

PROSPECTUS



**SUNSHINE HEART, INC.**

**1,600,000 Class A Units consisting of shares of common stock and warrants and 6,400 Class B Units consisting of Series E convertible preferred stock and warrants (and shares of common stock underlying such warrants)**

We are offering 1,600,000 Class A Units, with each Class A Unit consisting of one share of common stock, par value \$0.0001 per share, and one warrant to purchase one share of our common stock (together with the shares of common stock underlying such warrants, the "Class A Units") at a public offering price of \$1.00 per Class A Unit. Warrants included in the Class A Units have an exercise price of \$1.10 per whole share.

We are also offering 6,400 Class B Units to purchasers who prefer not to beneficially own more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering. Each Class B Unit will consist of one share of Series E Convertible Preferred Stock, par value \$0.0001 per share (the "Series E Preferred Stock"), convertible at any time at the holder's option into a number of shares of common stock equal to \$1,000 divided by the conversion price of \$1.00 (the "Conversion Price") and warrants to purchase a number of shares of our common stock equal to \$1,000 divided by the Conversion Price (together with the shares of common stock underlying such shares of Series E Preferred Stock and such warrants, the "Class B Units" and, together with the Class A Units, the "Units") at a public offering price of \$1,000 per Class B Unit. Each warrant included in the Class B Units entitles its holder to purchase a number of shares of common stock equal to 100% of the shares of common stock issuable upon conversion of the Series E Convertible Preferred Stock included in such units at an exercise price of \$1.10 per share.

The Class A Units and Class B Units will not be certificated and the shares of common stock, Series E Preferred Stock and warrants comprising such units are immediately separable and will be issued separately in this offering.

The price of our common stock on The Nasdaq Capital Market during recent periods will only be one of many factors in determining the public offering price. Other factors to be considered in determining the public offering price include our history, our prospects, the industry in which we operate, our past and present operating results, the previous experience of our executive officers, the general condition of the securities markets at the time of this offering and discussions between the underwriter and prospective investors.

Our common stock trades on The Nasdaq Capital Market under the ticker symbol "SSH". The closing price of our common stock on The Nasdaq Capital Market was \$1.35 on April 18, 2017. See "Prospectus Summary—Recent Developments—Nasdaq Compliance" in this prospectus for important information about the listing of our common stock on The Nasdaq Capital Market. We do not intend to list the warrants or preferred stock to be sold in this offering on any stock exchange or other trading market.

**Investing in our common stock involves a high degree of risk. Before making any investment in our securities, you should read and carefully consider the risks described in this prospectus under the section of this prospectus entitled "Risk Factors" on page 9 of this prospectus.**

	Per Class A Unit	Per Class B Unit(1)	Total
Public offering price	1.00	1,000.00	8,000,000
Underwriting discounts(2)	0.09	90.00	720,000
Proceeds, before expenses, to Sunshine Heart, Inc.	0.91	910.00	7,280,000

- (1) The public offering price and underwriting discount corresponds to (x) in respect of the Class A Units (i) a public offering price per share of common stock of \$0.99 and (ii) a public offering price per warrant of \$0.01 and (y) in respect of the Class B Units (i) a public offering price per share of Series E Preferred Stock of \$990 and (ii) a public offering price per warrant to purchase one share of common stock of \$0.01.
- (2) We have agreed to pay certain expenses of the underwriter in this offering. We refer you to "Underwriting" on page 58 for additional information regarding underwriting compensation.

Our Chief Executive Officer has indicated an interest in purchasing approximately \$100,000 of Class A Units in this offering on the same terms and at the same price as the Class A Units sold to the public in this offering. The underwriter will receive the same underwriting discount on any Class A Units purchased by our Chief Executive Officer as it will on any other Class A Units sold to the public in this offering.

**Neither the Securities and Exchange Commission or any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

The underwriter has the option to purchase up to (i) 1,200,000 additional shares of common stock, and/or (ii) additional warrants to purchase up to 1,200,000 additional shares of common stock solely to cover over-allotments, if any, at the public offering price per share of common stock and the public offering price per warrant set forth above less the underwriting discounts and commissions. The over-allotment option may be used to purchase shares of common stock or warrants, or any combination thereof, as determined by the underwriter, but such purchases cannot exceed an aggregate of 15% of the number of shares of common stock (including the number of shares of common stock issuable upon conversion of shares of Series E Preferred Stock) and 15% of the warrants sold in the primary offering. The over-allotment option is exercisable for 45 days from the date of this prospectus.

The underwriter expects to deliver the securities to purchasers on April 24, 2017.

*Sole Book-Running Manager*  
**Ladenburg Thalmann**

The date of this prospectus is April 19, 2017.

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**You should rely only on the information contained in this prospectus and any free-writing prospectus that we authorize to be distributed to you. We have not, and the underwriter has not, authorized anyone to provide you with information different from or in addition to that contained in this prospectus or any related free-writing prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. We are offering to sell, and are seeking offers to buy, the securities offered by this prospectus only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the securities. Our business, financial conditions, results of operations and prospects may have changed since that date.**

We obtained industry and market data used throughout and incorporated by reference into 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.

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## ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-1 that we filed with the Securities and Exchange Commission ("SEC"). It omits some of the information contained in the registration statement and reference is made to the registration statement for further information with regard to us and the securities being offered hereby. You should review the information and exhibits in the registration statement for further information about us and the securities being offered hereby. Statements in this prospectus concerning any document we filed as an exhibit to the registration statement or that we otherwise filed with the SEC are not intended to be comprehensive and are qualified by reference to the filings. You should review the complete document to evaluate these statements.

You should read this prospectus, any documents that we incorporate by reference in this prospectus and the additional information described below under "Where You Can Find Additional Information" and "Information Incorporated By Reference" before making an investment decision. You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized any other person to provide you with different information. If anyone provides you with additional, different or inconsistent information, you should not rely on it. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

You should not assume that the information in this prospectus or any documents we incorporate by reference herein is accurate as of any date other than the date on the front of such document. Our business, financial condition, results of operations and prospects may have changed since those dates.

## WHERE YOU CAN FIND ADDITIONAL INFORMATION

We file reports, proxy statements and other information with the SEC in accordance with the Securities Exchange Act of 1934, as amended (the "Exchange Act"). You may read and copy our reports, proxy statements and other information filed by us at the public reference room of the SEC located at 100 F Street, N.E., Washington, D.C. 20549, on official business days during the hours of 10 a.m. to 3 p.m. Please call the SEC at 1-800-SEC-0330 for further information about the public reference rooms. Our reports, proxy statements and other information filed with the SEC are available free of charge to the public over the Internet at the SEC's website at <http://www.sec.gov>.

## INFORMATION INCORPORATED BY REFERENCE

SEC rules allow us to "incorporate by reference" into this prospectus much of the information we file with the SEC, which means that we can disclose important information to you by referring you to those publicly available documents. The information that we incorporate by reference into this prospectus is considered to be part of this prospectus. These documents may include Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as proxy statements. You should read the information incorporated by reference because it is an important part of this prospectus.

This prospectus incorporates by reference the documents listed below, other than those documents or the portions of those documents deemed to be furnished and not filed in accordance with SEC rules:

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, filed with the SEC on March 8, 2017.
- our Current Reports on Form 8-K filed with the SEC on January 10, 2017, January 13, 2017, February 3, 2017, February 10, 2017, February 16, 2017, March 3, 2017, March 22, 2017, March 24, 2017, March 29, 2017 and April 11, 2017.

- 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.
- the description of our Series A Junior Participating Preferred Stock, par value \$0.0001 per share, in our registration statement on Form 8-A filed with the SEC on June 14, 2013.
- the description of our Series B-1 Convertible Preferred Stock, par value \$0.0001 per share, in our Current Report on Form 8-K filed with the SEC on October 31, 2016.
- the description of our Series C Convertible Preferred Stock, par value \$0.0001 per share, in our Current Report on Form 8-K filed with the SEC on October 31, 2016.
- the description of our Series D Convertible Preferred Stock in our Current Report on Form 8-K filed with the SEC on October 31, 2016.

Any statement contained in any document incorporated by reference herein shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or any prospectus modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

We also incorporate by reference any future filings, other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items, made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, in each case, other than those documents or the portions of those documents deemed to be furnished and not filed in accordance with SEC rules, until the offering of the securities under the registration statement of which this prospectus forms a part is terminated or completed. Information in such future filings updates and supplements the information provided in this prospectus. Any statements in any such future filings will be deemed to modify and supersede any information in any document we previously filed with the SEC that is incorporated or deemed to be incorporated herein by reference to the extent that statements in the later filed document modify or replace such earlier statements.

Because we are incorporating by reference future filings with the SEC, this prospectus is continually updated and later information filed with the SEC may update and supersede some of the information included or incorporated by reference in this prospectus. This means that you must look at all of the SEC filings that we incorporate by reference to determine if any of the statements in this prospectus or in any document previously incorporated by reference have been modified or superseded.

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

We will provide without charge to each person, including any beneficial owners, to whom this prospectus is delivered, upon his or her written or oral request, a copy of any or all reports or documents referred to above which have been or may be incorporated by reference into this prospectus but not delivered with this prospectus, excluding exhibits to those reports or documents unless they are specifically incorporated by reference into those documents. You may request a copy of these documents by writing or telephoning us at the following address.

Sunshine Heart, Inc.  
12988 Valley View Road  
Eden Prairie, Minnesota 55344  
(952) 345-4200  
Attention: Claudia Drayton  
Chief Financial Officer

## PROSPECTUS SUMMARY

*This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before deciding to invest in our securities, you should read this entire prospectus carefully, including our filings incorporated by reference herein to which we have referred you in the sections "Where You Can Find Additional Information", "Information Incorporated by Reference" and "Risk Factors", including our financial statements and related notes. Unless the context otherwise requires, references in this prospectus to the "Company," "SSH," "we," "us", and "our" refer to Sunshine Heart, Inc.*

### Company Overview

We are an early-stage medical device company focused on commercializing our Aquadex FlexFlow System.

In August 2016, we acquired our commercial product line, the Aquadex FlexFlow System (the "Aquadex Business"), from Gambro UF Solutions, Inc., a subsidiary of Baxter International Inc., a global leader in the hospital products and dialysis markets (collectively, "Baxter"). The Aquadex FlexFlow System (the "Aquadex FlexFlow") is indicated for temporary (up to eight hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy, and extended (longer than 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization.

Until July 2016, we were focused on developing the C-Pulse® Heart Assist System, or C-Pulse System, for treatment of Class III and ambulatory Class IV heart failure. On September 29, 2016, we announced a strategic refocus of our near-term strategy that includes halting clinical evaluations of the neuromodulation technology to fully focus our resources on our recently acquired Aquadex Business, taking actions to reduce our cash burn in connection with such strategic refocus and reviewing potential strategic alliances and financing alternatives.

You should read this prospectus, any documents that we incorporate by reference in this prospectus and the additional information described under "Where You Can Find Additional Information" and "Information Incorporated By Reference" before making an investment decision. You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized any other person to provide you with different information. If anyone provides you with additional, different or inconsistent information, you should not rely on it. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

### Corporate Information

Sunshine Heart, Inc. was incorporated in Delaware on August 22, 2002. We began operating our business in November 1999 through Sunshine Heart Company Pty Limited, which currently is a wholly owned Australian subsidiary of Sunshine Heart, Inc. In September of 2004, Chess Depositary Instruments or CDIs representing beneficial ownership of our common stock began trading on the Australian Securities Exchange or ASX under the symbol "SHC." Initially, each CDI represented one share of our common stock. In connection with the 1-for-200 reverse stock split we effected on January 27, 2012, we changed this ratio so that each CDI represented 1/200th of a share of our common stock. Our common stock began trading on the Nasdaq Capital Market on February 16, 2012. We delisted from the ASX 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](http://www.sunshineheart.com). Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current

Reports on Form 8-K and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Exchange Act will be made available free of charge on our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. 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 forms a part.

We qualify as an "emerging growth company" as defined in the Jumpstart our Business Startups Act of 2012 or the JOBS Act. Furthermore, we are and will remain a smaller reporting company as long as our public float remains less than \$75 million as of the last business day of our most recently-completed second fiscal quarter. An emerging growth company or smaller reporting company may take advantage of specified reduced reporting and other requirements that are otherwise applicable generally to U.S. public companies. These provisions include an exemption from the attestation requirement in the assessment of our internal control over financial reporting by our independent auditors pursuant to section 404 (b) of the Sarbanes-Oxley Act of 2002 ("SOX"), but do not preclude us from the requirement to make our own internal assessment of the effectiveness of our internal controls over financial reporting.

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 may take advantage of these provisions until December 31, 2017. 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.

## Recent Developments

### Nasdaq Compliance

On September 21, 2016, we received notice from the Listing Qualifications Staff (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") indicating that the Staff had determined to delist our securities from The Nasdaq Capital Market due to our then continued non-compliance with the minimum bid price requirement. We timely requested a hearing before the Nasdaq Hearings Panel (the "Panel"), which occurred on November 10, 2016.

On November 11, 2016, we received notice from the Staff that we no longer satisfied Nasdaq Listing Rule 5550(b) insofar as we did not expect to report stockholders' equity of at least \$2.5 million upon the filing of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2016 and that the deficiency could serve as an additional basis for the delisting of the Company's common stock from The Nasdaq Capital Market. On November 21, 2016, Nasdaq informed us that the Panel had granted us continued listing on The Nasdaq Capital Market while we implement our plan to regain compliance with the minimum bid price and minimum stockholders' equity requirements. The Panel granted us until January 30, 2017 to evidence a closing bid price of \$1.00 or more for a minimum of ten prior consecutive trading days. After implementing the reverse stock split described below, we received confirmation from Nasdaq on February 9, 2017 that we have regained compliance with the minimum bid price rule. The Panel has granted us until May 10, 2017 to evidence compliance with the \$2.5 million stockholder's equity requirement. While we believe that the proceeds from this offering will be sufficient to evidence compliance with the minimum stockholders' equity requirement of Nasdaq, we cannot assure you that we will be able to meet the minimum stockholders' equity requirement. If it appears to the Nasdaq staff that we will not be able to meet the minimum stockholders' equity or any other listing standard, our common stock may be subject to delisting.

## **Reverse Stock Split**

At a special meeting of our stockholders on January 9, 2017, our stockholders approved, among other things, a reverse stock split, and following such special meeting, our Board of Directors approved a 1-for-30 reverse split of our issued and outstanding shares of common stock. We filed with the Secretary of State of the State of Delaware a Certificate of Amendment to our Fourth Amended and Restated Certificate of Incorporation to effect the reverse stock split. The reverse stock split was effective as of 5:00 p.m. Eastern Time on January 12, 2017, and our common stock began trading on a split-adjusted basis on The Nasdaq Capital Market on January 13, 2017. The reverse stock split did not change the par value of our stock or the authorized number of common or preferred shares. All share and per share amounts in this prospectus and the registration statement of which it forms a part have been retroactively adjusted to reflect the reverse stock split for all periods presented.

## **Outstanding Preferred Stock**

As of March 23, 2017, all of our previously-outstanding shares of Series B-1 Convertible Preferred Stock, Series C Convertible Preferred Stock and Series D Convertible Preferred Stock have been converted in full and no shares of each such series remain outstanding.

## **Warrant Exercise Agreement**

On February 15, 2017, we entered into a letter agreement with the institutional investors (the "Investors") that hold the majority of our outstanding warrants (such warrants held by the Investors, the "Original Warrants"), to incent the cash exercise of these warrants on or before March 31, 2017 (the "Exercise Period"). In exchange for any such exercise, we agreed to provide the Investors a replacement warrant (the "Replacement Warrants") to purchase the same number of shares of common stock as were issued upon exercise of the Original Warrants, with an exercise price equal to the consolidated closing bid price of our common stock on the date of issuance. The agreement also (i) amends the definition of "Beneficial Ownership Limitation" in the Original Warrants to mean, solely for purposes of any exercises of Original Warrants that occur during the Exercise Period, "9.99%" and (ii) amends the Initial Exercise Date of the Original Warrants issued on November 3, 2016 and January 11, 2017 so that such Original Warrants are exercisable on or after the receipt of stockholder approval. Since such stockholder approval was received on January 9, 2017, such Original Warrants were immediately exercisable as of the date of the agreement. The Replacement Warrants are in the same form as the Original Warrants except the exercise price will not be subject to reduction for subsequent equity issuances and (ii) the Replacement Warrants will not allow the Investor to demand that we purchase the Replacement Warrants in the event of a fundamental transaction involving the Company. Concurrent with the signing of the agreement, the Investors exercised Original Warrants to purchase 104,419 shares of common stock for cash proceeds of approximately \$564,000, and we issued such Investors Replacement Warrants to purchase 104,419 shares of common stock at an exercise price of \$4.99 per share. From March 10, 2017 to March 28, 2017, the Investors exercised Original Warrants to purchase 763,498 shares of common stock for cash proceeds of approximately \$1,427,000, and we issued such Investors Replacement Warrants to purchase 763,498 shares of common stock with exercise prices equal to the closing consolidated bid price of our common stock available on the date of issuance (ranging from \$1.73 to \$3.77 per share). The Company entered into the letter agreement with the Investors to incent the exercise of the Original Warrants in order to receive the cash proceeds from the exercise of the Original Warrants and because the exercise of the Original Warrants would allow the Company to remove the warrant liability from its balance sheet and avoid future fair value adjustments and associated volatility in its financial statements. As of March 28, 2017, we have no Original Warrants held by the Investors remaining and all Replacement Warrants under the letter agreement have been issued.

