of an extended transition period to comply with new or revised accounting standards applicable to U.S. public companies. We have elected to take advantage of the benefits of this extended transition period, and as a result of this election, our financial statements may not be comparable to those of companies that comply with new or revised accounting standards for U.S. public companies.

The Securities We May Offer

We may offer shares of our common stock and preferred stock, warrants and/or debt securities, either individually or in combination, with a total value of up to \$75 million, from time to time at prices and on terms to be determined by market conditions at the time of the offering. This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities, including, to the extent applicable:

- designation or classification;
- aggregate principal amount or aggregate offering price;
- maturity, if applicable;
- original issue discount, if any;

[Table of Contents](#)

- rates and times of payment of interest, dividends or other payments, if any;
- redemption, conversion, exercise, exchange, settlement or sinking fund terms, if any;
- conversion, exchange or settlement prices or rates, if any, and, if applicable, any provisions for changes to or adjustments in the conversion, exchange or settlement prices or rates and in the securities or other property receivable upon conversion, exchange or settlement;
- ranking;
- restrictive covenants, if any;
- voting or other rights, if any; and
- certain federal income tax considerations.

A prospectus supplement and any related free writing prospectus may also add, update or change information contained in this prospectus or in documents we have incorporated by reference into this prospectus. However, no prospectus supplement or free writing prospectus shall offer a security that is not registered and described in this prospectus at the time of the effectiveness of the registration statement of which this prospectus is a part.

This prospectus may not be used to offer or sell any securities unless accompanied by a prospectus supplement.

We may sell the securities directly or through underwriters, dealers or agents. We and such underwriters, dealers or agents, reserve the right to accept or reject all or part of any proposed purchase of securities. If we do offer securities through underwriters or agents, we will include in the applicable prospectus supplement:

- the names of those underwriters or agents;
- applicable fees, discounts and commissions to be paid to them;
- details regarding over-allotment options, if any; and
- the net proceeds to us.

Common Stock

We may issue shares of our common stock from time to time. Holders of our common stock are entitled to one vote per share for the election of directors and on all other matters that require stockholder approval, as further set forth herein under the heading “Description of Common Stock.” Subject to any preferential rights of any then outstanding preferred stock, in the event of our liquidation, dissolution or winding up, holders of our common stock are

entitled to share ratably in the assets remaining after payment of liabilities and the liquidation preferences of any then outstanding preferred stock. Our common stock does not carry any preemptive rights enabling a holder to subscribe for, or receive shares of, any class of our common stock or any other securities convertible into shares of any class of our common stock, or any redemption rights.

[Table of Contents](#)

Preferred Stock

Our board of directors will determine the designations, voting powers, preferences and rights of the preferred stock, as well as the qualifications, limitations or restrictions thereof, including dividend rights, conversion rights, preemptive rights, terms of redemption or repurchase, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of any series. Convertible preferred stock will be convertible into our common stock or exchangeable for other securities. Conversion may be mandatory or at your option and would be at prescribed conversion rates.

We will fix the rights, preferences, privileges, qualifications and restrictions of the preferred stock of each series that we sell under this prospectus and applicable prospectus supplements in a certificate of designation relating to that series. We will incorporate by reference into the registration statement of which this prospectus is a part the form of any certificate of designation that describes the terms of the series of preferred stock we are offering before the issuance of the related series of preferred stock. We urge you to read the prospectus supplement (and any related free writing prospectus) related to the series of preferred stock being offered, as well as the complete certificate of designation that contains the terms of the applicable series of preferred stock.

Warrants

We may issue warrants for the purchase of common stock, preferred stock and/or debt securities in one or more series, from time to time. We may issue warrants independently or together with common stock, preferred stock and/or debt securities, and the warrants may be attached to or separate from those securities.

The warrants will be evidenced by warrant certificates issued under one or more warrant agreements, which are contracts between us and an agent for the holders of the warrants. In this prospectus, we have summarized certain general features of the warrants. We urge you, however, to read the prospectus supplement (and any related free writing prospectus) related to the series of warrants being offered, as well as the complete warrant agreements and warrant certificates that contain the terms of the warrants. Complete warrant agreements and warrant certificates containing the terms of the warrants being offered will be filed as exhibits to the registration statement of which this prospectus is a part or will be incorporated by reference from reports we file with the SEC.

Debt Securities

We may issue debt securities from time to time, in one or more series, as either senior or subordinated debt or as senior or subordinated convertible debt. The senior debt securities will rank equally with any other unsubordinated debt that we may have and may be secured or unsecured. The subordinated debt securities will be subordinate and junior in right of payment, to the extent and in the manner described in the instrument governing the debt, to all or some portion of our indebtedness. Any convertible debt securities that we issue will be convertible into or exchangeable for our common stock, preferred stock or other securities of ours. Conversion may be mandatory or at your option and would be at prescribed conversion rates.

The debt securities will be issued under one or more documents called indentures, which are contracts between us and a trustee for the holders of the debt securities. In this prospectus, we have summarized certain general features of the debt securities. We urge you, however, to read the prospectus supplement (and any related free writing prospectus) related to the series of debt securities being offered, as well as the complete indentures that contain the terms of the debt securities. Indentures have been filed as exhibits to the registration statement of which this prospectus is a part, and supplemental indentures

[Table of Contents](#)

and forms of debt securities containing the terms of debt securities being offered will be filed as exhibits to the registration statement of which this prospectus is a part or will be incorporated by reference from reports we file with the SEC.

[Table of Contents](#)

RISK FACTORS

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties under the heading “Risk Factors” contained in our most recent annual report on Form 10-K, which has been filed with the SEC and is incorporated by reference in this prospectus, as well as any updates thereto contained in subsequent filings with the SEC or any applicable prospectus supplement or free writing prospectus, before deciding whether to purchase any of the securities being registered pursuant to the registration statement of which this prospectus is a part. Each of the risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our securities, and the occurrence of any of these risks might cause you to lose all or a part of your investment. Moreover, the risks described are not the only risks that we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations.

FORWARD-LOOKING STATEMENTS

The SEC encourages companies to disclose forward-looking information so that investors can better understand a company’s future prospects and make informed investment decisions. This prospectus contains such “forward-looking statements” within the meaning of the Private Securities Litigation

Reform Act of 1995. These statements may be made directly in this prospectus, and they may also be made a part of this prospectus by reference to other documents filed with the SEC, which is known as “incorporation by reference.”

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

- anticipated results of financing activities;
- anticipated agreements with marketing partners;
- anticipated clinical trial timelines or results;
- anticipated research and product development results;
- projected regulatory timelines;
- descriptions of plans or objectives of management for future operations, products or services;
- forecasts of future economic performance;
- anticipated ability to utilize the equity line of credit facility with Aspire Capital Fund, LLC, an Illinois limited liability company, pursuant to that certain Common Stock Purchase Agreement dated January 15, 2013; and
- descriptions or assumptions underlying or relating to any of the above items.

