As filed with the Securities and Exchange Commission on February 14, 2017

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

SUNSHINE HEART, INC.

(Exact name of registrant as specified in its charter)

Delaware	**3845**	**68-0533453**
(State of Incorporation)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

12988 Valley View Road
Eden Prairie, Minnesota 55344
(952) 345-4200
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

John Erb
Chief Executive Officer
Sunshine Heart, Inc.
12988 Valley View Road
Eden Prairie, Minnesota 55344
(952) 345-4200
(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

Copies to:
Phillip D. Torrence, Esq.
Meredith Ervine, Esq.
Honigman Miller Schwartz and Cohn LLP
350 East Michigan Avenue, Suite 300
Kalamazoo, MI 49007
Tel: (269) 337-7700
Fax: (269) 337-7703

Approximate date of commencement of proposed sale to the public: From time to time after this Registration Statement becomes effective.

If any securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box: x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

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

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price Per Share(2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee
Shares of Common Stock, par value $0.0001 per share, underlying shares of Series D Convertible Preferred Stock(3)	**44,614**	**$ 5.73**	**$ 255,639**	**$ 29.63**
Shares of Common Stock, par value $0.0001 per share, issuable upon exercise of warrants issued on January 11, 2017(4)	**39,216**	**$ 5.73**	**$ 224,708**	**$ 26.05**
Shares of Common Stock, par value $0.0001 per share, issuable upon exercise of warrants issued on July 26, 2016(5)	**122,979**	**$ 5.73**	**$ 704,670**	**$ 81.67**
Total:	**206,809**		**$ 1,185,017**	**$ 137.35**

(1) Pursuant to Rule 416 under the Securities Act of 1933, as amended, the shares offered hereby also include an indeterminate number of additional shares of common stock as may from time to time become issuable by reason of stock splits, stock dividends, recapitalizations or other similar transactions and, with respect to the shares of common stock underlying the Series D Convertible Preferred Stock, an indeterminate number of shares of common stock issuable upon conversion of such Series D Convertible Preferred Stock as a result of adjustments in the conversion price of such Series D Convertible Preferred Stock as provided in the