## The Offering

<b>Issuer</b>	Sunshine Heart, Inc.
<b>Class A Units Offered</b>	We are offering 1,600,000 Class A Units. Each Class A Unit consists of one share of common stock and a warrant to purchase one share of our common stock (together with the shares of common stock underlying such warrants).
<b>Offering Price per Class A Unit</b>	\$1.00 combined price for each Class A Unit.
<b>Class B Units Offered</b>	We are also offering 6,400 Class B Units to purchasers who prefer not to beneficially own more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering. Each Class B Unit will consist of one share of Series E Preferred Stock, par value \$0.0001 per share, convertible into a number of shares of common stock equal to \$1,000 divided by a conversion price of \$1.00 (the "Conversion Price") and warrants to purchase a number of shares of our common stock equal to \$1,000 divided by the Conversion Price (together with the shares of common stock underlying such shares of Series E Preferred Stock and such warrants).
<b>Offering Price per Class B Unit</b>	\$1,000 combined price for each Class B Unit.
<b>Description of warrants</b>	The warrants will be exercisable beginning on the closing date and expire on the fifth anniversary of the closing date and have an initial exercise price per share equal to \$1.10 per share, subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock.
<b>Description of Series E Preferred Stock</b>	Each share of Series E Preferred Stock is convertible at any time at the holder's option into a number of shares of common stock equal to \$1,000 divided by the Conversion Price. Notwithstanding the foregoing, we shall not effect any conversion of Series E Preferred Stock, with certain exceptions, to the extent that, after giving effect to an attempted conversion, the holder of shares of Series E Preferred Stock (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of our common stock in excess of 4.99% (or, at the election of the purchaser, 9.99%) of the shares of our common stock then outstanding after giving effect to such exercise. For additional information, see "Description of Securities—Description of Capital Stock—Preferred Stock—Series E Preferred Stock" on page 52 of this prospectus.
<b>Shares of common stock underlying the warrants</b>	8,000,000 shares.



<b>Shares of common stock outstanding before this offering</b>	3,118,492 shares as of March 28, 2017.
<b>Shares of common stock to be outstanding after this offering</b>	4,718,492 shares (11,118,492 shares on an as-converted basis, assuming the conversion of the Series E Preferred Stock).
<b>Shares of Series E Preferred Stock outstanding before this offering</b>	None. We have no preferred stock outstanding prior to this offering.
<b>Shares of Series E Preferred Stock to be outstanding after this offering</b>	6,400 shares.
<b>Over-allotment option</b>	We have granted the underwriter an option to purchase additional shares of common stock equal to 15% of the shares (including shares of common stock underlying the Series E Preferred Stock) in the offering and/or additional warrants equal to 15% of the warrants in the offering at the public offering price per share of common stock and the public offering price per warrant set forth on the cover page hereto less the underwriting discounts and commission. This option is exercisable, in whole or in part, for a period of 45 days from the date of this prospectus.
<b>Market for the common stock</b>	Our common stock is listed on The Nasdaq Capital Market under the symbol "SSH". See " <a href="#">Recent Developments—Nasdaq Compliance</a> " above for important information about the listing of our common stock on The Nasdaq Capital Market.
<b>Use of Proceeds</b>	We intend to use the net proceeds of this offering to provide us with cash to fund our operations and grow our business, and to evidence compliance with the minimum stockholders' equity requirement of the Nasdaq Capital Market. See " <a href="#">Use of Proceeds</a> " herein.
<b>No listing of warrants</b>	We do not intend to apply for listing of the warrants on any securities exchange or trading system.
<b>No listing of Series E Preferred Stock</b>	We do not intend to apply for listing of the Series E Preferred Stock on any securities exchange or trading system.
<b>Potential Insider Participation</b>	Our Chief Executive Officer has indicated an interest in purchasing approximately \$100,000 of Class A Units in this offering on the same terms and at the same price as the Class A Units sold to the public in this offering. The underwriter will receive the same underwriting discount on any Class A Units purchased by our Chief Executive Officer as it will on any other Class A Units sold to the public in this offering.
<b>Risk Factors</b>	See " <a href="#">Risk Factors</a> " beginning on page 9 and other information included in this prospectus for a discussion of factors that you should consider carefully before deciding to invest in this offering.

Except as otherwise indicated, all information in this prospectus is based on 3,118,492 shares of common stock outstanding as of March 28, 2017 and excludes the shares of common stock being offered by this prospectus or issuable upon conversion of the Series E Preferred Stock or warrants being offered by this prospectus and also excludes the following:

- 57,102 shares of common stock issuable upon the exercise of outstanding stock options, having a weighted average exercise price of \$81.27 per share and 10,465 shares of common stock issuable upon the vesting of restricted stock units;
- 926,723 shares of our common stock issuable upon the exercise of outstanding warrants (other than the warrants offered hereby) with a weighted-average exercise price of \$4.05 per share;
- 363,501 shares of our common stock reserved for future issuance under our equity incentive plans; and
- 534,857 additional shares of our common stock to be reserved for future issuance under an equity incentive plan for which we expect to seek stockholder approval at our 2017 Annual Meeting.

## RISK FACTORS

*An investment in our securities has a high degree of risk. Before you invest you should carefully consider the risks and uncertainties described below and the other information in this prospectus. Any of the risks and uncertainties set forth herein could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the trading price or value of our securities. 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. As a result, you could lose all or part of your investment.*

### **Risks Related to Our Business**

***We have limited history of operations and limited experience in sales and marketing, and we might be unsuccessful in increasing our sales and cannot assure you that we will ever generate substantial revenue or be profitable.***

Prior to our acquisition of the Aquadex FlexFlow in August 2016, we did not have a product approved for commercial sale and focused our resources on developing, manufacturing and commercializing our C-Pulse System. On September 29, 2016, we announced a strategic refocus of our near-term strategy that includes halting all clinical evaluations to fully focus our resources on our recently acquired Aquadex FlexFlow, taking actions to reduce our cash burn in connection with such strategic refocus and reviewing potential strategic alliances and financing alternatives. Our business strategy depends in part on our ability to grow our Aquadex Business by establishing a sales force, selling our products to hospitals and other healthcare facilities and controlling costs all of which we may be unable to do. We have no prior experience with respect to manufacturing, sales and marketing. If we are unsuccessful at manufacturing, marketing and selling our Aquadex FlexFlow, our operations and potential revenues will be materially adversely affected.

***We have incurred operating losses since our inception and anticipate that we will continue to incur operating losses in the near-term. 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, 2016 expresses substantial doubt about our ability to continue as a going concern.***

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 \$15.8 million and \$26.6 million for the years ended December 31, 2016 and 2015, respectively. As of December 31, 2016, our accumulated deficit was \$169.0 million.

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, 2016 expresses substantial doubt about our ability to continue as a going concern. Prior to August 2016, we did not have any products approved for commercialization, generated only limited revenue from our clinical studies and had significant operating losses as we incurred costs associated with the conduct of clinical studies and our research and development programs for our C-Pulse System. We became a revenue generating company only a few months ago after acquiring the Aquadex Business in August 2016. We expect to incur additional losses in the near-term as we grow the Aquadex Business, including investments in expanding our sales and marketing capabilities, purchasing inventory, manufacturing components, and complying with the requirements related to being a U.S. public company listed on NASDAQ. To become and remain profitable, we must succeed in expanding the adoption and market acceptance of the Aquadex FlexFlow. This will require us to succeed in a range of challenging activities, including training personnel at hospitals and effectively and efficiently manufacturing, marketing and distributing the Aquadex FlexFlow and related components. There can be no assurance that we will succeed in

these activities, and we may never generate revenues sufficient to achieve profitability. If we do achieve profitability, we may not be able to sustain it.

***We believe that the net proceeds of this offering will be sufficient to fund our operations through 2017, and that we will need to raise additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations.***

We believe that the net proceeds of this offering will be sufficient to fund our operations through 2017, and that we will need to raise additional capital in the future. Changing circumstances may cause us to consume capital significantly faster than we currently anticipate and could adversely affect our ability to raise additional capital. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. 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.

***Failure to integrate our recently-acquired business into our operations successfully could adversely affect our business.***

Our integration of the operations of the Aquadex Business requires significant efforts and we may need to allocate more resources to integration and product development activities than originally anticipated. These efforts will result in additional expenses and involve significant amounts of management's time. Our failure to manage and coordinate the growth of the company could also have an adverse impact on our business. Investments in medical technology are inherently risky, and we cannot guarantee that the Aquadex Business will be profitable or successful or will not have a material unfavorable impact on us. Acquisitions can cause decrease in customer loyalty and product orders in connection with the change of ownership and management. Customers may be unwilling to continue doing business with us after our acquisition of the Aquadex Business from Baxter and some customers may not consent to the assignment of their contracts with Baxter or agree to enter into a new contract with us. Inconsistencies in standards, controls, procedures and policies may adversely affect our ability to achieve the anticipated benefits of the acquisition. We also could experience negative effects on our results of operations, cash flows, and financial condition from acquisition-related charges, amortization of intangible assets and asset impairment charges. These effects, individually or in the aggregate, could harm our business.

***Our near-term prospects are highly dependent on the development of a single product, the Aquadex FlexFlow. We face significant challenges in expanding market acceptance of the Aquadex FlexFlow, which could adversely affect our potential sales and revenues.***

Our near-term prospects are highly dependent on the development of a single product, the Aquadex FlexFlow, and we have no other commercial products or products in active development at this time. The established market or customer base for our Aquadex FlexFlow is limited and our success depends on our ability to increase adoption of the Aquadex FlexFlow. Acceptance of our product in the marketplace by health care providers is uncertain, and our failure to achieve sufficient market acceptance will significantly limit our ability to generate revenue and be profitable. Market

acceptance will require substantial marketing efforts and the expenditure of significant funds by us to inform health care providers of the benefits of using the Aquadex FlexFlow and to provide further training on its use. We may not be able to build key relationships with health care providers to drive further sales in the United States or sell the Aquadex FlexFlow outside the United States. Product orders may be cancelled, patients or customers currently using our products may cease to do so and patients or customers expected to begin using our products may not. Our ability to achieve acceptance of our Aquadex FlexFlow depends on our ability to demonstrate the safety, efficacy, ease-of-use and cost-effectiveness of the system. We may not be able to expand the adoption and market acceptance of the Aquadex FlexFlow to both the inpatient and outpatient markets and our potential sales and revenues could be harmed.

***We have no commercial manufacturing experience and could experience difficulty in producing the Aquadex FlexFlow and related components or may need to depend on third parties for manufacturing.***

We have no experience in commercial manufacturing and no experience in commercially manufacturing the Aquadex FlexFlow and related components. As a result, we may not be able to develop and implement efficient, low-cost manufacturing capabilities and processes that will enable us to manufacture the Aquadex FlexFlow or related components in significant volumes, while meeting the legal, regulatory, quality, price, durability, engineering, design and production standards required to market our products successfully. In addition, we depend upon third parties to manufacture and supply components for the Aquadex FlexFlow. We are party to a commercial manufacturing and supply agreement with Baxter which requires Baxter to manufacture Aquadex Blood Sets and Aquadex Catheters for a period of 18 months following our acquisition of the Aquadex Business. There is no such agreement relating to the manufacturing of Consoles. We plan to transfer Console manufacturing to us or a qualified contract manufacturer by mid-year 2017 and Aquadex Blood Set and Catheter manufacturing activities from Baxter to us or a qualified contract manufacturer by the end of 2017, but we may experience difficulties in doing so. Furthermore, we may not be able to contract for such manufacturing on terms favorable to us or at all. If we experience difficulties in transitioning manufacturing operations, we may experience delays in providing products and services to our customers, and our business could be harmed.

***We depend upon third-party suppliers, including single source suppliers to us and our customers, making us vulnerable to supply problems and price fluctuations.***

We will rely on third-party suppliers, including single source suppliers, to provide us with certain components of the Aquadex FlexFlow and to provide key components or supplies for use with our products. We depend on our suppliers to provide us and our customers with materials in a timely manner that meet our and their quality, quantity and cost requirements. The forecasts of demand we use to determine order quantities and lead times for components purchased from outside suppliers may be incorrect. Our failure to obtain required components or subassemblies when needed and at a reasonable cost would adversely affect our business. These suppliers may encounter problems during manufacturing for a variety of reasons, any of which could delay or impede their ability to meet our demand. Any difficulties in locating and hiring third-party manufacturers, or in the ability of third-party manufacturers to supply quantities of our products at the times and in the quantities we need, could have a material adverse effect on our business.

***If we cannot develop adequate distribution, customer service and technical support networks, then we may not be able to market and distribute the Aquadex system effectively and our sales and revenues will suffer.***

Our strategy requires us to provide a significant amount of customer service and maintenance and other technical service to our customers. To provide these services, we have begun, and will need to continue, to develop a network of distribution and a staff of employees and independent contractors in

each of the areas in which we intend to operate. We cannot assure that we will be able to organize and manage this network on a cost-effective basis. If we cannot effectively organize and manage this network, then it may be difficult for us to distribute our products and to provide competitive service and support to our customers, in which case customers may be unable, or decide not, to order our products and our sales and revenues will suffer.

***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 is intense and is expected to increase. Our Aquadex FlexFlow mainly competes against pharmacological therapies, diuretics, 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 life insurance on the lives of any of the members of our senior management. The loss of key personnel for any reason or our inability to hire, retain and motivate additional qualified personnel in the future could prevent us from sustaining or growing our business.

***Significant additional governmental regulation could subject us to unanticipated delays which would adversely affect our sales and revenues.***

Our business strategy depends in part on our ability to expand the use of the Aquadex FlexFlow in the market as quickly as possible. Health care laws in the United States and other countries are subject to ongoing changes, including changes to the amount of reimbursement for hospital services. Additional laws and regulations, or changes to existing laws and regulations that are applicable to our business may be enacted or promulgated, and the interpretation, application or enforcement of the existing laws and regulations may change. Legislative proposals can substantially change the way health care is financed by both governmental and private insurers and may negatively impact payment rates for our system. We cannot predict the nature of any future laws, regulations, interpretations, applications or enforcements or the specific effects any of these might have on our business. However, in the United States and international markets, we expect that both government and third-party payers will continue to attempt to contain or reduce the costs of health care by challenging the prices charged, or deny coverage, for health care products and services. Any future laws, regulations, interpretations, applications or enforcements could delay or prevent regulatory approval or clearance of our Aquadex FlexFlow and our ability to market our Aquadex FlexFlow. Moreover, changes that result in our failure to comply with the requirements of applicable laws and regulations could result in the types of enforcement actions by the U.S. Food and Drug Administration (the "FDA") and/or other agencies as described above, all of which could impair our ability to have manufactured and to sell the affected products.

In the United States, the Aquadex FlexFlow is purchased primarily by customers, such as hospitals or other health care providers. Customers bill various third-party payers for covered Aquadex FlexFlow services provided to patients. These payers, which include federal health care programs (e.g., Medicare and Medicaid), state health care programs, private health insurance companies and managed care organizations, would then reimburse our customers based on established payment formulas that take into account part or all of the cost associated with these devices and the related procedures performed.

While the agency responsible for administering the Medicare program, the Centers for Medicare and Medicaid Services, has not issued a favorable national coverage determination under its Investigational Device Exception Studies Program for ultrafiltration using the Aquadex FlexFlow, a number of private insurers have approved reimbursement for Aquadex FlexFlow for specific indications and points of service. In addition, patients and providers may see insurance coverage on a case-by-case basis. We are exploring the ability to increase the range of coverage for uses of Aquadex FlexFlow, such as use in the outpatient setting and use for decompensated heart failure and other indicated uses under its approved labeling, although we may not be successful in doing so.

The Patient Protection and Affordable Care Act of 2010, as modified by the Health Care and Education Reconciliation Act of 2010 (collectively, the "Health Reform Laws"), provides those states that expand their Medicaid coverage to otherwise eligible state residents with incomes at or below 138% of the federal poverty level with an increased federal medical assistance percentage, effective January 1, 2014, when certain conditions are met. On June 28, 2012, the United States Supreme Court upheld the individual mandate of the Health Reform Laws but partially invalidated the expansion of Medicaid. The ruling on Medicaid expansion allows states to elect not to participate in the expansion-and to forego funding for the Medicaid expansion-without losing their existing Medicaid funding. States will be expected to pay for part of costs of Medicaid expansion beginning in 2017. In

light of the current political environmental and the possibility that proposed legislation may significantly impact Medicaid funding to states, it is unclear how states will pay their share of these additional Medicaid costs and providers would be able to continue to receive reimbursement for services to all patients receiving treatment using the Aquadex FlexFlow who are currently enrolled in Medicaid.