[Table of Contents](#)

Please also see the discussion of risks and uncertainties under the heading “Risk Factors” beginning on page 10.

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

RATIOS OF EARNINGS TO FIXED CHARGES

If we offer debt securities and/or preference equity securities under this prospectus, then we will, if required at that time, provide a ratio of earnings to fixed charges and/or ratio of combined fixed charges and preference dividends to earnings, respectively, in the applicable prospectus supplement for such offering.

USE OF PROCEEDS

Unless otherwise provided in the applicable prospectus supplement, we intend to use the net proceeds from the sale of the securities under this prospectus for general corporate purposes, including the further development, manufacture and commercialization of our C-Pulse System and for other working capital expenditures.

DESCRIPTION OF COMMON STOCK

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

General Terms

We have authority to issue up to 100,000,000 shares of common stock, par value \$0.0001 per share. As of April 1, 2013, we had 9,509,867 shares of our common stock outstanding. All outstanding shares of our common stock are fully paid and non-assessable.

The transfer agent and registrar for transfers of shares of our common stock is American Stock Transfer & Trust Company, LLC.

The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future. Subject in all cases to the foregoing limitation, the holders of our common stock have the rights, preferences and privileges below.

[Table of Contents](#)

Dividends

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

Voting

Holders of our common stock are entitled to one vote for each share on each matter properly submitted to our stockholders for their vote; provided however, that except as otherwise required by law, holders of our common stock will not be entitled to vote on any amendment to our certificate of incorporation (including any certificate of designation filed with respect to any series of preferred stock) that relates solely to the terms of a series of outstanding preferred stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon by law or pursuant to our certificate of incorporation (including any certificate of designation filed with respect to any series of preferred stock).

Subject to the voting restrictions described above, holders of our common stock may adopt, amend or repeal our bylaws and/or alter certain provisions of our certificate of incorporation with the affirmative vote of the stockholders of at least 66 2/3% of the voting power of all of the then-outstanding shares of our capital stock entitled to vote generally in the election of directors, voting together as a single class, in addition to any vote of the holders of a class or series of our stock required by law or our certificate of incorporation. Those provisions of our certificate of incorporation that may be altered only by the super-majority vote described above relate to:

- the number of directors on our board of directors, the classification of our board of directors and the terms of the members of our board of directors;
- the limitations on removal of any of our directors described below under “—Anti-Takeover Effects of Certain Provisions of Delaware Law and Our Certificate of Incorporation and Bylaws”;
- the ability of our directors to fill any vacancy on our board of directors by the affirmative vote of a majority of the directors then in office under certain circumstances;
- the ability of our board of directors to adopt, amend or repeal our bylaws and the super-majority vote of our stockholders required to adopt, amend or repeal our bylaws described above;
- the limitation on action of our stockholders by written action described below under “—Anti-Takeover Effects of Certain Provisions of Delaware Law and Our Certificate of Incorporation and Bylaws”;
- the choice of forum provision described below under “—Choice of Forum”;
- the limitations on director liability and indemnification described below under the heading “Limitation on Liability of Directors and Officers and Indemnification”; and
- the super-majority voting requirement to amend our certificate of incorporation described above.

[Table of Contents](#)

Conversion, Redemption and Preemptive Rights

Holders of our common stock do not have any conversion, redemption or preemptive rights pursuant to our organizational documents.

Liquidation, Dissolution and Winding-up

In the event of our dissolution, liquidation or winding up, holders of our common stock are entitled to share ratably in any assets remaining after the satisfaction in full of the prior rights of creditors and the aggregate of any liquidation preference pursuant to the terms of any certificate of designation filed with respect to any series of preferred stock.

Anti-Takeover Effects of Certain Provisions of Delaware Law and Our Certificate of Incorporation and Bylaws

Certificate of Incorporation and Bylaws

Certain provisions of our certificate of incorporation and bylaws may be considered as having an anti-takeover effect, such as those provisions:

- providing for our board of directors to be divided into three classes with staggered three-year terms, with only one class of directors being elected at each annual meeting of our stockholders and the other classes continuing for the remainder of their respective three-year terms;
- authorizing our board of directors to issue from time to time any series of preferred stock and fix the voting powers, designation, powers, preferences and rights of the shares of such series of preferred stock;
- prohibiting stockholders from acting by written consent in lieu of a meeting;
- requiring advance notice of stockholder intention to put forth director nominees or bring up other business at a stockholders’ meeting;
- prohibiting stockholders from calling a special meeting of stockholders;
- requiring a 66 2/3% super-majority stockholder approval in order for stockholders to alter, amend or repeal certain provisions of our certificate of incorporation;

- requiring a 66 2/3% super-majority stockholder approval in order for stockholders to adopt, amend or repeal our bylaws;
- providing that, subject to the rights of the holders of any series of preferred stock to elect additional directors under specified circumstances, neither the board of directors nor any individual director may be removed without cause;
- creating the possibility that our board of directors could prevent a coercive takeover of our Company due to the significant amount of authorized, but unissued shares of our common stock and preferred stock;

[Table of Contents](#)

- providing that, subject to the rights of the holders of any series of preferred stock, the number of directors shall be fixed from time to time exclusively by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- providing that any vacancies on our board of directors under certain circumstances will be filled only by a majority of our board of directors then in office, even if less than a quorum, and not by the stockholders.

Delaware Law

We are also subject to Section 203 of the Delaware General Corporation Law, as amended (the “**DGCL**”), which generally prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder, unless:

- prior to that date, our board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of our voting stock outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned by (i) persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to that date, the business combination is approved by our board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 of the DGCL defines an interested stockholder as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by any of these entities or persons.

The above-summarized provisions of the DGCL and our certificate of incorporation and bylaws could make it more difficult to acquire us by means of a tender offer, a proxy contest or otherwise, or to remove incumbent officers and directors. These provisions are expected to discourage certain types of coercive takeover practices and takeover bids that our board of directors may consider inadequate and to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging takeover or acquisition proposals because, among other things, negotiation of these proposals could result in an improvement of their terms.

Choice of Forum

Our certificate of incorporation provides that, unless we consent in writing otherwise, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any (i) derivative action or proceeding brought on our behalf; (ii) action asserting a breach of fiduciary duty owed by any of our

[Table of Contents](#)

directors, officers or other employees or any of our stockholders; (iii) action asserting a claim pursuant to the DGCL; or (iv) action asserting a claim that is governed by the internal affairs doctrine.

Limitation on Liability of Directors and Indemnification

Our certificate of incorporation limits the liability of our directors to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for any:

- breach of their duty of loyalty to us or our stockholders;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares as provided in Section 174 of the DGCL; or
- transaction from which the directors derived an improper personal benefit.