***We enrolled patients in studies for the C-Pulse System through February 2016 and continue to have reporting obligations related to two open studies for the C-Pulse.***

Conducting clinical studies is a complex and uncertain process. Clinical trials are subject to extensive recordkeeping and reporting requirements. Any clinical trials must be conducted under the oversight of an institutional review board for the relevant clinical trial sites and must comply with FDA regulations, including, but not limited to, those relating to current good clinical practices. Each trial must obtain the written informed consent of patients in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. The testing company, the FDA or the IRB may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Similarly, in Europe, the clinical study must be approved by a local ethics committee and, in some cases, including studies with high-risk devices, by the ministry of health in the applicable country. Patients may experience serious adverse events or side effects during the study, which, whether or not related to our system, could cause the FDA or other regulatory authorities to investigate and potentially assess regulatory penalties. Any regulatory penalties assessed for failure to comply with the foregoing requirements could harm our business, results of operations, financial condition and prospects and cause us to seek additional funding.

***Product defects, including lawsuits for product liability, 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 Aquadex FlexFlow or any related components could result in significant costs, as well as negative publicity and damage to our reputation that could reduce demand for our products. Additionally, the C-Pulse 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 this system have a high risk of suffering adverse outcomes, regardless of the safety or efficacy of our system. In addition, because this system was implanted in a limited number of patients, 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. Personal injuries relating to the use of our products 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.

We may be held liable if any product we develop or 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 products will not protect us from any such liability. We carry product liability insurance with a \$5 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 approved product. 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 interest in our registry studies, decreased demand for our system, if approved for commercialization, injury to our reputation, diversion of management's attention from operating our business, withdrawal of study participants, significant costs of related litigation, loss of revenue or the inability to commercialize our products.

***We may face significant risks associated with international operations, which could have a material adverse effect on our business, financial condition and results of operations.***

We expect to manufacture and to market our products globally. Our international operations are subject to a number of risks, including the following: fluctuations in exchange rates of the United States dollar could adversely affect our results of operations, we may face difficulties in enforcing and collecting accounts receivable under some countries' legal systems, local regulations may restrict our ability to sell our products, have our products manufactured or conduct other operations, political instability could disrupt our operations, some governments and customers may have longer payment cycles, with resulting adverse effects on our cash flow, and some countries could impose additional taxes or restrict the import of our products. Any one or more of these factors could increase our costs, reduce our revenues, or disrupt our operations, which could have a material adverse effect on our business, financial condition and results of operations.

***If we are not able to maintain sufficient quality controls, then the approval or clearance of our products by the European Union, the FDA or other relevant authorities could be withdrawn, delayed or denied and our sales and revenues will suffer.***

Approval or clearance of our products could be withdrawn, delayed or denied by the European Union, the FDA and the relevant authorities of other countries if our manufacturing facilities do not comply with their respective manufacturing requirements. The European Union imposes requirements on quality control systems of manufacturers, which are inspected and certified on a periodic basis and may be subject to additional unannounced inspections. Failure by our manufacturers to comply with these requirements could prevent us from marketing our products in the European Community. The FDA also imposes requirements through quality system requirements, or QSR, regulations, which include requirements for good manufacturing practices, or GMP. Failure by our manufacturers to comply with these requirements could prevent us from obtaining FDA approval of our products and from marketing such products in the United States. Although the manufacturing facilities and processes that we use to manufacture our products have been inspected and certified by a worldwide testing and certification agency (also referred to as a notified body) that performs conformity assessments to European Union requirements for medical devices, they have not been inspected by the FDA. A "notified body" is a group accredited and monitored by governmental agencies that inspects manufacturing facilities and quality control systems at regular intervals and is authorized to carry out unannounced inspections. We cannot be sure that any of the facilities or processes we use will comply or continue to comply with their respective requirements on a timely basis or at all, which could delay or prevent our obtaining the approvals we need to market our products in the European Community and the United States.

To market our products in the European Community, the United States and other countries, where approved, manufacturers of such products must continue to comply or ensure compliance with the relevant manufacturing requirements. Although we cannot control the manufacturers of our products, if we choose to subcontract manufacturing to a contract manufacturer, we may need to expend time, resources and effort in product manufacturing and quality control to assist with their continued compliance with these requirements. If violations of applicable requirements are noted during periodic

inspections of the manufacturing facilities of our manufacturers or we fail to address issues raised by the FDA in these inspections, then we may not be able to continue to market the products manufactured in such facilities and our revenues may be materially adversely affected.

***If we violate any provisions of the Federal Food, Drug, and Cosmetic Act ("FDC Act") or any other statutes or regulations, then we could be subject to enforcement actions by the FDA or other governmental agencies.***

We face a significant compliance burden under the FDC Act and other applicable statutes and regulations which govern the testing, labeling, storage, record keeping, distribution, sale, marketing, advertising and promotion of our medically approved products.

If we violate the FDC Act or other regulatory requirements at any time during or after the product development and/or approval process, we could be subject to enforcement actions by the FDA or other agencies, including: fines, injunctions, civil penalties, recalls or seizures of products, total or partial suspension of the production of our products, withdrawal of any existing approvals or pre-market clearances of our products, refusal to approve or clear new applications or notices relating to our products, recommendations that we not be allowed to enter into government contracts and criminal prosecution. Any of the above could have a material adverse effect on our business, financial condition and results of operations.

***We cannot assure you that our products will be safe or that there will not be serious injuries or product malfunctions. Further, we are required under applicable law to report any circumstances relating to our medically approved products that could result in deaths or serious injuries. These circumstances could trigger recalls, class action lawsuits and other events that could cause us to incur expenses and may also limit our ability to generate revenues from such products.***

We cannot assure you that our products will prove to be safe or that there will not be serious injuries or product malfunctions, which could trigger recalls, class action lawsuits and other events that could cause us to incur significant expenses, limit our ability to market our products and generate revenues from such products or cause us reputational harm.

Under the FDC Act, we are required to submit medical device reports, or MDRs, to the FDA to report device-related deaths, serious injuries and malfunctions of medically approved products that could result in death or serious injury if they were to recur. Depending on their significance, MDRs could trigger events that could cause us to incur expenses and may also limit our ability to generate revenues from such products, such as the following: information contained in the MDRs could trigger FDA regulatory actions such as inspections, recalls and patient/physician notifications, because the reports are publicly available, MDRs could become the basis for private lawsuits, including class actions, and if we fail to submit a required MDR to the FDA, the FDA could take enforcement action against us.

If any of these events occur, then we could incur significant expenses and it could become more difficult for us to market and sell our products and to generate revenues from sales. Other countries may impose analogous reporting requirements that could cause us to incur expenses and may also limit our ability to generate revenues from sales of our products.

***We face significant uncertainty in the industry due to government healthcare reform.***

The Patient Protection and Affordable Care Act, as amended, (the "Affordable Care Act") as well as other healthcare reform, including possible repeal of the Affordable Care Act, may have a significant impact on our business. The impact of the Affordable Care Act on the health care industry is extensive and includes, among other things, the federal government assuming a larger role in the health care system, expanding healthcare coverage of United States citizens and mandating basic healthcare benefits. The Affordable Care Act contains many provisions designed to generate the revenues

necessary to fund the coverage expansions and to reduce costs of Medicare and Medicaid, including imposing a 2.3% excise tax on domestic sales of many medical devices by manufacturers that began in 2013. Although a moratorium was placed on the medical device excise tax in 2016 and 2017, if it is reinstated, it may adversely affect our sales and the cost of goods sold.

The Affordable Care Act includes a Hospital Readmission Reduction program and is designed to reduce payments to hospitals with excess heart failure readmissions, among other conditions. The penalty to hospitals can be significant, as much as 3% of total Medicare reimbursement. We believe the Aquadex FlexFlow may offer hospitals an economic benefit for using the device on a regular basis for in-patient or out-patient usage; however, if the Hospital Readmission Reduction program is repealed, hospitals may not be as inclined to take measures to reduce readmissions.

In addition, any healthcare reforms enacted in the future may, like the Affordable Care Act, be phased in over a number of years but, if enacted, could reduce our revenue, increase our costs, or require us to revise the ways in which we conduct business or put us at risk for loss of business. In addition, our results of operations, financial position and cash flows could be materially adversely affected by changes under the Affordable Care Act and changes under any federal or state legislation adopted in the future.

Moreover, the Physician Payment Sunshine Act (the Sunshine Act), which was enacted by Congress as part of the Patient Protection and Affordable Care Act on March 23, 2010, requires medical device companies to track and publicly report, with limited exceptions, all payments and transfers of value to physicians and teaching hospitals in the U.S. Implementing regulations for these tracking and reporting obligations were finalized in 2013, and companies are now required to track payments made since August 1, 2013. If we fail to comply with the data collection and reporting obligations imposed by the Sunshine Act, we may be subject to substantial civil monetary penalties.

***We are subject, directly or indirectly, to United States federal and state healthcare 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.***

Our operations are directly, or indirectly through customers, subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the Stark law and federal False Claims Act. These laws may impact, among other things, our sales, 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 healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare 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 healthcare industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs. The physician self-referral laws, commonly referred to as the Stark law is a strict liability statute that generally prohibits physicians from referring Medicare patients to providers of "designated health services," with whom the physician or the physician's immediate family member has an ownership interest or

compensation arrangement, unless an applicable exception applies. Moreover, many states have adopted or are considering adopting similar laws, some of which extend beyond the scope of the Stark law to prohibit the payment or receipt of remuneration for the prohibited referral of patients for designated healthcare services and physician self-referrals, regardless of the source of the payment for the patient's care. If it is determined that any of the relationships we may have with physicians violate the Stark law or similar statutes, we could become subject to civil and criminal penalties. The imposition of any such penalties could harm our business.

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 "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 healthcare companies to have to defend a False Claim Act action. 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. Various states have also enacted laws modeled after the federal False Claims Act.

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 or other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring of our operations.

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

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

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

## **Risks Related 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 Aquadex FlexFlow and related components. As of December 31, 2016, we owned over 35 issued patents and 13 pending patent applications in the United States and in foreign jurisdictions related to our C-Pulse System and had 2 pending applications for neuromodulation. We estimate that most of our currently issued U.S. patents will expire between approximately 2021 and 2027. Given the strategic refocus away from C-Pulse and towards Aquadex FlexFlow, we have chosen to limit the maintenance of issued C-Pulse related patents to those innovations that are of the highest value. Further, we have elected to emphasize a few of the most critical jurisdictions rather than maintain the earlier approach that involved multiple countries.

On August 5, 2016, upon closing of our acquisition of the Aquadex Business, we entered into a patent license agreement with Baxter, pursuant to which we obtained, for no additional consideration, a world-wide license to 49 exclusively licensed and 9 non-exclusively licensed patents used in connection with the Aquadex FlexFlow to make, have made, use, sell, offer for sale and import, the Aquadex FlexFlow in the "field of use." The "field of use" is defined as system and apparatus only capable of performing isolated ultrafiltration for treatment of congestive heart failure, and methods to the extent used therein (excluding system, apparatus, or methods performing any kind of renal therapy or dialysis and/or any system capable of providing substitution fluid). The license is exclusive, with respect to some patents, and non-exclusive, with respect to other patents. Under the patent license agreement, Baxter has agreed to use commercially reasonable efforts to continue maintenance of seven "required maintenance patents," and we have agreed to reimburse Baxter for all fees, costs, and expenses (internal or external) incurred by Baxter in connection with such continued maintenance. The rights granted to us under the patent license agreement will automatically revert to Baxter in the event we cease operation of the Aquadex Business or we file for, or have filed against us, or otherwise undertake any bankruptcy, reorganization, insolvency, moratorium, or other similar proceeding. In addition, for two years following the closing, the patent license agreement is not assignable by us (including in connection with a change of control) without Baxter's prior written consent. We estimate that the patents licensed from Baxter will expire between approximately 2020 and 2025.

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 our business.

***Intellectual property litigation could be costly and disruptive to us.***

In recent years, there has been significant litigation involving 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:

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

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

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

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

***Our products 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 products.***

Our commercial success depends on our ability to increase adoption of the Aquadex Business 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 or derivation proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions.

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

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

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

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

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

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

## Risks Related to Our Common Stock

***Nasdaq may delist our common stock from its exchange which could limit your ability to make transactions in our securities and subject us to additional trading restrictions.***

On September 21, 2016, we received notice from the Staff of Nasdaq indicating that the Staff had determined to delist our securities from The Nasdaq Capital Market due to our then continued non-compliance with the minimum bid price requirement. We timely requested a hearing before the Panel, which occurred on November 10, 2016. On November 11, 2016, we received notice from the Staff that we no longer satisfied Nasdaq Listing Rule 5550(b) insofar as we did not expect to report stockholders' equity of at least \$2.5 million upon the filing of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2016 and that the deficiency could serve as an additional basis for the delisting of the Company's common stock from The Nasdaq Capital Market. On November 21, 2016, Nasdaq informed us that the Panel had granted us continued listing on The Nasdaq Capital Market while we implement our plan to regain compliance with the minimum bid price and minimum stockholders' equity requirements. The Panel granted us until January 30, 2017 to evidence a closing bid price of \$1.00 or more for a minimum of ten prior consecutive trading days and until March 20, 2017 to evidence compliance with the \$2.5 million stockholder's equity requirement.

On December 9, 2016, we provided notice of our intention to call a special meeting of our stockholders on January 9, 2017 to, among other things, obtain stockholder approval for a reverse stock split. At a special meeting of our stockholders on January 9, 2017, our stockholders approved, among other things, a reverse stock split, and following such special meeting, our Board of Directors approved a 1-for-30 reverse split of the Company's issued and outstanding shares of common stock. The reverse stock split became effective as of 5:00 p.m. Eastern Time on January 12, 2017, and the Company's common stock began trading on a split-adjusted basis on The Nasdaq Capital Market on January 13, 2017. We received confirmation from Nasdaq on February 9, 2017 that we have regained compliance with the minimum bid price rule.

On March 28, 2017, Nasdaq granted our request to extend the deadline to comply with the \$2.5 million stockholders' equity requirement to May 10, 2017.

We believe that the proceeds from this offering will be sufficient to evidence compliance with the minimum stockholders' equity requirements of Nasdaq; however, despite our efforts, we cannot assure you that we will be able to meet the minimum stockholders' equity or other listing requirements. If it appears to the Nasdaq staff that we will not meet the minimum stockholders' equity or any other listing standard, our common stock may be subject to delisting. If our common stock is delisted, Baxter, pursuant to the asset purchase agreement for the Aquadex Business, has the right to require us to repurchase, in cash, all or part of the common stock held by Baxter at a price equal to their fair market value, as determined by a third party appraiser. In addition, our common stock would likely then trade only in the over-the-counter market. If our common stock were to trade on the over-the-counter market, selling our common stock could be more difficult because smaller quantities of shares would likely be bought and sold and transactions could be delayed, and we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity with respect to our securities;
- a determination that our shares are a "penny stock," which will require brokers trading in our securities to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our securities;
- a reduced amount of news and analyst coverage for our Company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.



These factors could result in lower prices and larger spreads in the bid and ask prices for our common stock and would substantially impair our ability to raise additional funds and could result in a loss of institutional investor interest and fewer development opportunities for us.

In addition to the foregoing, if our common stock is delisted from NASDAQ and it trades on the over-the-counter market, the application of the "penny stock" rules could adversely affect the market price of our common stock and increase the transaction costs to sell those shares. The SEC has adopted regulations which generally define a "penny stock" as an equity security that has a market price of less than \$5.00 per share, subject to specific exemptions. The closing price of our common stock on April 8, 2017 was \$1.35. If our common stock is delisted from NASDAQ and it trades on the over-the-counter market at a price of less than \$5.00 per share, our common stock would be considered a penny stock. The SEC's penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document that provides information about penny stocks and the risks in the penny stock market. The broker-dealer must also provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and the salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. In addition, the penny stock rules generally require that before a transaction in a penny stock occurs, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's agreement to the transaction. If applicable in the future, these rules may restrict the ability of brokers-dealers to sell our common stock and may affect the ability of investors to sell their shares, until our common stock no longer is considered a penny stock.

***The reverse split of our common stock could decrease our total market capitalization and increase the volatility of our stock price.***

We effected 1-for-30 reverse split of our issued and outstanding shares of common stock as of 5:00 p.m. Eastern Time on January 12, 2017, and our common stock began trading on a split-adjusted basis on The Nasdaq Capital Market on January 13, 2017. There can be no assurance that the total market capitalization of our common stock after the reverse stock split will be equal to or greater than the total market capitalization before the reverse stock split or that the per share market price of our common stock following the reverse stock split will increase in proportion to the reduction in the number of shares of common stock outstanding before the reverse stock split. Furthermore, a decline in the market price of our common stock after the reverse stock split may result in a greater percentage decline than would occur in the absence of a reverse stock split, and the liquidity of our common stock could be adversely affected following such a reverse stock split.

***The number of shares of common stock underlying 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 and conversion of such outstanding convertible securities will cause dilution to the existing holders of our common stock and to investors in this offering.***

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

As of March 28, 2017, we have warrants to purchase 926,723 shares of common stock outstanding. To the extent our outstanding warrants are exercised for shares of common stock, holders of our common stock and investors in this offering will experience further dilution.

***The rights of holders of our capital stock will be subject to, and could be adversely affected by, the rights of holders of our outstanding preferred stock any stock that may be issued in the future.***

Our board of directors has authority, without further stockholder approval, to issue additional 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.

The rights, preferences and privileges of the Series E Preferred Stock to be issued in this offering are described under "Description of Securities—Description of Capital Stock—Preferred Stock—Series E Preferred Stock" herein. As described therein, upon liquidation, dissolution or winding-up of the Company, the holders of Series E Preferred Stock are entitled to participate on an as-converted-to-common stock basis with holders of the common stock in any distribution of assets of the Company.

Our board of directors may issue additional series of preferred stock in the future pursuant to this authority. As a result, the rights of holders of our capital stock will be subject to, and could be adversely affected by, the rights of holders of any stock that may be issued in the future.

***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.***

We effected 1-for-30 reverse split of our issued and outstanding shares of common stock as of 5:00 p.m. Eastern Time on January 12, 2017, and our common stock began trading on a split-adjusted basis on The Nasdaq Capital Market on January 13, 2017.

Because the number of authorized shares of our common stock was not reduced proportionately, the reverse stock split increased our board of directors' ability to issue authorized and unissued shares without further stockholder action. As of the date of this prospectus, our certificate of incorporation provides for 100,000,000 shares of authorized common stock and 40,000,000 shares of authorized preferred stock. As of March 28, 2017, we had 3,118,492 shares of common stock outstanding, 994,290 shares reserved for issuance upon the exercise or vesting of outstanding warrants, options and restricted stock units, and 363,501 shares of common stock reserved for future issuance under the Company's equity incentive plans. We expect to request stockholder approval at our 2017 Annual Meeting of a new equity incentive plan, which will include an additional share reserve of 534,857.

With respect to authorized but unissued and unreserved shares, we could also use such shares to oppose a hostile takeover attempt or delay or prevent changes in control or changes in or removal of management. The issuance of additional shares of common stock or securities convertible into 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 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.

***The price of our common stock may fluctuate significantly, and this may make it difficult for you to resell the common stock you want or at prices you find attractive.***

The price of our common stock constantly changes. The price of our common stock could fluctuate significantly for many reasons, including the following:

- future announcements concerning us, including our clinical and product development strategy, or our competitors;
- regulatory developments, disclosure regarding completed, ongoing or future clinical studies and enforcement actions bearing on advertising, marketing or sales;
- reports and recommendations of analysts and whether or not we meet the milestones and metrics set forth in such reports;
- introduction of new products;
- acquisition or loss of significant manufacturers, distributors or suppliers or an inability to obtain sufficient quantities of materials needed to manufacture our system;
- quarterly variations in operating results, which we have experienced in the past and expect to experience in the future;
- business acquisitions or divestitures;
- changes in governmental or third-party reimbursement practices;
- fluctuations of investor interest in the medical device sector; and
- fluctuations in the economy, world political events or general market conditions.

In addition, stock markets in general, and the market for shares of health care stocks in particular, have experienced extreme price and volume fluctuations in recent years, fluctuations that frequently have been unrelated to the operating performance of the affected companies. These broad market fluctuations may adversely affect the market price of our common stock. The market price of our common stock could decline below its current price and the market price of our shares may fluctuate significantly in the future. These fluctuations may be unrelated to our performance. We expect that the market price of our common stock will continue to fluctuate.

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

As of December 31, 2016, we had U.S. net operating loss ("NOL") carryforwards of approximately \$110.6 million for U.S. income tax purposes, which expire from 2024 through 2034. 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, 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, 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, 2016, we had tax losses in the Commonwealth of Australia of approximately AU\$49.0 million. Continuing utilization of carryforward tax losses in Australia may also be affected by the issuance of our common stock. This is because one test for carrying forward tax losses in Australia from year to year requires continuity of ultimate ownership (subject to the relevant tests in Australian tax law) of more than 50% between the loss year and the income year in which the loss is claimed.

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

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

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

***We will continue to incur increased costs as a result of being a U.S. reporting company.***

In connection with the effectiveness of our registration statement on Form 10, as of February 14, 2012, we became subject to the periodic reporting requirements of the Exchange Act. Although we were previously listed on the Australian Securities Exchange and had been required to file financial information and make certain other filings with the Australian Securities Exchange, our status as a U.S. reporting company under the Exchange Act has caused us, and will continue to cause us, to incur additional legal, accounting and other expenses that we did not previously incur, including costs related to compliance with the requirements of SOX and the listing requirements of The Nasdaq Capital Market. We expect these rules and regulations will continue to increase our legal and financial compliance costs and 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. Furthermore, now that we are a revenue-generating company following the acquisition of the Aquadex Business in August 2016, our costs to comply with regulations applicable to U.S. reporting companies may further increase. 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 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 will no longer qualify as an "emerging growth company" on or before December 31, 2017, although we will remain a "smaller reporting company" as long as our public float remains less than \$75 million as of the last business day of our most recently-completed second fiscal quarter.

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. It may be more difficult for us to manage our internal control over financial reporting following our acquisition of the Aquadex Business now that we are a revenue generating company. Investors could lose confidence in our financial reports, and the value of our common stock may be harmed, if our internal controls over financial reporting are found not to be effective by management or by an independent registered public accounting firm or if we make disclosure of existing or potential material weaknesses in those controls.

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

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, as amended (the "DGCL"), or (iv) any other action asserting a claim governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions described above. This forum selection provision may limit our stockholders' ability to obtain a judicial forum that they find favorable for disputes with us or our directors, officers or other employees.

***Our certificate of incorporation and bylaws, as well as certain provisions of the DGCL, may delay or deter a change in control transaction.***

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

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

We are an "emerging growth company" and a "smaller reporting company" under federal securities laws. For as long as we continue to be an emerging growth company or a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies, including not being required to comply with the external auditor

attestation requirements of Section 404 of SOX, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and, for emerging growth companies, exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. The JOBS Act also permits emerging growth companies to take advantage of an extended transition period to comply with new or revised accounting standards applicable to U.S. public companies. We will be an emerging growth company until December 31, 2017, although we will remain a smaller reporting company so long as our public float remains less than \$75 million as of the last business day of our most recently-completed second fiscal quarter. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline or be more volatile.

As explained above, Section 102(b)(1) of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. An emerging growth company can delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period, and as a result of this election, our financial statements may not be comparable to those of companies that comply with public company effective dates for new or revised accounting standards for U.S. public companies. We will be an emerging growth company until December 31, 2017 and after such date can no longer take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act.

## **Risks Relating to this Offering**

***If you purchase Units in this offering, you will incur immediate and substantial dilution in the net tangible book value of your shares.***

The public offering price of the Units is substantially higher than the net tangible book value per share of our common stock. Investors purchasing Units in this offering will pay a price per share of common stock that substantially exceeds the pro forma book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing Units in this offering will incur immediate dilution of \$0.37 per share of common stock, based on a public offering price of \$1.00 per Class A Unit. See "Dilution."

As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of a liquidation of our company.

***Because our management will have broad discretion and flexibility in how the net proceeds from this offering are used, our management may use the net proceeds in ways with which you disagree or which may not prove effective.***

We currently intend to use the net proceeds from this offering as discussed under "Use of Proceeds" in this prospectus. We have not allocated specific amounts of the net proceeds from this offering for any of the foregoing purposes. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds of this offering. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the net proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for us. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flow.

***The Series E Preferred Stock and the warrants are unlisted securities and there is no public market for them.***

There is no established public trading market for the Series E Preferred Stock or the warrants, and we do not expect a market to develop. In addition, neither the Series E Preferred Stock nor the warrants are listed, and we do not intend to apply for listing of the Series E Preferred Stock or the warrants on any securities exchange or trading system. Without an active market, the liquidity of the Series E Preferred Stock and the warrants is limited, and investors may be unable to liquidate their investments in the Series E Preferred Stock or the warrants.

***The warrants may not have any value.***

The warrants will be exercisable for five years from the closing date at an initial exercise price of \$1.10 per share. In the event that the price of a share of our common stock does not exceed the exercise price of the warrants during the period when the warrants are exercisable, the warrants may not have any value.

***The warrants purchased in this offering do not entitle the holder to any rights as common stockholders until the holder exercises the warrant for shares of our common stock.***

Until you acquire shares of our common stock upon exercise of your warrants purchased in this offering, such warrants will not provide you any rights as a common stockholder, except as set forth in the warrants. Upon exercise of your warrants purchased in this offering, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs on or after the exercise date.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the documents that we incorporate by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but are not always, made through the use of words or phrases such as "anticipates," "estimates," "plans," "projects," "continuing," "ongoing," "expects," "management believes," "we believe," "we intend" and similar words or phrases. Accordingly, these statements involve estimates, assumptions and uncertainties which could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this prospectus, and in particular those factors included in the section entitled "Risk Factors."

Because the factors referred to in the preceding paragraph could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements we make, you should not place undue reliance on any such forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

You should carefully read this prospectus and any related free writing prospectus, together with the information incorporated herein or therein by reference as described under the section titled "Information Incorporated By Reference," and with the understanding that our actual future results may materially differ from what we expect.

Except as required by law, forward-looking statements speak only as of the date they are made, and we assume no obligation to update any forward-looking statements publicly, or to update the reasons why actual results could differ materially from those anticipated in any forward-looking statements, even if new information becomes available.



## USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of the securities offered by this prospectus in this offering will be approximately \$7.0 million after deducting commissions and estimated offering expenses payable by us.

The purpose of this offering is to provide us with cash to fund our operations and grow our business, and to evidence compliance with the minimum stockholders' equity requirement of The Nasdaq Capital Market. We believe that the proceeds from this offering will be sufficient to evidence compliance with the minimum stockholders' equity requirements of Nasdaq; however, despite our efforts, we cannot assure you that Nasdaq will agree that we have regained compliance. We intend to use the net proceeds from this offering for working capital needs for our recently-acquired Aquadex product and for general corporate purposes. We purchased the assets of Aquadex™ FlexFlow product on August 5, 2016. The Aquadex FlexFlow product is a medical device that can be used to treat heart failure patients with fluid overload.

The allocation of the net proceeds of the offering set forth above represents our estimates based upon our current plans and assumptions regarding industry and general economic conditions, our future revenues and expenditures.

The amounts and timing of our actual expenditures will depend upon numerous factors, including market conditions, cash generated by our operations, business developments and related rate of growth. We may find it necessary or advisable to use portions of the proceeds from this offering for other purposes.

Circumstances that may give rise to a change in the use of proceeds and the alternate purposes for which the proceeds may be used include:

- the existence of other opportunities or the need to take advantage of changes in timing of our existing activities;
- the need or desire on our part to accelerate, increase or eliminate existing initiatives due to, among other things, changing market conditions and competitive developments; and/or
- if strategic opportunities present themselves (including acquisitions, joint ventures, licensing and other similar transactions).

From time to time, we evaluate these and other factors and we anticipate continuing to make such evaluations to determine if the existing allocation of resources, including the proceeds of this offering, is being optimized.

Pending such uses, we intend to invest the net proceeds of this offering in direct and guaranteed obligations of the United States, interest-bearing, investment-grade instruments or certificates of deposit.

We believe that the net proceeds of this offering will be sufficient to fund our operations through 2017, and we will need to raise additional capital to fund our operations thereafter. Additional capital may not be available on terms favorable to us, or at all. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve restrictive covenants or additional security interests in our assets. Any additional debt or equity financing that we complete may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or products, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to delay, reduce the scope of, or eliminate some or all of, our development programs or liquidate some or all of our assets.

## PRICE RANGE OF COMMON STOCK AND DIVIDEND POLICY

Our common stock is currently listed on The Nasdaq Capital Market under the symbol "SSH." See "Prospectus Summary—Recent Developments—Nasdaq Compliance" in this prospectus for important information about the listing of our common stock on The Nasdaq Capital Market. Neither the Series E Preferred Stock nor the warrants will be traded on a national securities exchange. The following table contains, for the periods indicated, the intraday high and low sale prices per share of our common stock. These prices have been adjusted to reflect the 1-for-30 reverse split of our common stock that was effected after trading on January 12, 2017.

	<u>High</u>	<u>Low</u>
<b>2015</b>		
First Quarter	\$ 207.0207	\$ 114.0114
Second Quarter	\$ 148.8149	\$ 96.6097
Third Quarter	\$ 107.0777	\$ 60.006
Fourth Quarter	\$ 81.9082	\$ 31.8032
<b>2016</b>		
First Quarter	\$ 41.4041	\$ 16.8017
Second Quarter	\$ 29.2139	\$ 12.0012
Third Quarter	\$ 48.6049	\$ 13.2013
Fourth Quarter	\$ 28.8029	\$ 4.5005
<b>2017</b>		
First Quarter (through April 18, 2017)	\$ 12.0012	\$ 1.30

As of April 18, 2017, the last reported sale price of our common stock on The Nasdaq Capital Market was \$1.35.

As of March 13, 2017, there were approximately 226 stockholders of record for our common stock. A substantially greater number of stockholders may be "street name" or beneficial holders, whose shares are held of record by banks, brokers and other financial institutions.

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.

Our transfer agent is American Stock Transfer & Trust Company LLC, 6201 15th Avenue, Brooklyn, New York 11219; Telephone: 800-937-5449.

## CAPITALIZATION

The following table sets forth our actual cash and cash equivalents and our capitalization as of December 31, 2016 on a pro forma as adjusted basis to give effect to the transactions described below, the sale of the securities offered hereby and the use of proceeds, as described in the section entitled "Use of Proceeds."

You should read this information in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated audited financial statements and related notes appearing in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, which is incorporated by reference into this prospectus. The information provided below has been adjusted to reflect our 1-for-30 reverse stock split that was effected after trading on January 12, 2017.

	As of December 31, 2016 (in thousands, except share and per share data)	
	Actual	Pro Forma As Adjusted
Cash and cash equivalents	\$ 1,323	\$ 10,314
Common stock warrant liability	1,843	—
<b>Temporary stockholders' equity:</b>		
Series D convertible preferred, par value \$0.0001 per share; authorized 900 and none, respectively, issued and outstanding 700 and none, respectively	485	—
<b>Stockholders' equity:</b>		
Series A junior participating preferred stock, par value \$0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Series B-1 convertible preferred, par value \$0.0001 per share; authorized 1,824.4 and none, respectively, issued and outstanding 1,824.4 and none, respectively	—	—
Series C convertible preferred, par value \$0.0001 per share; authorized 2,900 shares and none, respectively, issued and outstanding 2,900 and none, respectively		
Series E convertible preferred, par value \$0.0001 per share; authorized none and 6,400 respectively, issued and outstanding none and 6,400, respectively	—	—
Preferred stock, par value \$0.0001 per share; authorized 39,964,375.6 and 39,963,600, respectively, none outstanding		
Common stock, par value \$0.0001 per share; authorized 100,000,000 shares, issued and outstanding 777,238 and 11,117,138, respectively	—	—
Additional paid-in capital	169,496	180,815
<b>Accumulated other comprehensive income:</b>		
Foreign currency translation adjustment	1,235	1,235
Accumulated deficit	(168,974)	(168,974)
Total stockholders' equity	1,757	13,076

The pro forma as adjusted column above reflects (i) the full conversion of all outstanding shares of our Series B-1 Convertible Preferred Stock, Series C Convertible Preferred Stock and Series D Convertible Preferred Stock (including those issued on January 11, 2017) into 1,471,983 shares of common stock subsequent to December 31, 2016, (ii) the exercise of the Original Warrants to purchase 867,917 shares of common stock, receipt of approximately \$2.0 million reflecting the aggregate cash exercise price thereof and issuance of such underlying shares subsequent to December 31, 2016 and (iii) our sale of Units in this offering. The 867,917 Original Warrants exercised subsequent to December 31, 2016 represented all of our warrants reflected under "common stock warrant liability" and, as a result, we have reclassified the warrant liability balance to Additional Paid in Capital in the

pro forma as adjusted column above. Final valuation of the Original Warrants may require a fair value adjustment through our Statement of Operations, and therefore there may be offsetting differences in the accounting of this reclassification between Additional Paid in Capital and Accumulated Deficit, with no impact to Total Stockholders' Equity.

In connection with the exercise of the 867,917 Original Warrants, we issued Replacement Warrants for 867,917 shares of common stock under the letter agreement described under "Prospectus Summary—Recent Developments—Warrant Exercise Agreement". We have not reflected the fair value of the Replacement Warrants in the pro forma projections as we have not finalized the valuation of these Replacement Warrants. We believe that the Replacement Warrants will be classified as equity and will have a positive impact to Total Stockholders' Equity. The above discussion and table are based on 777,238 shares of common stock outstanding (actual) as of December 31, 2016 and:

- assume no exercise of outstanding options or warrants (other than the pro forma adjustments noted above);
- exclude 87,870 shares of common stock issuable upon the exercise of stock options, having a weighted average exercise price of \$115.41 per share and 10,332 shares of common stock issuable upon the vesting of restricted stock units, in each case outstanding as of December 31, 2016;
- except as noted in the pro forma adjustments above, exclude 885,601 shares of our common stock issuable upon the exercise of warrants with a weighted-average exercise price of \$7.05 per share outstanding as of December 31, 2016;
- exclude 69,129 shares of our common stock reserved for future issuance under our equity incentive plans as of December 31, 2016; and
- exclude 8,000,000 shares of our common stock initially issuable upon the exercise of the warrants to be sold in this offering.

We expect to request stockholder approval at our 2017 Annual Meeting of a new equity incentive plan, which will include an additional share reserve of 534,857.