These limitations of liability do not apply to liabilities arising under federal securities laws and do not affect the availability of equitable remedies such as injunctive relief or rescission.

Our bylaws provide that we will indemnify and advance expenses to our directors and officers to the fullest extent permitted by law or, if applicable, pursuant to indemnification agreements. They further provide that we may choose to indemnify our other employees or agents from time to time. Subject to certain exceptions and procedures, our bylaws also require us to advance to any person who was or is a party, or is threatened to be made a party, to any proceeding by reason of the person's service as one of our directors or officers all expenses incurred by the person in connection with such proceeding.

Section 145(g) of the DGCL and our bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to us, regardless of whether our bylaws permit indemnification. We maintain a directors' and officers' liability insurance policy.

We entered into indemnification agreements with each of our directors and executive officers that provide, in general, that we will indemnify them to the fullest extent permitted by law in connection with their service to us or on our behalf and, subject to certain exceptions and procedures, that we will advance to them all expenses that they incur in connection with any proceeding to which they are, or are threatened to be, a party.

At present, there is no pending litigation or proceeding involving any of our directors or officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

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

[Table of Contents](#)

Listing

Our common stock is listed on the NASDAQ Capital Market under the symbol "SSH." Our shares of common stock in the form of Chess Depositary Instruments are listed on the Australian Securities Exchange under the symbol "SHC." On January 29, 2013, we announced our intention to de-list from the official list of the ASX during the first half of the 2013 calendar year. On February 5, 2013, we received conditional approval from the ASX to delist from the official list of the ASX. The delisting is expected to occur upon the close of trading on May 6, 2013.

CDIs

In order for our shares of common stock in the form of CDIs to trade electronically on the ASX, we participate in the electronic transfer system known as the Clearing House Electronic Subregister System ("**CHESS**"), operated by ASX Settlement Pty Limited ("**ASX Settlement**"). ASX Settlement provides settlement services for the ASX markets to assist participants and issuers to understand the operation of the rules and procedures governing settlement facilities. The ASX Settlement Operating Rules form part of the overall listing and market rules which we are required to comply with as an entity listed on the ASX.

CHESS is an electronic system which manages the settlement of transactions executed on the ASX and facilitates the paperless transfer of legal title to the ASX quoted securities. CHESS cannot be used directly for the transfer of securities of companies domiciled in certain jurisdictions outside of Australia, such as the United States. Accordingly, to enable our shares of common stock to be cleared and settled electronically through CHESS, we have issued and will continue to issue depositary interests called CDIs. No share certificates are issued in respect of shareholdings that are quoted on the ASX and settled on CHESS, nor is it a requirement for transfer forms to be executed in relation to transfers that occur on CHESS.

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

A holder of CDIs who does not wish to have its trades settled in CDIs may request that such holder's CDIs be converted into shares of common stock, in which case legal title to the shares of common stock will be transferred to the holder of CDIs and a book entry for the shares of common stock will be made on the records of our transfer agent. If thereafter such holder wishes to sell its investment on the ASX, it will be necessary for such holder to convert its shares of common stock back into CDIs.

On January 29, 2013, we announced our intention to de-list from the official list of the ASX during the first half of the 2013 calendar year. On February 5, 2013, we received conditional approval from the ASX to delist from the official list of the ASX. The delisting is expected to occur upon the close of trading on May 6, 2013.

DESCRIPTION OF PREFERRED STOCK

We have authority to issue up to 40,000,000 shares of preferred stock, par value \$0.0001 per share, none of which were outstanding as of April 1, 2013.

We may issue any class of preferred stock in any series. Our board of directors has the authority to establish and designate series, and to fix the number of shares included in each such series and to

[Table of Contents](#)

determine or alter for each such series, such voting powers, designation, preferences, and relative participating, optional, or other rights and such qualifications, limitations or restrictions thereof. Our board of directors is not restricted in repurchasing or redeeming such stock while there is any arrearage in the payment of dividends or sinking fund installments. Our board of directors is authorized to increase or decrease the number of shares of any series

subsequent to the issuance of shares of that series, but not below the number of shares of such series then outstanding. The number of authorized shares of preferred stock may be increased or decreased, but not below the number of shares thereof then outstanding, by the affirmative vote of the holders of a majority of the common stock, without a vote of the holders of the preferred stock, or of any series thereof, unless a vote of any such holders is required pursuant to the terms of any certificate of designation filed with respect to any series of preferred stock.

Prior to issuance of shares of any series of preferred stock, our board of directors is required by Delaware law to adopt resolutions and file a certificate of designation with the Secretary of State of the State of Delaware. The certificate of designation fixes for each class or series the terms, preferences, conversion or other rights, voting powers, restrictions, limitations as to dividends or other distributions, qualifications and terms or conditions of redemption for each class or series. Any shares of preferred stock will, when issued, be fully paid and non-assessable.

For any series of preferred stock that we may issue, our board of directors will determine and the prospectus supplement relating to such series will describe:

- the title and stated value of the preferred stock;
- the number of shares of the preferred stock offered, the liquidation preference per share and the offering price of the preferred stock;
- the dividend rate(s), period(s) or payment date(s) or method(s) of calculation applicable to the preferred stock;
- whether dividends are cumulative or non-cumulative and, if cumulative, the date from which dividends on the preferred stock will accumulate;
- our right, if any, to defer payment of dividends and the maximum length of any such deferral period;
- the procedures for auction and remarketing, if any, for the preferred stock;
- the provisions for a sinking fund, if any, for the preferred stock;
- the provision for redemption, if applicable, of the preferred stock;
- any listing of the preferred stock on any securities exchange;
- the terms and conditions, if applicable, upon which the preferred stock will be convertible into common stock, including the conversion price or manner of calculation and conversion period;
- voting rights, if any, of the preferred stock;
- whether interests in the preferred stock will be represented by depositary shares;

[Table of Contents](#)

- a discussion of any material or special U.S. federal income tax considerations applicable to the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights upon the liquidation, dissolution or winding up of our affairs;
- any limitations on issuance of any class or series of preferred stock ranking senior to or on a parity with the class or series of preferred stock as to dividend rights and rights upon the liquidation, dissolution or winding up of our affairs; and
- any other specific terms, preferences, rights, limitations or restrictions of the preferred stock.

Delaware law provides that the holders of preferred stock will have the right to vote separately as a class (or, in some cases, as a series) on an amendment to our certificate of incorporation if the amendment would change the par value or, unless the certificate of incorporation then in effect provided otherwise, the number of authorized shares of such class or change the powers, preferences or special rights of such class or series so as to adversely affect the class or series, as the case may be. This right is in addition to any voting rights that may be provided for in the applicable certificate of designation.

DESCRIPTION OF WARRANTS

The following is a general description of the terms of the warrants we may issue from time to time unless we provide otherwise in the prospectus supplement. Particular terms of any warrants we offer will be described in the prospectus supplement relating to such warrants.