## DILUTION

A purchaser of our securities in this offering will be diluted to the extent of the difference between the price per share of our common stock in this offering and the net tangible book value per share of our common stock after this offering. As of December 31, 2016, our pro forma net tangible book value was (\$1.6 million), or \$(0.51) per share of common stock. Our net tangible book value per share represents the amount of our total tangible assets reduced by the amount of our total liabilities, divided by the total number of shares of our common stock. Pro forma net tangible book value per share gives effect to (i) the full conversion of our Series B-1 Convertible Preferred Stock, Series C Convertible Preferred Stock and Series D Convertible Preferred Stock into 1,471,983 shares of common stock subsequent to December 31, 2016, (ii) the exercise of Original Warrants to purchase 867,917 shares of common stock, receipt of approximately \$2.0 million, reflecting the aggregate cash exercise price thereof and the issuance of such underlying shares subsequent to December 31, 2016 and (iii) the 1-for-30 reverse stock split that was effected after trading on January 12, 2017.

After giving effect to our sale in this offering of 8,000,000 shares of common stock, inclusive of the 6,400,000 shares of common stock that the Series E Preferred Stock to be issued is convertible into, at the public offering price of \$1.00 per Class A Unit, excluding shares that may be issued upon exercise of the underwriter's overallotment option and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our net tangible book value as of December 31, 2016 would have been \$8.6 million, or \$0.63 per share of our common stock. This amount represents an immediate increase of net tangible book value to our existing stockholders of \$1.14 per share and an immediate dilution of \$0.37 per share to the new investors purchasing securities in this offering. The following table illustrates this per share dilution:

Public offering price per Class A Unit	\$ 1.00
Pro forma net tangible book value per share at December 31, 2016	\$ (0.51)
Increase per share attributable to investors purchasing securities in this offering	\$ 1.14
Net tangible book value per share, as adjusted to give effect to this offering	\$ 0.63
Dilution per share to investors in this offering	<u>\$ 0.37</u>

The above is based on 777,238 shares of common stock outstanding (actual) as of December 31, 2016 and:

- assumes no exercise of outstanding options or warrants (other than the pro forma adjustments noted above);
- excludes 87,870 shares of common stock issuable upon the exercise of stock options, having a weighted average exercise price of \$115.41 per share and 10,332 shares of common stock issuable upon the vesting of restricted stock units, in each case outstanding as of December 31, 2016;
- except as noted in the pro forma adjustments above, excludes 885,601 shares of our common stock issuable upon the exercise of warrants with a weighted-average exercise price of \$7.05 per share outstanding as of December 31, 2016;
- excludes 69,129 shares of our common stock reserved for future issuance under our equity incentive plans as of December 31, 2016; and
- excludes 8,000,000 shares of our common stock initially issuable upon the exercise of the warrants to be sold in this offering.

We expect to request stockholder approval at our 2017 Annual Meeting of a new equity incentive plan, which will include an additional share reserve of 534,857.

In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of additional equity, the issuance of these shares could result in further dilution to our stockholders.

## BUSINESS

### Overview

We are an early-stage medical device company focused on commercializing our Aquadex FlexFlow® System. Our commercial product, the Aquadex FlexFlow® System, is indicated for temporary (up to eight hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy, and extended (longer than 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization.

### Company History

Prior to July 2016, we were focused on developing the C-Pulse® Heart Assist System for treatment of Class III and ambulatory Class IV heart failure. The C-Pulse System utilized the known concept of counterpulsation applied to the aorta. In March 2016, we announced that we were no longer enrolling patients into our two clinical studies for the C-Pulse System and that we planned to pursue a new strategic direction. In July 2016, we announced that we were moving forward with a therapeutic strategy utilizing neuromodulation rather than counterpulsation.

In August 2016, we acquired the Aquadex Business from Baxter, a global leader in the hospital products and dialysis markets.

On September 29, 2016, we announced a strategic refocus of our near-term strategy that includes halting clinical evaluations of our neuromodulation technology to fully focus our resources on our recently acquired Aquadex Business, taking actions to reduce our cash burn in connection with such strategic refocus, and reviewing potential strategic alliances and financing alternatives.

### The Aquadex FlexFlow System

The Aquadex FlexFlow is designed to simply, safely, and precisely remove excess fluid (primarily excess salt and water) from patients suffering from fluid overload who have failed diuretic therapy. With the Aquadex FlexFlow, medical practitioners can specify and control the amount of fluid to be extracted at a safe, predictable, and effective rate. The Aquadex FlexFlow has been shown to have no clinically significant impact on electrolyte balance, blood pressure or heart rate. (1)

The Aquadex FlexFlow is indicated for temporary (up to 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy; and extended (longer than 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization. All treatments must be administered by a healthcare provider, under physician prescription, both of whom have received training in extracorporeal therapies.

#### *Benefits of the Aquadex FlexFlow*

The Aquadex FlexFlow ultrafiltration system offers a safe approach to treating fluid overload and:

- Provides complete control over rate and total volume of fluid removed by allowing a medical practitioner to specify the amount of fluid to be removed from each individual patient
- Aquapheresis therapy can be performed via peripheral or central venous access
- Removes isotonic fluid (extracts sodium while sparing potassium and magnesium)(2)

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(1) SAFE Trial: Jaski BE, et al. *J Card Fail.* 2003 Jun; 9(3): 227-231; RAPID Trial: Bart BA, et al. *J Am Coll Cardiol.* 2005 Dec 6; 46(11): 2043-2046.

(2) Ali SS, et al. *Congest Heart Fail.* 2009; 15(1):1-4.

- Following ultrafiltration, neurohormonal activation is reset toward a more physiological condition and diuretic efficacy is restored(3)
- Provides highly automated operation with only one setting required to begin
- Utilizes a single-use, disposable auto-loading blood filter circuit that facilitates easy set-up
- The console guides medical practitioner through the setup and operational process
- Decreased hospital length of stay and readmissions(4)

The Aquadex FlexFlow consists of:

- A console, a piece of capital equipment containing electromechanical pumps and an LCD screen
- A one-time disposable blood set (the "Aquadex Blood Set"), an integrated collection of tubing, filter, sensors, and connectors that contain and deliver the blood from and back to the patient, and
- A disposable catheter (the "Aquadex Catheter"), a small, dual-lumen catheter designed to access the peripheral venous system of the patient and to simultaneously withdraw blood and return filtered blood to the patient. The Aquadex Blood Set is proprietary and the Aquadex FlexFlow can only be used with the Aquadex Blood Set. The Aquadex Catheter is often used in conjunction with the Aquadex FlexFlow, although it is one of many potential catheter options available to the provider.

### **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 870,000 new cases diagnosed each year and 670,000 emergency department visits. Congestive heart failure is the highest U.S. chronic health care expense category(5).

Heart failure is a progressive disease caused by impairment of the left heart's ability to pump blood to the various organs of the body. Patients with heart failure commonly experience shortness of breath, fatigue, difficulty exercising and swelling of the legs. The heart becomes weak or stiff and enlarges over time, making it harder for the left heart to pump the blood needed for the body to function properly. The severity of heart failure depends on how well a person's heart is able to pump blood throughout the body.

Heart failure is the leading cause of fluid overload, a condition where patients become decompensated resulting in lengthy and costly hospitalizations. In fact, 90% of heart failure patients present symptoms of fluid overload.(6) Our system is indicated for temporary (up to eight hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy, and extended (longer than 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization.

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(3) Marenzi G, et al. *J Am Coll Cardiol*. 2001 Oct; 38(4): 963-968.

(4) Costanzo MR, et al. *J Am Coll Cardiol*. 2005 Dec 6; 46(11): 2047-2051.

(5) Mozaffarian D, Benjamin EJ, Go AS, et al. on behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2016 update: a report from the American Heart Association. *Circulation*. 2016;133:e38-e360.

(6) Costanzo MR, et al. *J Am Coll Cardiol*. 2007 Feb 13; 49(6): 675-683.

According to a nationwide study of over 140,000 patients suffering from acute decompensated heart failure, over 38% of patients discharged were still symptomatic and about half of the patients were discharged with less than five pounds lost.<sup>(7)</sup> This clinical evidence from the ADHERE Registry clearly shows patients are discharged too early while still showing evidence of fluid overload. By not truly addressing the fluid overload problem, patients are being readmitted to the hospital too frequently with 30 day readmissions of 22% and 6-month readmissions of 44%, with 78% of patients admitted directly to the Emergency Department as the first point of care.<sup>(8)(9)</sup>

The Affordable Care Act includes a Hospital Readmission Reduction program and is designed to reduce payments to hospitals with excess heart failure readmissions, among other conditions. The penalty to hospitals can be significant, as much as 3% of total Medicare reimbursement. The Aquadex FlexFlow is positioned to assist hospitals with the Affordable Care Act and may offer hospitals an economic benefit for using the device on a regular basis for in-patient or out-patient usage.

There are two market segments for treating fluid overload with the Aquadex FlexFlow:

- 1) **Inpatient Care**—Given to a patient admitted to a hospital, extended care facility, nursing home or other facility. Long term care is the range of services typically provided at skilled nursing, intermediate-care, personal care or eldercare facilities.
- 2) **Outpatient Care**—Any health care service provided to a patient who is not admitted to a facility. Outpatient care can be provided in a doctor's office, clinic, or hospital outpatient department.

Our target customers for the Aquadex FlexFlow include large academic hospitals specializing in advanced treatment of chronic heart failure, other large hospitals with heart failure related admissions and clinical practices with transplant or LVAD programs.

## Our Strategy

Our goal is to become a leader in the treatment of moderate to severe heart failure and related conditions. We believe that our technology will provide us with a competitive advantage in the market for treating specific segments of heart failure patients.

On September 29, 2016, we announced a strategic refocus of our near-term strategy that includes halting clinical evaluations of our neuromodulation technology to fully focus our resources on our recently acquired Aquadex Business, taking actions to reduce our cash burn in connection with such strategic refocus and reviewing potential strategic alliances and financing alternatives.

There is currently a large installed base of over 500 Aquadex FlexFlow consoles in U.S. hospitals that, once reactivated and reengaged, should enable increased utilization of the already installed console with ongoing purchases of the Aquadex Blood Sets. In order to grow our Aquadex Business, we intend to focus our efforts in providing superior service to our customers through our direct field organization, our in-house customer service team, our technical service team, and our clinical education efforts. We are actively focused on strengthening our capabilities in all of these areas.

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(7) ADHERE Scientific Advisory Committee. ADHERE Final Cumulative National Benchmark Report. Mountain View, CA: Scios Inc.; 2006.

(8) Centers for Medicare & Medicaid Services. Hospital Compare datasets. National Rate (READM\_30\_HF); 3Q2011—2Q2014.

(9) Krumholz HM et. al. Arch Intern Med. 1997 Jan 13;157(1): 99-104—Ross JS, et al. Circ Heart Fail. 2010 Jan; 3(1): 97-103.



We are executing on our growth strategy in deliberate stages by:

- Initially, focusing on the top 55 hospital accounts that generated eighty percent of the revenue for the Aquadex Business in 2015 through customer support and therapy development and by diagnosing each hospital's use of the Aquadex FlexFlow to gain additional opportunity for increased utilization.
- Expanding our efforts to re-engage the additional 110 hospital accounts that also purchased Aquadex Blood Sets in 2015.
- Re-educating customers to help increase the utilization of the Aquadex FlexFlow owned by an additional 200 hospital accounts prior to 2015.

#### *Aquadex FlexFlow Growth Drivers*

The Aquadex Business will benefit from re-engaging clients, targeting new customers and markets as well as positive industry dynamics favoring technologies that reduce hospital readmission rates. We plan to reach these customers and markets by:

- **Established Customer Base**—Continuing to service the top 55 accounts producing 80% of the business with customer support and therapy development and diagnosing each hospital's use of Aquadex FlexFlow to gain additional opportunity for increased utilization.
- **Enhancing the Outpatient Market**—Continue supporting outpatient usage and expanding to include a registry and possible collaboration with payer/providers to allow greater opportunity in the future.
- **International Opportunity**—Currently, there is limited activity in Europe. Investigate use of distributors to expand usage of the Aquadex FlexFlow outside the United States.
- **Differentiated Technology & Product Development**—Work to enhance the current product to provide a better performance for our customers and patients.
- **Alignment with Market Dynamics**—Utilize existing and new data to demonstrate to hospital administrators that Aquadex FlexFlow can be a solution for 30-day readmissions and challenges with length of stay. Therefore, every Aquadex FlexFlow usage is economically advantageous driving increased demand.
- **Reimbursement Opportunity**—Work to build acceptance through clinical evidence and a registry to gain reimbursement coding for Aquapheresis therapy.

#### **Sales and Marketing**

As of March 14, 2017, we had 8 full-time employees in sales and marketing. During 2016, we trained our existing field personnel and hired additional sales personnel with prior experience with the Aquadex Business. Our sales force includes therapy development managers as well as field clinical engineers who provide training, technical and other support services to our customers. Since the acquisition of the Aquadex Business from Baxter in August 2016, our direct sales force has focused on reengaging hospital accounts that ordered Aquadex Blood Sets in prior years, re-educating customers on the therapy and diagnosing each hospital's use of the Aquadex FlexFlow to gain additional opportunity for increased utilization. We plan to grow the sales and marketing organization as necessary to support future growth.

Our sales representatives implement consumer marketing programs and provide physicians and nurses with educational patient materials. We also market to potential referral source clinicians in order to build awareness.

## **Clinical Experience**

Several large-scale, multi-center, randomized, controlled trials have evaluated the use of ultrafiltration using the Aquadex FlexFlow in patients with acute decompensated heart failure compared to standard-of-care treatment with intravenous diuretics. These trials followed early-stage studies which primarily focused on safety of ultrafiltration treatment with Aquadex FlexFlow.

The UNLOAD trial enrolled 200 patients and showed that average weight and fluid loss were greater in the ultrafiltration group 48 hours following randomization. No differences were noted in symptoms of dyspnea between the groups. In addition, through 90 days of follow-up, the ultrafiltration group experienced fewer re-hospitalizations for heart failure, while renal function assessed by serum creatinine level was not significantly different between the groups.

The CARESS trial studied 188 randomized acute decompensated heart failure patients over the course of 96 hours and found no difference in weight loss and an increase in creatinine level relative to the control group treated with intravenous diuretics. The creatinine increase was interpreted as a sign of potential worsening renal function in the ultrafiltration group. Results of CARESS have been criticized on several grounds, particularly that trial results were impacted by centers unfamiliar with the use of ultrafiltration therapy and that the diuretic regimen employed was not representative of standard-of-care. In addition, a recent analysis of the DOSE trial to explore the putative link between short-term changes in creatinine level and outcome in acute decompensated heart failure has found that the intragroup difference observed in CARESS does not fall into a range associated with adverse long-term outcomes including death, re-hospitalization or visits to the emergency department. Such events were examined in CARESS over 60 days and no differences were detected between the groups.

Disparate results between UNLOAD and CARESS led to initiation of the AVOID trial. AVOID was designed to prospectively address the question of patient outcomes when treated with ultrafiltration versus intravenous diuretics for acute decompensated heart failure. Trial design assumptions indicated that 810 patients would need to be randomized to achieve adequate statistical power. However, the study was terminated at 224 patients for business reasons by Baxter. Despite being underpowered, the results of AVOID indicated distinct trends toward reduced composite heart-failure events in the ultrafiltration group over 90 days. In addition, pre-specified secondary endpoints demonstrated significant reductions in heart failure re-hospitalization at 30 days. No significant differences were observed in creatinine level between the groups, although a trend toward increase may have been present at 48 hours. In totality, AVOID recapitulated the results of both UNLOAD and CARESS while providing evidence that had AVOID been followed to completion it would likely have met its primary endpoint of improved outcome in acute decompensated heart failure patients.

Other uses of ultrafiltration with the Aquadex FlexFlow have not been studied extensively. Case studies and case series demonstrating the use of ultrafiltration in the maintenance of outpatient chronic heart failure have been published but there has been no prospective, systematic evaluation of ultrafiltration versus standard-of-care for this population. Other potential uses also largely remain to be formally evaluated.

## **Research and Development**

Research and development costs include activities related to research, development, design, testing and manufacturing of prototypes of the Aquadex FlexFlow. The Aquadex FlexFlow software will require periodic modifications for feature additions and performance improvements. We will make such design changes as needed based on pro-active and reactive mechanisms.

## **Manufacturers and Suppliers**

We are party to a commercial manufacturing and supply agreement with Baxter which requires Baxter to manufacture Aquadex Blood Sets and Aquadex Catheters for a period of 18 months following our acquisition of the Aquadex Business. There is no such agreement relating to the manufacturing of Consoles. As an initial focus, we plan to transfer Console manufacturing to Sunshine Heart or a qualified contract manufacturer by mid-year 2017. We plan to transfer the Aquadex Blood Set and Aquadex Catheter manufacturing activities from Baxter to Sunshine Heart or a qualified contract manufacturer by the end of 2017.

## **Intellectual Property**

We have established an intellectual property portfolio through which we seek to protect our system and technology. As of December 31, 2016, our portfolio consisted of over 35 patents issued and 13 patents pending in the United States and abroad for our counterpulsation technology. In addition, our portfolio includes over 50 exclusively and non-exclusively licensed patents with respect to ultrafiltration and the Aquadex system. Finally, Sunshine Heart has two patents pending in the neuromodulation space. Our patents and patent applications cover various aspects of both the methodology as well as the design of our discontinued C-Pulse System device and related components, our discontinued neuromodulation technology, and the Aquadex FlexFlow.

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

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

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

## **Competition**

Competition from medical device companies and medical device divisions of health care companies, pharmaceutical companies and gene- and cell-based therapies is intense and expected to increase. The vast majority of heart failure patients with fluid overload receive pharmacological treatment (diuretics) as a standard of care. There are no direct competitors in the U.S. other than diuretics. Other ultrafiltration systems, such as Baxter's Prismaflex, a filter-based device that is approved for continuous renal replacement therapy for patients weighing 20kg or more with acute renal failure and/or fluid overload, represent indirect competitors.

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

- Financial resources;
- Product performance and design;
- Risk management;
- Product safety;

- Acceptance of our system in the marketplace;
- Sales, marketing and distribution capabilities;
- Manufacturing and assembly costs;
- Pricing of our system and of our competitors' products;
- The availability of reimbursement from government and private health insurers;
- Success and timing of new product development and introductions;
- Regulatory approvals; and
- Intellectual property protection.

### **Third-Party Reimbursement**

In the United States, the Aquadex FlexFlow is purchased primarily by customers, such as hospitals or other health care providers. Customers bill various third-party payers for covered Aquadex FlexFlow services provided to patients. These payers, which include federal health care programs (e.g., Medicare and Medicaid), state health care programs, private health insurance companies and managed care organizations, would then reimburse our customers based on established payment formulas that take into account part or all of the cost associated with these devices and the related procedures performed.

While the agency responsible for administering the Medicare program, the Centers for Medicare and Medicaid Services has not issued a favorable national coverage for ultrafiltration using the Aquadex FlexFlow, a number of private insurers have approved reimbursement for Aquadex FlexFlow for specific indications and points of service. In addition, patients and providers may see insurance coverage on a case-by-case basis.

We are exploring the ability to increase the range of coverage for uses of Aquadex FlexFlow, such as use in the outpatient setting and use for decompensated heart failure and other indicated uses under its approved labeling.

Legislative proposals can substantially change the way health care is financed by both governmental and private insurers and may negatively impact payment rates for our system. Also, from time to time there are a number of legislative, regulatory and other proposals both at the federal and state levels; it remains uncertain whether there will be any future changes that will be proposed or finalized and what effect, if any, such legislation or regulations would have on our business. However, in the United States and international markets, we expect that both government and third-party payers will continue to attempt to contain or reduce the costs of health care by challenging the prices charged, or deny coverage, for health care products and services.

### **Government Regulations**

Regulation by governmental authorities in the United States and foreign countries is a significant factor in the manufacture and marketing of our current system and any future products and in our ongoing research and development activities. In particular, medical devices are subject to rigorous pre-clinical testing as a condition of approval by the FDA and by similar authorities in foreign countries. Any proposed products will require regulatory approval prior to commercialization.

#### ***United States***

The FDC Act and the FDA's implementing regulations govern medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import,

and post market surveillance. Medical devices and their manufacturers are also subject to inspection by the FDA. The FDC Act, supplemented by other federal and state laws, also provides civil and criminal penalties for violations of its provisions. We manufacture and market medical devices that are regulated by the FDA, comparable state agencies and regulatory bodies in other countries.

Unless an exemption applies, each medical device we wish to commercially distribute in the U.S. will require marketing authorization from the FDA prior to distribution. The two primary types of FDA marketing authorization are premarket notification (also called 510(k) clearance) and premarket approval (PMA). The type of marketing authorization applicable to a device—510(k) clearance or PMA—is generally linked to classification of the device. The FDA classifies medical devices into one of three classes (Class I, II or III) based on the degree of risk the FDA determines to be associated with a device and the extent of control deemed necessary to ensure the device's safety and effectiveness. Devices requiring fewer controls because they are deemed to pose lower risk are placed in Class I or II. Class I devices are deemed to pose the least risk and are subject only to general controls applicable to all devices, such as requirements for device labeling, premarket notification, and adherence to the FDA's current good manufacturing practice requirements, as reflected in its Quality System Regulation ("QSR"). Class II devices are intermediate risk devices that are subject to general controls and may also be subject to special controls such as performance standards, product-specific guidance documents, special labeling requirements, patient registries or post market surveillance. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through general or special controls, and include life-sustaining, life-supporting or implantable devices, and devices not "substantially equivalent" to a device that is already legally marketed.

Most Class I devices and some Class II devices are exempted by regulation from the 510(k) clearance requirement and can be marketed without prior authorization from FDA. Class I and Class II devices that have not been exempted are eligible for marketing through the 510(k) clearance pathway. By contrast, devices placed in Class III generally require PMA prior to commercial marketing. The PMA process is generally more stringent, time-consuming and expensive than the 510(k) clearance process.

*510(k) Clearance.* To obtain 510(k) clearance for a medical device, an applicant must submit a premarket notification to the FDA demonstrating that the device is "substantially equivalent" to a predicate device legally marketed in the United States. A device is substantially equivalent if, with respect to the predicate device, it has the same intended use and has either (i) the same technological characteristics or (ii) different technological characteristics and the information submitted demonstrates that the device is as safe and effective as a legally marketed device and does not raise different questions of safety or effectiveness. A showing of substantial equivalence sometimes, but not always, requires clinical data. Generally, the 510(k) clearance process can exceed 90 days and may extend to a year or more.

After a device has received 510(k) clearance for a specific intended use, any modification that could significantly affect its safety or effectiveness, such as a significant change in the design, materials, method of manufacture or intended use, will require a new 510(k) clearance or PMA (if the device as modified is not substantially equivalent to a legally marketed predicate device). The determination as to whether new authorization is needed is initially left to the manufacturer; however, the FDA may review this determination to evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing the modified device until 510(k) clearance or PMA is obtained. The manufacturer may also be subject to significant regulatory fines or penalties.

The Aquadex FlexFlow was granted FDA 510(k) clearance for commercial use on June 3, 2002. Additional 510(k) clearances have been received for the Aquadex FlexFlow in subsequent years.

*Clinical Trials.* To obtain FDA approval to market the C-Pulse System, clinical trials are required to support a PMA application. These trials generally require submission of an application for an IDE

to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for more abbreviated IDE requirements. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate institutional review boards at the clinical trial sites.

FDA approval of an IDE allows clinical testing to go forward but does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria. With certain exceptions, changes made to an investigational plan after an IDE is approved must be submitted in an IDE supplement and approved by FDA (and by governing institutional review boards when appropriate) prior to implementation.

All clinical trials must be conducted in accordance with regulations and requirements collectively known as Good Clinical Practice. Good clinical practices include the FDA's IDE regulations, which describe the conduct of clinical trials with medical devices, including the recordkeeping, reporting and monitoring responsibilities of sponsors and investigators, and labeling of investigational devices. They also prohibit promotion, test marketing or commercialization of an investigational device and any representation that such a device is safe or effective for the purposes being investigated. Good Clinical Practices also include the FDA's regulations for institutional review board approval and for protection of human subjects (such as informed consent), as well as disclosure of financial interests by clinical investigators.

Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant approval or clearance of a product. The commencement or completion of any clinical trials may be delayed or halted, or be inadequate to support approval of a PMA application or clearance of a premarket notification for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial (or a change to a previously approved protocol or trial that requires approval), or place a clinical trial on hold;
- patients do not enroll in clinical trials or follow up at the rate expected;
- patients do not comply with trial protocols or experience greater than expected adverse side effects;
- institutional review boards and third-party clinical investigators may delay or reject the trial protocol or changes to the trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, investigator agreements, good clinical practices or other FDA requirements;
- third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- regulatory inspections of the clinical trials or manufacturing facilities, which may, among other things, require corrective action or suspension or termination of the clinical trials;
- changes in governmental regulations or administrative actions;
- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or efficacy; or

- the FDA concludes that the trial design is inadequate to demonstrate safety and efficacy.

*Continuing Regulation.* After a device is cleared or approved for use and placed in commercial distribution, numerous regulatory requirements continue to apply. These include:

- establishment registration and device listing upon the commencement of manufacturing;
- the QSR, which requires manufacturers, including third-party manufacturers, to follow design, testing, control, documentation and other quality assurance procedures during medical device design and manufacturing processes;
- labeling regulations, which prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling and promotional activities;
- medical device reporting regulations, which require that manufacturers report to the FDA if a device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if malfunctions were to recur;
- corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections; and
- product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDC Act caused by the device that may present a risk to health.

In addition, the FDA may require a company to conduct post market surveillance studies or order it to establish and maintain a system for tracking its products through the chain of distribution to the patient level.

Failure to comply with applicable regulatory requirements, including those applicable to the conduct of clinical trials, can result in enforcement action by the FDA, which may lead to any of the following sanctions:

- warning letters or untitled letters;
- fines, injunctions and civil penalties;
- product recall or seizure;
- unanticipated expenditures;
- delays in clearing or approving or refusal to clear or approve products;
- withdrawal or suspension of FDA approval;
- orders for physician notification or device repair, replacement or refund;
- operating restrictions, partial suspension or total shutdown of production or clinical trials; or
- criminal prosecution.

We and our contract manufacturers and suppliers are also required to manufacture our products in compliance with Current Good Manufacturing Practice requirements set forth in the QSR.

The QSR requires a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of marketed devices, and includes extensive requirements with respect to quality management and organization, device design, buildings, equipment, purchase and handling of components, production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing and record keeping. The FDA enforces the QSR through periodic announced and unannounced inspections that may include the manufacturing facilities of subcontractors. If the FDA believes that we or any of our contract manufacturers or regulated suppliers is not in compliance with these requirements, it can shut down our manufacturing operations,

require recall of our products, refuse to clear or approve new marketing applications, institute legal proceedings to detain or seize products, enjoin future violations or assess civil and criminal penalties against us or our officers or other employees. Any such action by the FDA would have a material adverse effect on our business.

**Employees**

As of March 14, 2017, we had 29 full-time employees and no part-time employees. None of our employees are covered by a collective bargaining agreement. We consider relations with our employees to be good.



## SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information regarding the beneficial ownership (as defined in Rule 13d-3 of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**")) of our common stock as of March 28, 2017 by (i) each of the directors and named executive officers, (ii) all of the directors and executive officers as a group, and (iii) to our knowledge, beneficial owners of more than 5% of our common stock. As of March 28, 2017, there were 3,118,492 shares of our common stock outstanding. Unless otherwise indicated and subject to applicable community property laws, each owner has sole voting and investment powers with respect to the securities listed below.

Name of Beneficial Owner	Number of Shares	Right to Acquire (1)	Total	Aggregate Percent of Class (2)
John L. Erb	8,028	7,827	15,855	*
Steve Brandt	—	588	588	*
Matthew E. Likens	—	588	588	*
Jon W. Salveson	1,232	2,002	3,234	*
Gregory D. Waller	1,351	1,621	2,972	*
Warren S. Watson	1,232	2,002	3,234	*
Claudia Drayton	739	2,779	3,518	*
All directors and executive officers as a group (7 persons)	12,582	17,407	29,989	*
Sabby Management, LLC 10 Mountainview Road, Suite 205 Upper Saddle River, NJ 07458	154,348(3)	—	154,348	4.9%
Ki Yong Choi 36 Great Circle Drive Mill Valley, California 94941	245,000(4)	—	245,000	7.9%

\* Less than one percent.

- (1) Except as otherwise described below, amounts reflect the number of shares that such holder could acquire through (i) the exercise of outstanding stock options, (ii) the vesting/settlement of outstanding RSUs and (iii) the exercise of outstanding warrants to purchase common stock, in each case within 60 days of March 28, 2017.
- (2) Based on 3,118,492 shares outstanding as of March 28, 2017.
- (3) Based on information provided by Sabby Management, LLC as of March 13, 2017.
- (4) Based on the Schedule 13D/A filed by the reporting person on March 28, 2017.

## DESCRIPTION OF SECURITIES

### Description of Units

We are offering 1,600,000 Class A Units, with each Class A Unit consisting of one share of common stock and a warrant to purchase one share of our common stock (together with the shares of common stock underlying such warrants) at a public offering price of \$1.00 per Class A Unit. Each warrant included in the Class A Units entitles its holder to purchase one share of Common Stock at an exercise price of \$1.10.

We are also offering 6,400 Class B Units to purchasers who prefer not to beneficially own more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering with each Class B Unit consisting of one share of Series E Preferred Stock, par value \$0.0001 per share, convertible into a number of shares of common stock equal to \$1,000 divided by the conversion price of \$1.00 (the "Conversion Price") and warrants to purchase a number of shares of common stock equal to \$1,000 divided by the Conversion Price (together with the shares of common stock underlying such warrants) at a public offering price of \$1,000 per Class B Unit. Each warrant included in the Class B Units entitles its holder to purchase a number of shares of Common Stock equal to 100% of the shares of Common Stock issuable upon conversion of the Series E Preferred Stock included in such units at an exercise price of \$1.10 per share.

The securities of which the units are composed (the "underlying securities") are being sold in this offering only as part of the units. However, the Class A Units and Class B Units will not be certificated and the underlying securities comprising such units are immediately separable. Each underlying security purchased in this offering will be issued independent of each other underlying security and not as part of a unit. Upon issuance, each underlying security may be transferred independent of any other underlying security, subject to applicable law and transfer restrictions.

### Description of Warrants Included in the Units

The material terms and provisions of the warrants being offered pursuant to this prospectus are summarized below. This summary of some provisions of the warrants is not complete. For the complete terms of the warrants, you should refer to the form of warrant filed as an exhibit to the registration statement of which this prospectus is a part.

Pursuant to a warrant agency agreement between us and American Stock Transfer & Trust Company LLC, as warrant agent, the warrants will be issued in book-entry form and shall initially be represented only by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

Each Class A Unit includes a warrant to purchase one share of our common stock at an exercise price of \$1.10 per share at any time for up to five years after the date of the closing of this offering. Each Class B Unit issued in this offering includes a warrant to purchase a number of shares of common stock equal to \$1,000 divided by the Conversion Price at any time for up to five years after the date of the closing of this offering. The warrants issued in this offering will be governed by the terms of a global warrant held in book-entry form. The holder of a warrant will not be deemed a holder of our underlying common stock until the warrant is exercised, except as set forth in the warrants.

Subject to limited exceptions, a holder of warrants will not have the right to exercise any portion of its warrants if the holder (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of common stock in excess of 4.99% (or, at the election of the holder, 9.99%) of the shares of our common stock then outstanding after giving effect to such exercise (the "Beneficial Ownership

Limitation"); provided, however, that upon notice to the Company, the holder may increase or decrease the Beneficial Ownership Limitation, provided that in no event shall the Beneficial Ownership Limitation exceed 9.99% and any increase in the Beneficial Ownership Limitation will not be effective until 61 days following notice of such increase from the holder to us.

The exercise price and the number of shares issuable upon exercise of the warrants is subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock. The warrant holders must pay the exercise price in cash upon exercise of the warrants, unless such warrant holders are utilizing the cashless exercise provision of the warrants, which is only available in certain circumstances such as if the underlying shares are not registered with the SEC pursuant to an effective registration statement. We intend to use commercially reasonable efforts to have the registration statement of which this prospectus forms a part, effective when the warrants are exercised.

In addition, in the event we consummate a merger or consolidation with or into another person or other reorganization event in which our common shares are converted or exchanged for securities, cash or other property, or we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets or we or another person acquire 50% or more of our outstanding shares of common stock, then following such event, the holders of the warrants will be entitled to receive upon exercise of the warrants the same kind and amount of securities, cash or property which the holders would have received had they exercised the warrants immediately prior to such fundamental transaction. Any successor to us or surviving entity shall assume the obligations under the warrants. Further, as more fully described in the warrants, in the event of certain fundamental transactions, the holders of the warrants will be entitled to receive consideration in an amount equal to the Black-Scholes value of the warrants as of the date of consummation of such transaction.

Upon the holder's exercise of a warrant, we will issue the shares of common stock issuable upon exercise of the warrant within the earlier of three trading days following our receipt of a notice of exercise or the standard settlement period for the market on which the common stock is then listed, provided that payment of the exercise price has been made (unless exercised via the "cashless" exercise provision).

Prior to the exercise of any warrants to purchase common stock, holders of the warrants will not have any of the rights of holders of the common stock purchasable upon exercise, including the right to vote, except as set forth therein.

Warrant holders may exercise warrants only if the issuance of the shares of common stock upon exercise of the warrants is covered by an effective registration statement, or an exemption from registration is available under the Securities Act and the securities laws of the state in which the holder resides. We intend to use commercially reasonable efforts to have the registration statement of which this prospectus forms a part effective when the warrants are exercised. The warrant holders must pay the exercise price in cash upon exercise of the warrants unless there is not an effective registration statement or, if required, there is not an effective state law registration or exemption covering the issuance of the shares underlying the warrants (in which case, the warrants may only be exercised via a "cashless" exercise provision).