General Terms

We may issue warrants to purchase common stock, preferred stock or debt securities. Warrants may be issued independently or together with other securities and may be attached or separate from such securities. We will issue each series of warrants under a separate warrant agreement to be entered into between us and a warrant agent. The warrant agent will act solely as our agent and will not assume any obligation or relationship of agency for or with holders or beneficial owners of warrants.

A prospectus supplement will describe the particular terms of any series of warrants we may issue, including the following:

- the title and aggregate number of the warrants;
- the price or prices at which the warrants will be issued and the currency or currencies in which the price of the warrants may be payable;

- if applicable, the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security or each principal amount of such security;
- in the case of warrants to purchase debt securities, the principal amount of debt securities purchasable upon exercise of one warrant;
- in the case of warrants to purchase common stock or preferred stock, the number of shares of common stock or preferred stock, as the case may be, purchasable upon the exercise of one warrant and the price at which those shares may be purchased upon such exercise;

[Table of Contents](#)

- the date on which the right to exercise the warrants will commence and the date on which such right will expire (subject to any extension);
- whether the warrants will be issued in registered form or bearer form;
- if applicable, the minimum or maximum amount of the warrants that may be exercised at any one time;
- if applicable, the date on and after which the warrants and the related securities will be separately transferable;
- if applicable, the procedures for adjusting the exercise price and number of shares of common stock or preferred stock purchasable upon the exercise of each warrant upon the occurrence of certain events, including stock splits, reverse stock splits, combinations, subdivisions or reclassifications of common stock or preferred stock;
- the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreement and the warrants;
- the terms of any rights to redeem or call the warrants;
- information with respect to book-entry procedures, if any;
- the terms of the securities issuable upon exercise of the warrants;
- if applicable, a discussion of any material or special U.S. federal income tax consequences of holding or exercising the warrants; and
- any other terms of the warrants, including terms, procedures and limitations relating to the exchange and exercise of the warrants.

We and the warrant agent may amend or supplement the warrant agreement for a series of warrants without the consent of the holders of the warrants issued thereunder to effect changes that are not inconsistent with the provisions of the warrants and that do not materially and adversely affect the interests of the holders of the warrants.

Exercise of Warrants

Each warrant will entitle the holder to purchase for cash such common stock or preferred stock at the exercise price or such principal amount of debt securities as shall in each case be set forth in, or be determinable as set forth in, the prospectus supplement relating to the warrants offered thereby. Warrants may be exercised as set forth in the prospectus supplement beginning on the date specified therein and continuing until the close of business on the expiration date set forth in the prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Upon receipt of the required payment and the warrant certificate properly completed and duly executed at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement, we will issue and deliver the securities purchasable upon such exercise. If fewer than all of the warrants represented by the warrant certificate are exercised, then we will issue a new warrant certificate for the remaining amount of warrants. If we so indicate in the applicable prospectus

[Table of Contents](#)

supplement, holders of the warrants may surrender securities as all or part of the exercise price for warrants.

Prior to exercising their warrants, holders of warrants will not have any of the rights of holders of the securities purchasable upon such exercise, including, in the case of warrants to purchase common stock or preferred stock, the right to receive dividends, if any, or payments upon our liquidation, dissolution or winding up or to exercise any voting rights or, in the case of warrants to purchase debt securities, the right to receive principal, premium, if any, or interest payments, on the debt securities purchasable upon exercise or to enforce covenants in the applicable indenture.

Governing Law

Any warrants and related warrant agreements will be governed by, and construed in accordance with, the laws of the State of New York.

DESCRIPTION OF DEBT SECURITIES

The following is a general description of the terms of debt securities we may issue from time to time unless we provide otherwise in the prospectus supplement. Particular terms of any debt securities we offer will be described in the prospectus supplement relating to such debt securities. Unless the context requires otherwise, whenever we refer to the indentures, we also are referring to any supplemental indentures that specify the terms of a particular series of debt securities.

We will issue the senior debt securities under the senior indenture that we will enter into with the trustee named in the senior indenture. We will issue the subordinated debt securities under the subordinated indenture that we will enter into with the trustee named in the subordinated indenture. The indentures will be qualified under the Trust Indenture Act of 1939 (the “*Trust Indenture Act*”). We use the term “*debenture trustee*” to refer to either the trustee under the senior indenture or the trustee under the subordinated indenture, as applicable. We have filed forms of indentures to the registration statement of which this prospectus is a part, and supplemental indentures and forms of debt securities containing the terms of the debt securities being offered will be filed as exhibits to the registration statement of which this prospectus is a part or will be incorporated by reference from reports that we file with the SEC.

The following summaries of material provisions of the senior debt securities, the subordinated debt securities and the indentures are subject to, and qualified in their entirety by reference to, all of the provisions of the indenture applicable to a particular series of debt securities. We urge you to read the applicable prospectus supplements and any related free writing prospectuses related to the debt securities that we may offer under this prospectus, as well as the complete indentures that contain the terms of the debt securities. Except as we may otherwise indicate, the terms of the senior indenture and the subordinated indenture are identical.

General

We will describe in the applicable prospectus supplement the terms of the series of debt securities being offered, including:

- the title;
- the principal amount being offered, and if a series, the total amount authorized and the total amount outstanding;

[Table of Contents](#)

- any limit on the amount that may be issued;
- whether or not we will issue the series of debt securities in global form, the terms and who the depository will be;
- the maturity date;
- whether and under what circumstances, if any, we will pay additional amounts on any debt securities held by a person who is not a U.S. person for tax purposes, and whether we can redeem the debt securities if we have to pay such additional amounts;
- the annual interest rate, which may be fixed or variable, or the method for determining the rate and the date interest will begin to accrue, the dates interest will be payable and the regular record dates for interest payment dates or the method for determining such dates;
- whether or not the debt securities will be secured or unsecured, and the terms of any secured debt;
- the terms of the subordination of any series of subordinated debt;
- the place where payments will be payable;
- restrictions on transfer, sale or other assignment, if any;
- our right, if any, to defer payment of interest and the maximum length of any such deferral period;
- the date, if any, after which, and the price at which, we may, at our option, redeem the series of debt securities pursuant to any optional or provisional redemption provisions and the terms of those redemption provisions;
- the date, if any, on which, and the price at which we are obligated, pursuant to any mandatory sinking fund or analogous fund provisions or otherwise, to redeem, or at the holder’s option to purchase, the series of debt securities and the currency or currency unit in which the debt securities are payable;
- whether the indenture will restrict our ability and/or the ability of our subsidiaries to: incur additional indebtedness; issue additional securities; create liens; pay dividends and make distributions in respect of our capital stock and the capital stock of our subsidiaries; redeem capital stock; place restrictions on our subsidiaries’ ability to pay dividends, make distributions or transfer assets; make investments or other restricted payments; sell or otherwise dispose of assets; enter into sale-leaseback transactions; engage in transactions with stockholders and affiliates; issue or sell stock of our subsidiaries; or effect a consolidation or merger;
- whether the indenture will require us to maintain any interest coverage, fixed charge, cash flow-based, asset-based or other financial ratios;
- a discussion of any material U.S. federal income tax considerations applicable to the debt securities;

[Table of Contents](#)

- information describing any book-entry features;
- provisions for a sinking fund purchase or other analogous fund, if any;
- the applicability of the provisions in the indenture on discharge;

- whether the debt securities are to be offered at a price such that they will be deemed to be offered at an “original issue discount” as defined in paragraph (a) of Section 1273 of the Internal Revenue Code of 1986, as amended;
- the denominations in which we will issue the series of debt securities, if other than denominations of \$1,000 and any integral multiple thereof;
- the currency of payment of debt securities if other than U.S. dollars and the manner of determining the equivalent amount in U.S. dollars; and
- any other specific terms, preferences, rights or limitations of, or restrictions on, the debt securities, including any additional events of default or covenants provided with respect to the debt securities, and any terms that may be required by us or advisable under applicable laws or regulations.

Conversion or Exchange Rights

We will set forth in the prospectus supplement the terms on which a series of debt securities may be convertible into or exchangeable for our common stock or our other securities, if applicable. We will include provisions as to whether conversion or exchange is mandatory, at the option of the holder, or at our option. We may include provisions pursuant to which the number of shares of our common stock or our other securities that the holders of the series of debt securities receive would be subject to adjustment.

Consolidation, Merger or Sale

Unless we provide otherwise in the prospectus supplement applicable to a particular series of debt securities, the indentures will not contain any covenant that restricts our ability to merge or consolidate, or sell, convey, transfer or otherwise dispose of all or substantially all of our assets. However, any successor to or acquirer of such assets must assume all of our obligations under the indentures or the debt securities, as appropriate. If the debt securities are convertible into or exchangeable for our other securities or securities of other entities, the person with whom we consolidate or merge or to whom we sell all of our property must make provisions for the conversion of the debt securities into securities that the holders of the debt securities would have received if they had converted the debt securities before the consolidation, merger or sale.

Events of Default Under the Indenture

Unless we provide otherwise in the prospectus supplement applicable to a particular series of debt securities, the following are events of default under the indentures with respect to any series of debt securities that we may issue:

- if we fail to pay interest when due and payable and our failure continues for 90 days and the time for payment has not been extended or deferred;

[Table of Contents](#)

- if we fail to pay the principal, premium or sinking fund payment, if any, when due and payable and the time for payment has not been extended or delayed;
- if we fail to observe or perform any other covenant contained in the debt securities or the indentures, other than a covenant specifically relating to another series of debt securities, and our failure continues for 90 days after we receive notice from the debenture trustee or holders of at least 25% in aggregate principal amount of the outstanding debt securities of the applicable series; and
- if specified events of bankruptcy, insolvency or reorganization occur.

If an event of default with respect to debt securities of any series occurs and is continuing, other than an event of default specified in the last bullet point above, the debenture trustee or the holders of at least 25% in aggregate principal amount of the outstanding debt securities of that series, by notice to us in writing, and to the debenture trustee if notice is given by such holders, may declare the unpaid principal of, premium, if any, and accrued interest, if any, due and payable immediately. If an event of default specified in the last bullet point above occurs with respect to us, the principal amount of and accrued interest, if any, of each issue of debt securities then outstanding shall be due and payable without any notice or other action on the part of the debenture trustee or any holder.

The holders of a majority in principal amount of the outstanding debt securities of an affected series may waive any default or event of default with respect to the series and its consequences, except defaults or events of default regarding payment of principal, premium, if any, or interest, unless we have cured the default or event of default in accordance with the indenture. Any waiver shall cure the default or event of default.

Subject to the terms of the indentures, if an event of default under an indenture shall occur and be continuing, the debenture trustee will be under no obligation to exercise any of its rights or powers under such indenture at the request or direction of any of the holders of the applicable series of debt securities, unless such holders have offered the debenture trustee reasonable indemnity. The holders of a majority in principal amount of the outstanding debt securities of any series will have the right to direct the time, method and place of conducting any proceeding for any remedy available to the debenture trustee, or exercising any trust or power conferred on the debenture trustee, with respect to the debt securities of that series, provided that:

- the direction so given by the holder is not in conflict with any law or the applicable indenture; and
- subject to its duties under the Trust Indenture Act, the debenture trustee need not take any action that might involve it in personal liability or might be unduly prejudicial to the holders not involved in the proceeding.

A holder of the debt securities of any series will have the right to institute a proceeding under the indentures or to appoint a receiver or trustee, or to seek other remedies only if:

- the holder has given written notice to the debenture trustee of a continuing event of default with respect to that series;

- the holders of at least 25% in aggregate principal amount of the outstanding debt securities of that series have made written request, and such holders have offered reasonable indemnity to the debenture trustee to institute the proceeding as trustee; and

[Table of Contents](#)

- the debenture trustee does not institute the proceeding, and does not receive from the holders of a majority in aggregate principal amount of the outstanding debt securities of that series other conflicting directions within 90 days after the notice, request and offer.

These limitations do not apply to a suit instituted by a holder of debt securities if we default in the payment of the principal, premium, if any, or interest on, the debt securities.

We will periodically file statements with the debenture trustee regarding our compliance with specified covenants in the indentures.

Modification of Indenture; Waiver

We and the debenture trustee may change an indenture without the consent of any holders with respect to specific matters:

- to fix any ambiguity, defect or inconsistency in the indenture;
- to comply with the provisions described above under “Description of Debt Securities—Consolidation, Merger or Sale;”
- to comply with any requirements of the SEC in connection with the qualification of any indenture under the Trust Indenture Act;
- to add to, delete from or revise the conditions, limitations, and restrictions on the authorized amount, terms, or purposes of issue, authentication and delivery of debt securities, as set forth in the indenture;
- to provide for the issuance of and establish the form and terms and conditions of the debt securities of any series as provided under “Description of Debt Securities—General” to establish the form of any certifications required to be furnished pursuant to the terms of the indenture or any series of debt securities, or to add to the rights of the holders of any series of debt securities;
- to evidence and provide for the acceptance of appointment hereunder by a successor trustee;
- to provide for uncertificated debt securities in addition to or in place of certificated debt securities and to make all appropriate changes for such purpose;
- to add to our covenants such new covenants, restrictions, conditions or provisions for the protection of the holders, and to make the occurrence, or the occurrence and the continuance, of a default in any such additional covenants, restrictions, conditions or provisions an event of default; or
- to change anything that does not materially adversely affect the interests of any holder of debt securities of any series.

In addition, under the indentures, the rights of holders of a series of debt securities may be changed by us and the debenture trustee with the written consent of the holders of at least a majority in aggregate principal amount of the outstanding debt securities of each series that is affected. However, unless we provide otherwise in the prospectus supplement applicable to a particular series of debt

[Table of Contents](#)

securities, we and the debenture trustee may make the following changes only with the consent of each holder of any outstanding debt securities affected:

- extending the fixed maturity of the series of debt securities;
- reducing the principal amount, reducing the rate of or extending the time of payment of interest, or reducing any premium payable upon the redemption of any debt securities; or
- reducing the percentage of debt securities, the holders of which are required to consent to any amendment, supplement, modification or waiver.

Discharge

Each indenture provides that we can elect to be discharged from our obligations with respect to one or more series of debt securities, except for specified obligations, including obligations to:

- register the transfer or exchange of debt securities of the series;
- replace stolen, lost or mutilated debt securities of the series;
- maintain paying agencies;
- hold monies for payment in trust;
- recover excess money held by the debenture trustee;

- compensate and indemnify the debenture trustee; and
- appoint any successor trustee.

In order to exercise our rights to be discharged, we must deposit with the debenture trustee money or government obligations sufficient to pay all the principal of, any premium, if any, and interest on, the debt securities of the series on the dates payments are due.

Form, Exchange and Transfer

We will issue the debt securities of each series only in fully registered form without coupons and, unless we provide otherwise in the applicable prospectus supplement, in denominations of \$1,000 and any integral multiple thereof. The indentures provide that we may issue debt securities of a series in temporary or permanent global form and as book-entry securities that will be deposited with, or on behalf of, The Depository Trust Company (“*DTC*”) or another depository named by us and identified in a prospectus supplement with respect to that series. See “Legal Ownership of Securities” for a further description of the terms relating to any book-entry securities.

At the option of the holder, subject to the terms of the indentures and the limitations applicable to global securities described in the applicable prospectus supplement, the holder of the debt securities of any series can exchange the debt securities for other debt securities of the same series, in any authorized denomination and of like tenor and aggregate principal amount.

Subject to the terms of the indentures and the limitations applicable to global securities set forth in the applicable prospectus supplement, holders of the debt securities may present the debt securities for

[Table of Contents](#)

exchange or for registration of transfer, duly endorsed or with the form of transfer endorsed thereon duly executed if so required by us or the security registrar, at the office of the security registrar or at the office of any transfer agent designated by us for this purpose. Unless otherwise provided in the debt securities that the holder presents for transfer or exchange, we will impose no service charge for any registration of transfer or exchange, but we may require payment of any taxes or other governmental charges.

We will name in the applicable prospectus supplement the security registrar, and any transfer agent in addition to the security registrar, that we initially designate for any debt securities. We may at any time designate additional transfer agents or rescind the designation of any transfer agent or approve a change in the office through which any transfer agent acts, except that we will be required to maintain a transfer agent in each place of payment for the debt securities of each series.

If we elect to redeem the debt securities of any series, we will not be required to:

- issue, register the transfer of, or exchange any debt securities of that series during a period beginning at the opening of business 15 days before the day of mailing of a notice of redemption of any debt securities that may be selected for redemption and ending at the close of business on the day of the mailing; or
- register the transfer of or exchange any debt securities so selected for redemption, in whole or in part, except the unredeemed portion of any debt securities we are redeeming in part.

Information Concerning the Debenture Trustee

The debenture trustee, other than during the occurrence and continuance of an event of default under an indenture, undertakes to perform only those duties as are specifically set forth in the applicable indenture. Upon an event of default under an indenture, the debenture trustee must use the same degree of care as a prudent person would exercise or use in the conduct of his or her own affairs. Subject to this provision, the debenture trustee is under no obligation to exercise any of the powers given it by the indentures at the request of any holder of debt securities unless it is offered reasonable security and indemnity against the costs, expenses and liabilities that it might incur.

Payment and Paying Agents

Unless we otherwise indicate in the applicable prospectus supplement, we will make payment of the interest on any debt securities on any interest payment date to the person in whose name the debt securities, or one or more predecessor securities, are registered at the close of business on the regular record date for the interest.

We will pay principal of and any premium and interest on the debt securities of a particular series at the office of the paying agents designated by us, except that unless we otherwise indicate in the applicable prospectus supplement, we will make interest payments by check that we will mail to the holder or by wire transfer to certain holders. Unless we otherwise indicate in the applicable prospectus supplement, we will designate the corporate trust office of the debenture trustee in the City of New York as our sole paying agent for payments with respect to debt securities of each series. We will name in the applicable prospectus supplement any other paying agents that we initially designate for the debt securities of a particular series. We will maintain a paying agent in each place of payment for the debt securities of a particular series.

All money we pay to a paying agent or the debenture trustee for the payment of the principal of or any premium or interest on any debt securities that remains unclaimed at the end of two years after such

[Table of Contents](#)

principal, premium or interest has become due and payable will be repaid to us, and the holder of the debt security thereafter may look only to us for payment thereof.

Governing Law

The indentures and the debt securities will be governed by and construed in accordance with the laws of the State of New York, except to the extent that the Trust Indenture Act is applicable.

Subordination of Subordinated Debt Securities

The subordinated debt securities will be unsecured and will be subordinate and junior in priority of payment to certain of our other indebtedness to the extent described in a prospectus supplement. The subordinated indenture does not limit the amount of subordinated debt securities that we may issue, nor does it limit us from issuing any other secured or unsecured debt.

LEGAL OWNERSHIP OF SECURITIES

We can issue securities in registered form or in the form of one or more global securities. We describe global securities in greater detail below. We refer to those persons who have securities registered in their own names on the books that we or any applicable trustee or depository or warrant agent maintain for this purpose as the “holders” of those securities. These persons are the legal holders of the securities. We refer to those persons who, indirectly through others, own beneficial interests in securities that are not registered in their own names, as “indirect holders” of those securities. As we discuss below, indirect holders are not legal holders, and investors in securities issued in book-entry form or in street name will be indirect holders.

Book-Entry Holders

We may issue securities in book-entry form only, as we will specify in the applicable prospectus supplement or free writing prospectus. This means securities may be represented by one or more global securities registered in the name of a financial institution that holds them as depository on behalf of other financial institutions that participate in the depository’s book-entry system. These participating institutions, which are referred to as participants, in turn, hold beneficial interests in the securities on behalf of themselves or their customers.

Only the person in whose name a security is registered is recognized as the holder of that security. Global securities will be registered in the name of the depository or its participants. Consequently, for global securities, we will recognize only the depository as the holder of the securities, and we will make all payments on the securities to the depository. The depository passes along the payments it receives to its participants, which in turn pass the payments along to their customers who are the beneficial owners. The depository and its participants do so under agreements they have made with one another or with their customers; they are not obligated to do so under the terms of the securities.