The warrants are callable by us in certain circumstances. Subject to certain exceptions, in the event that the warrants are outstanding, following the date that is 180 days after the closing date, (i) the volume weighted average price of our common stock for each of 30 consecutive trading days (the "Measurement Period"), which Measurement Period commences after the date that is 180 days after the closing date, exceeds 300% of the initial exercise price (subject to adjustment for forward and reverse stock splits, recapitalizations, stock dividends and similar transactions), (ii) the average daily trading volume for such Measurement Period exceeds \$500,000 per trading day and (iii) the holder is not in possession of any information that constitutes or might constitute, material non-public

information which was provided by the Company, and subject to the Beneficial Ownership Limitation, then we may, within one trading day of the end of such Measurement Period, upon notice (a "Call Notice"), call for cancellation of all or any portion of the warrants for which a notice of exercise has not yet been delivered (a "Call") for consideration equal to \$0.0001 per share. Any portion of a warrant subject to such Call Notice for which a notice of exercise shall not have been received by the Call Date (as hereinafter defined) will be canceled at 6:30 p.m. (New York City time) on the tenth trading day after the date the Call Notice is sent by the Company (such date and time, the "Call Date"). Our right to call the warrants shall be exercised ratably among the holders based on the outstanding warrants.

We do not intend to apply for listing of the warrants on any securities exchange or other trading system.

### **Description of Capital Stock**

Our authorized capital stock consists of 100,000,000 shares of common stock, par value \$0.0001 per share, and 40,000,000 shares of preferred stock, par value \$0.0001 per share, as of March 28, 2017, 30,000 of which are designated as Series A Junior Participating Preferred Stock.

As of March 28, 2017, we had (i) 3,118,492 outstanding shares of common stock, (ii) outstanding options to acquire 57,102 shares of our common stock, (iii) 10,465 outstanding restricted stock units and (iv) outstanding warrants to purchase 926,723 shares of our common stock.

The following description summarizes the most important terms of our capital stock. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description you should refer to our certificate of incorporation and bylaws, copies of which have been incorporated by reference herein, and to the applicable provisions of the Delaware General Corporation Law.

### **Common Stock**

#### ***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 holders of at least 66<sup>2</sup>/<sub>3</sub>% 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 Our Certificate of Incorporation and Bylaws and Delaware Law;"
- 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 Our Certificate of Incorporation and Bylaws and Delaware Law;"
- 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 Indemnification;" and
- the super-majority voting requirement to amend our certificate of incorporation described above.

### ***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 liquidation, dissolution 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.

### ***Listing***

Our common stock is listed on The Nasdaq Capital Market under the symbol "SSH." See "Prospectus Summary—Recent Developments—Nasdaq Compliance" in this prospectus for important information about the listing of our common stock on The Nasdaq Capital Market.

### ***Preferred Stock***

We may issue any class of preferred stock in any series. Our board of directors has the authority to establish and designate series, and to fix the number of shares included in each such series and to determine or alter for each such series, such voting powers, designation, preferences, and relative participating, optional, or other rights and such qualifications, limitations or restrictions thereof. Our board of directors is not restricted in repurchasing or redeeming such stock while there is any arrearage in the payment of dividends or sinking fund installments. Our board of directors is authorized to increase or decrease the number of shares of any series subsequent to the issuance of shares of that series, but not below the number of shares of such series then outstanding. The number of authorized shares of preferred stock may be increased or decreased, but not below the number of shares thereof

then outstanding, by the affirmative vote of the holders of a majority of the common stock, without a vote of the holders of the preferred stock, or of any series thereof, unless a vote of any such holders is required pursuant to the terms of any certificate of designation filed with respect to any series of preferred stock.

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.

*Series E Preferred Stock.* Our board of directors has designated 6,400 shares of our preferred stock as Series E Convertible Preferred Stock ("Series E Preferred Stock"), none of which are currently issued and outstanding. The preferences and rights of the Series E Preferred Stock will be as set forth in a Certificate of Designation (the "Series E Certificate of Designation") filed as an exhibit to the registration statement of which this prospectus is a part.

Pursuant to a transfer agency agreement between us and American Stock Transfer & Trust Company LLC, as transfer agent, the Series E Preferred Stock will be issued in book-entry form and shall initially be represented only by one or more global certificates deposited with The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

In the event of a liquidation, the holders of Series E Preferred Stock are entitled to participate on an as-converted-to-Common Stock basis with holders of the Common Stock in any distribution of assets of the Company to the holders of the Common Stock. The Series E Certificate of Designation provides, among other things, that we shall not pay any dividends on shares of Common Stock (other than dividends in the form of Common Stock) unless and until such time as we pay dividends on each Series E Preferred Share on an as-converted basis. Other than as set forth in the previous sentence, the Series E Certificate of Designation provides that no other dividends shall be paid on Series E Preferred Shares and that we shall pay no dividends (other than dividends in the form of common stock) on shares of common stock unless we simultaneously comply with the previous sentence. The Series E Certificate of Designation does not provide for any restriction on the repurchase of Series E Preferred Shares by us while there is any arrearage in the payment of dividends on the Series E Preferred Shares. There are no sinking fund provisions applicable to the Series E Preferred Shares.

In addition, in the event we consummate a merger or consolidation with or into another person or other reorganization event in which our common shares are converted or exchanged for securities, cash or other property, or we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets or we or another person acquire 50% or more of our outstanding shares of common stock, then following such event, the holders of the Series E Preferred Shares will be entitled to receive upon conversion of the Series E Preferred Shares the same kind and amount of securities, cash or property which the holders would have received had they converted the Series E Preferred immediately prior to such fundamental transaction. Any successor to us or surviving entity shall assume the obligations under the Series E Preferred Shares.

With certain exceptions, as described in the Series E Certificate of Designation, the Series E Preferred Shares have no voting rights. However, as long as any shares of Series E Preferred Shares remain outstanding, the Series E Certificate of Designation provides that we shall not, without the affirmative vote of holders of a majority of the then-outstanding Series E Preferred Shares, (a) alter or change adversely the powers, preferences or rights given to the Series E Preferred Shares or alter or amend the Series E Certificate of Designation, (b) increase the number of authorized shares of

Series E Preferred Shares or (c) amend our certificate of incorporation or other charter documents in any manner that adversely affects any rights of holders of Series E Preferred Shares.

Each Series E Preferred Share is convertible at any time at the holder's option into a number of shares of common stock equal to \$1,000 divided by the Series E Conversion Price. The "Series E Conversion Price" is initially \$1.00 and is subject to adjustment for stock splits, stock dividends, distributions, subdivisions and combinations. Notwithstanding the foregoing, the Series E Certificate of Designation further provides that we shall not affect any conversion of Series E Preferred Shares, with certain exceptions, to the extent that, after giving effect to an attempted conversion, the holder of Series E Preferred Shares (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of Common Stock in excess of 4.99% (or, at the election of the holder, 9.99%) of the shares of our Common Stock then outstanding after giving effect to such exercise (the "Preferred Stock Beneficial Ownership Limitation"); provided, however, that upon notice to the Company, the holder may increase or decrease the Preferred Stock Beneficial Ownership Limitation, provided that in no event shall the Preferred Stock Beneficial Ownership Limitation exceed 9.99% and any increase in the Preferred Stock Beneficial Ownership Limitation will not be effective until 61 days following notice of such increase from the holder to us.

Additionally, subject to certain exceptions, at any time after the issuance of the Series E Preferred Stock, subject to the Preferred Stock Beneficial Ownership Limitation, we will have the right to cause each holder of the Series E Preferred Stock to convert all or part of such holder's Series E Preferred Stock in the event that (i) the volume weighted average price of our common stock for 30 consecutive trading days (the "Measurement Period") exceeds 300% of the conversion price of the Series E Preferred Stock (subject to adjustment for forward and reverse stock splits, recapitalizations, stock dividends and similar transactions), (ii) the average daily trading volume for such Measurement Period exceeds \$500,000 per trading day and (iii) the holder is not in possession of any information that constitutes or might constitute, material non-public information which was provided by the Company and subject to the Preferred Stock Beneficial Ownership Limitation. Our right to cause each holder of the Series E Preferred Stock to convert all or part of such holder's Series E Preferred Stock shall be exercised ratably among the holders of the then outstanding preferred stock.

We do not intend to apply for listing of the Series E Preferred Shares on any securities exchange or other trading system.

### **Description of Outstanding Warrants**

As of March 28, 2017, there were warrants outstanding to purchase a total of 926,723 shares of our common stock, which expire between 2017 and 2025. Each of these warrants entitles the holder to purchase one share of common stock at prices ranging from \$1.73 to \$210.00 per common share, with a weighted average exercise price of \$4.05 per share. Certain of these warrants have a net exercise provision under which its holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of our common stock at the time of exercise of the warrant after deduction of the aggregate exercise price. Each of these warrants also contains provisions for the adjustment of the exercise price and the aggregate number of shares issuable upon the exercise of the warrant in the event of dividends, share splits, reorganizations and reclassifications and consolidations. Certain of these warrants provide that, subject to limited exceptions, a holder will not have the right to exercise any portion of its warrants if the holder, together with its affiliates, would beneficially own over 4.99% of our then outstanding common stock following such exercise; provided, however, that upon prior notice to us, the warrant holder may increase its ownership, provided that in no event will the ownership exceed 9.99%.

## **Warrant Exercise Agreement**

On February 15, 2017, we entered into a letter agreement with the institutional investors (the "Investors") that hold the majority of our outstanding warrants (such warrants held by the Investors, the "Original Warrants"), to incent the cash exercise of these Original Warrants on or before March 31, 2017 (the "Exercise Period"). In exchange for any such exercise, we agreed to provide the Investors a replacement warrant (the "Replacement Warrants") to purchase the same number of shares of common stock as were issued upon exercise of the Original Warrants, with an exercise price equal to the consolidated closing bid price of our common stock on the date of issuance. The agreement also (i) amends the definition of "Beneficial Ownership Limitation" in the Original Warrants to mean, solely for purposes of any exercises of Original Warrants that occur during the Exercise Period, "9.99%" and (ii) amends the Initial Exercise Date of the Original Warrants issued on November 3, 2016 and January 11, 2017 so that such Original Warrants are exercisable on or after the receipt of stockholder approval. Since such stockholder approval was received on January 9, 2017, such Original Warrants were immediately exercisable as of the date of the agreement. The Replacement Warrants are in the same form as the Original Warrants except the exercise price will not be subject to reduction for subsequent equity issuances and (ii) the Replacement Warrants will not allow the Investor to demand that we purchase the Replacement Warrants in the event of a fundamental transaction involving the Company. Concurrent with the signing of the agreement, the Investors exercised Original Warrants to purchase 104,419 shares of common stock for cash proceeds of approximately \$564,000, and we issued such Investors Replacement Warrants to purchase 104,419 shares of common stock at an exercise price of \$4.99 per share. From March 10, 2017 to March 28, 2017, the Investors exercised Original Warrants to purchase 763,498 shares of common stock for cash proceeds of approximately \$1.4 million, and we issued such Investors Replacement Warrants to purchase 763,498 shares of common stock with exercise prices equal to the closing consolidated bid price of our common stock available on the date of issuance (ranging from \$1.73 to \$3.77 per share). The Company entered into the letter agreement with the Investors to incent the exercise of the Original Warrants in order to receive the cash proceeds from the exercise of the Original Warrants and because the exercise of the Original Warrants would allow the Company to remove the warrant liability from its balance sheet and avoid future fair value adjustments and associated volatility in its financial statements. As of March 28, 2017, we have no Original Warrants remaining outstanding and all Replacement Warrants under the letter agreement have been issued.

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

### ***Certificate of Incorporation and Bylaws***

Certain provisions of our certificate of incorporation and bylaws may be considered to have 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<sup>2</sup>/<sub>3</sub>% super-majority stockholder approval in order for stockholders to alter, amend or repeal certain provisions of our certificate of incorporation;
- requiring a 66<sup>2</sup>/<sub>3</sub>% super-majority stockholder approval in order for stockholders to adopt, amend or repeal our bylaws;
- providing that, subject to the rights of the holders of any series of preferred stock to elect additional directors under specified circumstances, neither the board of directors nor any individual director may be removed without cause;
- creating the possibility that our board of directors could prevent a coercive takeover of our Company due to the significant amount of authorized, but unissued shares of our common stock and preferred stock;
- providing that, subject to the rights of the holders of any series of preferred stock, the number of directors shall be fixed from time to time exclusively by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- providing that any vacancies on our board of directors under certain circumstances will be filled only by a majority of our board of directors then in office, even if less than a quorum, and not by the stockholders.

#### **Delaware Law**

We are also subject to Section 203 of 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<sup>2</sup>/<sub>3</sub>% 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 our certificate of incorporation and bylaws and the above-summarized provisions of the DGCL 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 directors, officers or other employees to us 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 made, 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.

## **Registration Rights**

### *Investor Replacement Warrants*

We intend to register for resale the shares of common stock underlying the Replacement Warrants issued to the Investors under the Warrant Exercise Agreement described above before they become exercisable.

### *Aquadex Acquisition*

On August 5, 2016, upon closing of the acquisition of the Aquadex Business, we entered into a registration rights agreement with Baxter, pursuant to which Baxter or its affiliates has the right to request that we file a registration statement with the SEC to register all or part of the 33,333 shares of common stock that Baxter received in connection with the acquisition. Upon receipt of any such request, we have agreed to use reasonable best efforts to prepare and file a registration statement as expeditiously as possible but in any event within 30 days of such request, to cause the registration statement to become effective in accordance with Baxter's intended method of distribution, and to pay the expenses incurred in connection with any such registration.

## **Participation and Repurchase Rights**

In the securities purchase agreement dated July 20, 2016 with Sabby Healthcare Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. (collectively, "Sabby"), we granted Sabby the right, if we issue any shares of common stock or common stock equivalents for cash consideration, indebtedness or a combination of units within 12 months of July 26, 2016 (with certain exceptions), to participate in up to 50% of such financing on the same terms, conditions and price provided for in such financing.

In the asset purchase agreement for the Aquadex Business, we granted Baxter the right, in the event we propose to issue or sell new shares of our common stock or securities convertible into, exchangeable or exercisable for common stock on or prior to July 31, 2017 (with certain exceptions), to purchase all or a part of its pro rata portion of any such new securities on terms not less favorable than the most favorable terms received by any other party in such financing. Furthermore, under the asset purchase agreement, Baxter has the right to require us to repurchase, in cash, all or part of the common stock held by Baxter at a price equal to the fair market value, as determined by a third party appraiser.

## **Transfer Agent and Registrar**

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

## **Listing**

Our common stock trades on The Nasdaq Capital Market under the symbol "SSH." See "Prospectus Summary—Recent Developments—Nasdaq Compliance" in this prospectus for important information about the listing of our common stock on The Nasdaq Capital Market.

## UNDERWRITING

We have entered into an underwriting agreement dated April 19, 2017 with the Ladenburg Thalmann & Co. Inc., as underwriter. Subject to the terms and conditions of the underwriting agreement, the underwriter has agreed to purchase the number of our securities set forth opposite its name below.

<u>Underwriter</u>	<u>Class A Units</u>	<u>Class B Units</u>
Ladenburg Thalmann & Co. Inc.	1,600,000	6,400
Total	<u>1,600,000</u>	<u>6,400</u>

A copy of the underwriting agreement will be filed as an exhibit to the registration statement of which this prospectus is part.

We have been advised by the underwriter that it proposes to offer the Units directly to the public at the public offering price set forth on the cover page of this prospectus. The underwriter may sell Class A Units or Class B Units separately to purchasers or may sell a combination of Class A Units and Class B Units to purchasers in any proportion. Any securities sold by the underwriter to securities dealers will be sold at the public offering price less a selling concession not in excess of \$0.054 per Class A Unit.

The underwriting agreement provides that the underwriter's obligation to purchase the securities we are offering is subject to conditions contained in the underwriting agreement.

No action has been taken by us or the underwriter that would permit a public offering of the units, or the shares, of common stock, shares of preferred stock and warrants included in the units, in any jurisdiction outside the United States where action for that purpose is required. None of our securities included in this offering may be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sales of any of the securities offering hereby be distributed or published in any jurisdiction except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons who receive this prospectus are advised to inform themselves about and to observe any restrictions relating to this offering of securities and the distribution of this prospectus. This prospectus is neither an offer to sell nor a solicitation of any offer to buy the securities in any jurisdiction where that would not be permitted or legal.

The underwriter has advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

### Underwriting Discount and Expenses

The following table summarizes the underwriting discount and commission to be paid to the underwriter by us.

	<u>Per Class A Unit(1)</u>	<u>Per Class B Unit(1)</u>	<u>Total</u>	<u>Total with Overallotment</u>
Public offering price	1.00	1,000.00	8,000,000	9,200,000
Underwriting discount to be paid to the underwriter by us (9%)(2)(3)	0.09	90.00	720,000	828,000
Proceeds to us (before expenses)	0.91	910.00	7,280,000	8,372,000

- (1) The public offering price and underwriting discount corresponds to (x) in respect of the Class A Units (i) a public offering price per share of common stock of \$0.99 and (ii) a public offering price

per warrant of \$0.01 and (y) in respect of the Class B Units (i) a public offering price per share of Series E Preferred Stock of \$990 and (ii) a public offering price per warrant of \$0.01 to purchase one share of common stock.