As a result, investors in a global security will not own securities directly. Instead, they will own beneficial interests in a global security, through a bank, broker or other financial institution that participates in the depository’s book-entry system or holds an interest through a participant. As long as the securities are issued in global form, investors will be indirect holders, and not holders, of the securities.

[Table of Contents](#)

Street Name Holders

We may terminate a global security or issue securities that are not issued in global form. In these cases, investors may choose to hold their securities in their own names or in “street name.” Securities held by an investor in street name would be registered in the name of a bank, broker or other financial institution that the investor chooses, and the investor would hold only a beneficial interest in those securities through an account he or she maintains at that institution.

For securities held in street name, we or any applicable trustee or depository will recognize only the intermediary banks, brokers and other financial institutions in whose names the securities are registered as the holders of those securities, and we or any such trustee or depository will make all payments on those securities to them. These institutions pass along the payments they receive to their customers who are the beneficial owners, but only because they agree to do so in their customer agreements or because they are legally required to do so. Investors who hold securities in street name will be indirect holders, not holders, of those securities.

Legal Holders

Our obligations, as well as the obligations of any applicable trustee or third party employed by us or a trustee, run only to the legal holders of the securities. We do not have obligations to investors who hold beneficial interests in global securities, in street name or by any other indirect means. This will be the case whether an investor chooses to be an indirect holder of a security or has no choice because we are issuing the securities only in global form.

For example, once we make a payment or give a notice to the holder, we have no further responsibility for the payment or notice even if that holder is required, under agreements with depository participants or customers or by law, to pass it along to the indirect holders but does not do so. Similarly, we may want to obtain the approval of the holders to amend an indenture, to relieve us of the consequences of a default or of our obligation to comply with a particular provision of an indenture, or for other purposes. In such an event, we would seek approval only from the legal holders, and not the indirect holders, of the securities. Whether and how the holders contact the indirect holders is up to the legal holders.

Special Considerations for Indirect Holders

If you hold securities through a bank, broker or other financial institution, either in book-entry form because the securities are represented by one or more global securities or in street name, you should check with your own institution to find out:

- how it handles securities payments and notices;

- whether it imposes fees or charges;
- how it would handle a request for the holders' consent, if ever required;
- whether and how you can instruct it to send you securities registered in your own name so you can be a holder, if that is permitted in the future;
- how it would exercise rights under the securities if there were a default or other event triggering the need for holders to act to protect their interests; and

[Table of Contents](#)

- if the securities are global securities, how the depositary's rules and procedures will affect these matters.

Global Securities

A global security is a security which represents one or any other number of individual securities held by a depositary. Generally, all securities represented by the same global securities will have the same terms.

Each security issued in book-entry form will be represented by a global security that we issue to, deposit with and register in the name of a financial institution or its nominee that we select. The financial institution that we select for this purpose is called the depositary. Unless we specify otherwise in the applicable prospectus supplement or a free writing prospectus, DTC will be the depositary for all global securities issued under this prospectus.

A global security may not be transferred to or registered in the name of anyone other than the depositary, its nominee or a successor depositary, unless special termination situations arise. We describe those situations below under "—Special Situations When a Global Security Will Be Terminated." As a result of these arrangements, the depositary, or its nominee, will be the sole registered owner and holder of all securities represented by a global security, and investors will be permitted to own only beneficial interests in a global security. Beneficial interests must be held by means of an account with a broker, bank or other financial institution that in turn has an account with the depositary or with another institution that does. Thus, an investor whose security is represented by a global security will not be a holder of the security, but only an indirect holder of a beneficial interest in the global security.

If the prospectus supplement or a free writing prospectus for a particular security indicates that the security will be issued as a global security, then the security will be represented by a global security at all times unless and until the global security is terminated. If termination occurs, we may issue the securities through another book-entry clearing system or decide that the securities may no longer be held through any book-entry clearing system.

Special Considerations for Global Securities

As an indirect holder, an investor's rights relating to a global security will be governed by the account rules of the investor's financial institution and of the depositary, as well as general laws relating to securities transfers. We do not recognize an indirect holder as a legal holder of securities and instead deal only with the depositary that holds the global security.

If securities are issued only as a global security, an investor should be aware of the following:

- An investor cannot cause the securities to be registered in his or her name, and cannot obtain non-global certificates for his or her interest in the securities, except in the special situations we describe below.
- An investor will be an indirect holder and must look to his or her own bank or broker for payments on the securities and protection of his or her legal rights relating to the securities, as we describe above.
- An investor may not be able to sell interests in the securities to some insurance companies and to other institutions that are required by law to own their securities in non-book-entry form.

[Table of Contents](#)

- An investor may not be able to pledge his or her interest in the global security in circumstances where certificates representing the securities must be delivered to the lender or other beneficiary of the pledge in order for the pledge to be effective.
- The depositary's policies, which may change from time to time, will govern payments, transfers, exchanges and other matters relating to an investor's interest in the global security. We and any applicable trustee have no responsibility for any aspect of the depositary's actions or for its records of ownership interests in the global security. We and the trustee also do not supervise the depositary in any way.
- The depositary may, and we understand that DTC will, require that those who purchase and sell interests in the global security within its book-entry system use immediately available funds, and your broker or bank may require you to do so as well.
- Financial institutions that participate in the depositary's book-entry system, and through which an investor holds its interest in the global security, may also have their own policies affecting payments, notices and other matters relating to the securities. There may be more than one financial intermediary in the chain of ownership for an investor. We do not monitor and are not responsible for the actions of any of those intermediaries.

Special Situations When a Global Security Will Be Terminated

In a few special situations described below, a global security will terminate and interests in it will be exchanged for physical certificates representing those interests. After that exchange, the choice of whether to hold securities directly or in street name will be up to the investor. Investors must consult their own banks or brokers to find out how to have their interests in securities transferred to their own name, so that they will be direct holders. We have described the rights of holders and street name investors above.

A global security will terminate when the following special situations occur:

- if the depositary notifies us that it is unwilling, unable or no longer qualified to continue as depositary for that global security and we do not appoint another institution to act as depositary within 90 days;
- if we notify any applicable trustee that we wish to terminate that global security; or
- if an event of default has occurred with regard to securities represented by that global security and has not been cured or waived.

The prospectus supplement or a free writing prospectus may also list additional situations for terminating a global security that would apply only to the particular series of securities covered by the prospectus supplement or a free writing prospectus. When a global security terminates, the depositary, and not we or any applicable trustee, is responsible for deciding the names of the institutions that will be the initial direct holders.

PLAN OF DISTRIBUTION

We may sell the securities covered hereby from time to time pursuant to underwritten public offerings, direct sales to the public, negotiated transactions, block trades or a combination of these methods. A distribution of the securities offered by this prospectus may also be effected through the issuance of derivative securities, including without limitation, warrants and subscriptions. We may sell

[Table of Contents](#)

the securities to or through underwriters or dealers, through agents, or directly to one or more purchasers. We may distribute securities from time to time in one or more transactions:

- at a fixed price or prices, which may be changed;
- at market prices prevailing at the time of sale;
- at prices related to such prevailing market prices;
- at varying prices determined at the time of sale; or
- at negotiated prices.