- (2) We have also agreed to reimburse the accountable expenses of the underwriter, including legal fees, in this offering, up to a maximum of \$90,000.
- (3) We have granted a 45 day option to the underwriter to purchase up to 1,200,000 additional shares of common stock (up to 15% of the shares of common stock plus the number of shares of common stock issuable upon conversion of shares of Series E Preferred Stock) and/or additional warrants exercisable for up to an additional 1,200,000 shares of common stock (up to 15% of the warrants sold in this offering) at the public offering price per share of common stock and the public offering price per warrant set forth above less the underwriting discounts and commissions solely to cover over-allotments, if any.

We estimate the total expenses payable by us for this offering to be approximately \$1.0 million, which amount includes (i) the underwriting discount of \$720,000 (\$828,000 if the underwriter's over-allotment option is exercised in full) and (ii) reimbursement of the accountable expenses of the underwriter of \$75,000, including the legal fees of the underwriter payable by us and (iii) other estimated company expenses of approximately \$205,000 which includes legal accounting printing costs and various fees associated with the registration and listing of our shares.

The securities we are offering are being offered by the underwriter subject to certain conditions specified in the underwriting agreement.

### **Over-allotment Option**

We have granted to the underwriter an option exercisable not later than 45 days after the date of this prospectus to purchase up to a number of additional shares of common stock and/or warrants equal to 15% of the number of shares of common stock sold in the primary offering (including the number of shares of common stock issuable upon conversion of shares of Series E Preferred Stock but excluding any shares of common stock underlying the warrants issued in this offering and any shares of common stock issued upon any exercise of the underwriter's over-allotment option) and/or 15% of the warrants sold in the primary offering at the public offering price per share of common stock and the public offering price per warrant set forth on the cover page hereto less the underwriting discounts and commissions. The underwriter may exercise the option solely to cover over-allotments, if any, made in connection with this offering. If any additional shares of common stock and/or warrants are purchased, the underwriter will offer these shares of common stock and/or warrants on the same terms as those on which the other securities are being offered.

### **Other Relationships**

Upon completion of this offering, we have granted the underwriter a right of first refusal to act as sole bookrunner or exclusive placement agent in connection with any subsequent public or private offering of equity securities or other capital markets financing by us. This right of first refusal extends for 12 months from the closing date of this offering. The terms of any such engagement of the underwriter will be determined by separate agreement.

### **Determination of Offering Price**

Our common stock is currently traded on The Nasdaq Capital Market under the symbol "SSH." See "Prospectus Summary—Recent Developments—Nasdaq Compliance" for important information about the listing of our common stock on The Nasdaq Capital Market. On April 18, 2017 the closing

price of our common stock was \$1.35 per share. We do not intend to apply for listing of the Series E Preferred Stock or the warrants on any securities exchange or other trading system.

The public offering price of the securities offered by this prospectus will be determined by negotiation between us and the underwriter among the factors considered in determining the public offering price of the shares were;

- our history and our prospects;
- the industry in which we operate;
- our past and present operating results;
- the previous experience of our executive officers; and
- the general condition of the securities markets at the time of this offering, including discussions between the underwriter and prospective investors.

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

### **Lock-up Agreements**

Our officers, directors and each of their respective affiliates and associated partners have agreed with the underwriter to be subject to a lock-up period of 90 days following the date of this prospectus. This means that, during the applicable lock-up period, such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock. Certain limited transfers are permitted during the lock-up period if the transferee agrees to these lock-up restrictions. We have also agreed, in the underwriting agreement, to similar lock-up restrictions on the issuance and sale of our securities for 90 days following the closing of this offering, although we will be permitted to issue stock options or stock awards to directors, officers and employees under our existing plans. The underwriter may, in its sole discretion and without notice, waive the terms of any of these lock-up agreements.

### **Transfer Agent and Registrar**

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

### **Stabilization, Short Positions and Penalty Bids**

The underwriter may engage in syndicate covering transactions stabilizing transactions and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of our common stock;

- Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. Such a naked short position would be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriter is concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect investors who purchase in the offering.
- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specific maximum.

- Penalty bids permit the underwriter to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These syndicate covering transactions, stabilizing transactions, and penalty bids may have the effect of raising or maintaining the market prices of our securities or preventing or retarding a decline in the market prices of our securities. As a result the price of our common stock may be higher than the price that might otherwise exist in the open market. Neither we nor the underwriter make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on the Nasdaq Capital Market, in the over-the-counter market or on any other trading market and, if commenced, may be discontinued at any time.

In connection with this offering, the underwriter also may engage in passive market making transactions in our common stock in accordance with Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of the distribution. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for that security. However, if all independent bids are lowered below the passive market maker's bid that bid must then be lowered when specific 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.

Neither we, nor the underwriter make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the prices of our securities. In addition, neither we nor the underwriter make any representation that the underwriter will engage in these transactions or that any transactions, once commenced will not be discontinued without notice.

### **Indemnification**

We have agreed to indemnify the underwriter against certain liabilities, including certain liabilities arising under the Securities Act or to contribute to payments that the underwriter may be required to make for these liabilities.

## MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following is a general discussion of material U.S. federal income considerations relating to the purchase, ownership and disposition of our common stock, Series E Preferred Stock or warrants. This discussion is based on current provisions of the Internal Revenue Code of 1986 (the "Internal Revenue Code"), existing and proposed U.S. Treasury Regulations promulgated or proposed thereunder and current administrative and judicial interpretations thereof, all as in effect as of the date of this prospectus and all of which are subject to change or to differing interpretation, possibly with retroactive effect. We have not sought and will not seek any rulings from the Internal Revenue Service (the "IRS") regarding the matters discussed below. There can be no assurance that the IRS or a court will not take a contrary position.

This discussion is limited to U.S. holders and non-U.S. holders who hold our common stock, Series E Preferred Stock or warrants as capital assets within the meaning of Section 1221 of the Internal Revenue Code (generally, as property held for investment). This discussion does not address all aspects of U.S. federal income taxation, such as the U.S. alternative minimum income tax and the additional tax on net investment income, nor does it address any aspect of state, local or non-U.S. taxes, or U.S. federal taxes other than income taxes, such as federal estate taxes. This discussion does not consider any specific facts or circumstances that may apply to a holder and does not address the special tax considerations that may be applicable to particular holders, such as:

- insurance companies;
- tax-exempt organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;
- pension plans;
- controlled foreign corporations;
- passive foreign investment companies;
- corporations that accumulate earnings to avoid U.S. federal income tax;
- certain U.S. expatriates;
- U.S. persons that have a "functional currency" other than the U.S. dollar;
- persons that acquire our common stock as compensation for services;
- owners that hold our common stock, Series E Preferred Stock or warrants as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;
- entities that are treated as disregarded entities for U.S. federal income tax purposes (regardless of their places of organization or formation) and their investors; and
- partnerships or other entities treated as partnerships for U.S. federal income tax purposes and their investors.

If any entity taxable as a partnership for U.S. federal income tax purposes holds our common stock, Series E Preferred Stock or warrants, the U.S. federal income tax treatment of a partner in the partnership generally will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. An investor in a partnership or entity treated as disregarded for U.S. federal income tax purposes should consult his, her or its own tax advisor



regarding the applicable tax consequences relating to the purchase, ownership and disposition of our common stock, Series E Preferred Stock or warrants.

For purposes of this discussion, the term "U.S. holder" means a beneficial owner of our common stock, Series E Preferred Stock or warrants that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized in or under the laws of the United States or of any political subdivision of the United States;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if (1) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (2) the trust has a valid election to be treated as a U.S. person under applicable U.S. Treasury Regulations.

A "non-U.S. holder" is a beneficial owner of our common stock, Series E Preferred Stock or warrants that is, for U.S. federal income tax purposes, an individual, corporation, estate or trust that is not a U.S. holder.

**Prospective investors should consult their own tax advisors regarding the U.S. federal, state, local and non-U.S. income and other tax considerations of purchasing, holding and disposing of our common stock, Series E Preferred Stock or warrants.**

## **U.S. Holders**

### ***Purchase of Units***

For U.S. federal income tax purposes, the purchase of a Class A Unit will be treated as the purchase of two components: a component consisting of one share of our common stock and a component consisting of one warrant to purchase one share of our common stock. The purchase of a Class B Unit will be treated as the purchase of two components: a component consisting of one share of our Series E Preferred Stock and a component consisting of warrants to purchase a number of shares of our common stock equal to \$1,000 divided by the Conversion Price. The purchase price for each Unit will be allocated between its components in proportion to the relative fair market value of each at the time the Unit is purchased by the holder. This allocation of the purchase price for each Unit will establish a holder's initial tax basis for U.S. federal income tax purposes in the shares and warrants that compose each Unit.

### ***Exercise of Warrants***

A U.S. holder generally will not recognize gain or loss on the exercise of a warrant and related receipt of shares of our common stock (unless cash is received in lieu of the issuance of a fractional share of our common stock). A U.S. holder's initial tax basis in the shares of our common stock received upon the exercise of a warrant will be equal to the sum of (a) such U.S. holder's tax basis in such warrant plus (b) the exercise price paid by such U.S. holder on the exercise of such warrant. A U.S. holder's holding period for the shares of our common stock received upon the exercise of a warrant will begin on the day after the date that the warrant is exercised.

In certain limited circumstances, a U.S. holder may be permitted to undertake a cashless exercise of warrants into shares of our common stock. The U.S. federal income tax treatment of a cashless exercise of warrants into shares of common stock is unclear, and the tax consequences of a cashless exercise could differ from the consequences upon the exercise of a warrant described in the preceding

paragraph. U.S. holders should consult their own tax advisors regarding the U.S. federal income tax consequences of a cashless exercise of warrants.

#### ***Certain Adjustments to the Warrants or Series E Preferred Stock***

An adjustment to the number of shares of our common stock that will be issued upon the exercise of a warrant or conversion of a share of Series E Preferred Stock, or an adjustment to the exercise price of a warrant, may be treated as a constructive distribution to a U.S. holder of the warrant or share depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our shareholders). Adjustments to the exercise price of warrants or conversion price of Series E Preferred Stock made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution of the interest of the holders thereof generally should not be considered to result in a constructive distribution. Any such constructive distribution would be taxable whether or not there is an actual distribution of cash or other property. See the more detailed discussion of the rules applicable to distributions made by us under the heading "Distributions on Common Stock or Series E Preferred Stock" below.

#### ***Expiration of the Warrants without Exercise***

Upon the lapse or expiration of a warrant, a U.S. holder will recognize a loss in an amount equal to such U.S. holder's tax basis in the warrant. Any such loss generally will be a capital loss and will be long-term capital loss if the warrant is held for more than one year. Deductions for capital losses are subject to certain limitations.

#### ***Conversion of Series E Preferred Stock***

A U.S. holder generally will not recognize gain or loss upon the conversion of a share of Series E Preferred Stock into common stock. A U.S. holder's initial tax basis in the shares of our common stock received upon the conversion of a share of Series E Preferred Stock will be equal to such U.S. holder's tax basis in the share of Series E Preferred Stock. A U.S. holder's holding period for the shares of our common stock received upon the conversion of a share of Series E Preferred Stock will include the U.S. holder's holding period in such share of Series E Preferred Stock.

#### ***Distributions on Common Stock or Series E Preferred Stock***

If we pay distributions of cash or property with respect to our common stock or Series E Preferred Stock (including constructive distributions as described above under the heading "Certain Adjustments to the Warrants or Series E Preferred Stock"), those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the U.S. holder's investment, up to such holder's tax basis in its shares of our common stock or Series E Preferred Stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below under the heading "—Gain on Sale, Exchange or Other Taxable Disposition."

#### ***Gain on Sale, Exchange or Other Taxable Disposition***

Upon the sale or other taxable disposition of common shares, Series E Preferred Stock or warrants, a U.S. holder generally will recognize capital gain or loss in an amount equal to the difference between (a) the amount of cash plus the fair market value of any property received and (b) such U.S. holder's tax basis in such common shares, Series E Preferred Stock or warrants sold or otherwise disposed of. Such gain or loss generally will be long-term capital gain or loss if, at the time of the sale or other disposition, the common shares, Series E Preferred Stock or warrants have been

held by the U.S. holder for more than one year. Preferential tax rates may apply to long-term capital gain of a U.S. holder that is an individual, estate, or trust. Deductions for capital losses are subject to certain limitations.

## **Non-U.S. Holders**

### ***Distributions on Common Stock or Series E Preferred Stock***

If we pay distributions of cash or property with respect to our common stock or Series E Preferred Stock (including constructive distributions as described above under the heading "Certain Adjustments to the Warrants or Series E Preferred Stock"), those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's tax basis in its shares of our common stock or Series E Preferred Stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below under the heading "—Gain on Sale, Exchange or Other Taxable Disposition." Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence. In the case of any constructive distribution, it is possible that this tax would be withheld from any amount owed to the non-U.S. holder, including, but not limited to, distributions of cash, common stock or sales proceeds subsequently paid or credited to that holder. If we are unable to determine, at the time of payment of a distribution, whether the distribution will constitute a dividend, we may nonetheless choose to withhold any U.S. federal income tax on the distribution as permitted by U.S. Treasury Regulations.

Distributions that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States are generally not subject to the 30% withholding tax if the non-U.S. holder provides a properly executed IRS Form W-8ECI stating that the distributions are not subject to withholding because they are effectively connected with the non-U.S. holder's conduct of a trade or business in the United States. If a non-U.S. holder is engaged in a trade or business in the United States and the distribution is effectively connected with the conduct of that trade or business, the distribution will generally have the consequences described above for a U.S. holder (subject to any modification provided under an applicable income tax treaty). Any U.S. effectively connected income received by a non-U.S. holder that is treated as a corporation for U.S. federal income tax purposes may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate (or such lower rate as may be specified by an applicable income tax treaty).

A non-U.S. holder who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E, as applicable, and satisfy applicable certification and other requirements. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty generally may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS. Non-U.S. holders should consult their own tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

### ***Gain on Sale, Exchange or Other Taxable Disposition***

Subject to the discussion below in "—Information Reporting and Backup Withholding" and "—Foreign Account Tax Compliance Act," a non-U.S. holder generally will not be subject to

U.S. federal income tax on gain recognized on a sale, exchange or other taxable disposition of our common stock, Series E Preferred Stock or warrants unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment maintained by the non-U.S. holder in the United States; in these cases, the non-U.S. holder will be taxed on a net income basis at the regular graduated rates and in the manner applicable to a U.S. holder, and, if the non-U.S. holder is a corporation, an additional branch profits tax at a rate of 30%, or a lower rate as may be specified by an applicable income tax treaty, may also apply;
- the non-U.S. holder is an individual present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the amount by which such non-U.S. holder's capital gains allocable to U.S. sources exceed capital losses allocable to U.S. sources during the taxable year of the disposition; or
- we are or were a "U.S. real property holding corporation" during the shorter of the five-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. Generally, a corporation is a "U.S. real property holding corporation" if the fair market value of its "U.S. real property interests" (within the meaning of the Internal Revenue Code) equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. We believe that we are not currently, and we do not anticipate becoming, a "U.S. real property holding corporation" for U.S. federal income tax purposes.

### **Information Reporting and Backup Withholding**

Distributions on, and the payment of the proceeds of a disposition of, our common stock, Series E Preferred Stock or warrants generally will be subject to information reporting if made within the United States or through certain U.S.-related financial intermediaries. Information returns are required to be filed with the IRS and copies of information returns may be made available to the tax authorities of the country in which a holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding may also apply if the holder fails to provide certification of exempt status or a correct U.S. taxpayer identification number and otherwise comply with the applicable backup withholding requirements. Generally, a holder will not be subject to backup withholding if it provides a properly completed and executed IRS Form W-9 or appropriate IRS Form W-8, as applicable. Backup withholding is not an additional tax. Amounts withheld under the backup withholding rules may be refunded or credited against the holder's U.S. federal income tax liability, if any, provided certain information is timely filed with the IRS.

### **Foreign Account Tax Compliance Act**

Legislation commonly referred to as the Foreign Account Tax Compliance Act, or FATCA, generally imposes a U.S. federal withholding tax of 30% on payments to certain non-U.S. entities (including certain intermediaries) unless such persons comply with FATCA's information reporting and withholding regime. This regime and its requirements are different from, and in addition to, the certification requirements described elsewhere in this discussion. The FATCA withholding rules apply to dividend payments and, in the case of certain sales or other dispositions occurring after December 31, 2018 (including a distribution to the extent it is treated as a return of capital or capital gain), the gross proceeds of such disposition.

The United States has entered into, and continues to negotiate, intergovernmental agreements (each, an "IGA") with a number of other jurisdictions to facilitate the implementation of FATCA. An IGA may significantly alter the application of FATCA and its information reporting and withholding requirements with respect to any particular investor. FATCA is particularly complex and its application remains uncertain. Prospective investors should consult their own tax advisors regarding how these rules may apply in their particular circumstances.

## **LEGAL MATTERS**

Honigman Miller Schwartz and Cohn LLP, Kalamazoo, Michigan, will issue a legal opinion as to the validity of the securities offered by this prospectus. Ellenoff Grossman & Schole LLP, New York, New York, is acting as counsel for the underwriter in connection with certain legal matters in connection with this offering.

## **EXPERTS**

The consolidated financial statements of Sunshine Heart, Inc. and subsidiaries appearing in Sunshine Heart, Inc.'s Annual Report (Form 10-K) for the year ended December 31, 2016, 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.