A prospectus supplement or supplements will describe the terms of the offering of the securities, including:

- the name or names of the underwriters, dealers or agents participating in the offering, if any;
- the purchase price of the securities sold by us to any underwriter or dealer and the net proceeds we expect to receive from the offering;
- any over-allotment options under which underwriters may purchase additional securities from us;
- any agency fees or underwriting discounts or commissions and other items constituting agents' or underwriters' compensation;
- any public offering price;
- any discounts or concessions allowed or reallocated or paid to dealers; and
- any securities exchange or market on which the securities may be listed.

Only underwriters named in the prospectus supplement will be underwriters of the securities offered by the prospectus supplement.

If underwriters are used in the sale, they will acquire the securities for their own account and may resell the securities from time to time in one or more transactions at a fixed public offering price or at varying prices determined at the time of sale. The obligations of the underwriters to purchase the securities will be subject to the conditions set forth in the applicable underwriting agreement. We may offer the securities to the public through underwriting syndicates represented by managing underwriters or by underwriters without a syndicate. Subject to certain conditions, the underwriters will be obligated to purchase all of the securities offered by the prospectus supplement, other than securities covered by any over-allotment option. Any public offering price and any discounts or commissions or concessions allowed or reallocated or paid to dealers may change from time to time. We may use underwriters with whom we have a material relationship. We will describe in the prospectus supplement, naming the underwriter, the nature of any such relationship.

[Table of Contents](#)

We may sell securities directly or through agents we designate from time to time. We will name any agent involved in the offering and sale of securities and we will describe any commissions and other compensation we will pay the agent in the prospectus supplement. Unless the prospectus supplement states otherwise, our agent will act on a best-efforts basis for the period of its appointment.

We may authorize agents or underwriters to solicit offers by certain types of institutional investors to purchase securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. We will describe the conditions to these contracts and the commissions we must pay for solicitation of these contracts in the prospectus supplement.

We may provide agents and underwriters with indemnification against civil liabilities related to this offering, including liabilities under the Securities Act, or contribution with respect to payments that the agents or underwriters may make with respect to these liabilities. Agents and underwriters may engage in transactions with, or perform services for, us in the ordinary course of business.

All securities we may offer, other than common stock, will be new issues of securities with no established trading market. Any agents or underwriters may make a market in these securities, but will not be obligated to do so and may discontinue any market making at any time without notice. We cannot guarantee the liquidity of the trading markets for any securities. There is currently no market for any of the offered securities, other than our common stock which is listed on the NASDAQ Capital Market. We have no current plans for listing of the preferred stock, warrants to purchase common stock, preferred stock or debt securities, or debt securities, on any securities exchange or quotation system; any such listing with respect to any particular preferred stock, warrants to purchase common stock, preferred stock or debt securities, or debt securities, will be described in the applicable prospectus supplement or other offering materials, as the case may be.

Any underwriter may engage in overallocation, stabilizing transactions, short covering transactions and penalty bids in accordance with Regulation M under the Exchange Act. Overallocation involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Short covering transactions involve purchases of the securities in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a stabilizing or covering transaction to cover short positions. Those activities may cause the price of the securities to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time.

Any agents and underwriters who are qualified market makers on Nasdaq may engage in passive market making transactions in the securities on Nasdaq in accordance with Regulation M, during the business day prior to the pricing of the offering, before the commencement of offers or sales of the securities. Passive market makers must comply with applicable volume and price limitations and must be identified as passive market makers. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for such security; if all independent bids are lowered below the passive market maker's bid, however, the passive market maker's bid must then be lowered when certain purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

In compliance with guidelines of the Financial Industry Regulatory Authority, Inc. ("**FINRA**") the maximum compensation to be received by any FINRA member or independent broker dealer may not

[Table of Contents](#)

exceed 8% of the aggregate amount of the securities offered pursuant to this prospectus and any applicable prospectus supplement.

LEGAL MATTERS

The validity of the securities offered by this prospectus will be passed upon for us by Honigman Miller Schwartz and Cohn LLP.

EXPERTS

The consolidated financial statements of Sunshine Heart, Inc. appearing in Sunshine Heart, Inc.'s Annual Report (Form 10-K) for the year ended December 31, 2012, have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 1 to the consolidated financial statements), incorporated by reference therein, and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

INCORPORATION BY REFERENCE

We "incorporate by reference" certain documents that we have filed with the SEC into this prospectus, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is deemed to be part of this prospectus, except for any information superseded by information contained directly in this prospectus. This prospectus incorporates by reference our:

- annual report on Form 10-K for the year ended December 31, 2012 filed with the SEC on March 12, 2013;
- current reports on Form 8-K filed with the SEC on January 16, 2013, February 4, 2013, February 6, 2013, March 13, 2013 and April 2, 2013 respectively (other than the portions of these reports furnished but not filed pursuant to SEC rules and the exhibits filed on such form that relate to such portions);
- the information specifically incorporated by reference into our Annual Report on Form 10-K for the year ended December 31, 2012 from our definitive Proxy Statement for the Annual Meeting of Stockholders to be held on May 23, 2013, to be filed with the SEC within 120 days after the end of the fiscal year covered by the Annual Report on Form 10-K for the year ended December 31, 2012; and
- the description of our common stock in our Registration Statement on Form 10 filed with the SEC on September 30, 2011, including any amendment or report filed for the purpose of updating such description.

We incorporate by reference the documents listed above and any future filings made by us with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the initial filing of the registration statement that contains this prospectus and prior to the termination of the offering of securities

[Table of Contents](#)

including information furnished under Items 2.02 or 7.01 of any Current Report on Form 8-K, will be incorporated by reference into, or otherwise included in, this prospectus.

These documents may also be accessed on our website at www.sunshineheart.com. Information contained in, or accessible through, our website is not a part of this prospectus.

You may obtain documents incorporated by reference into this prospectus at no cost by writing or telephoning us at the following address:

Sunshine Heart, Inc.
Attention: David Rosa, Chief Executive Officer
12988 Valley View Road
Eden Prairie, MN 55344
Tel: (952) 345-4200

Any statements contained in a document incorporated by reference in this prospectus shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus (or in any other subsequently filed document which also is incorporated by reference in this prospectus) modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed to constitute a part of this prospectus except as so modified or superseded.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the informational requirements of the Exchange Act and file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any reports, proxy statements and other information we file at the SEC's public reference room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. You may also access filed documents at the SEC's web site at www.sec.gov.

[Table of Contents](#)



Shares

Sunshine Heart, Inc.

Common Stock

PROSPECTUS

Canaccord Genuity

April , 2013
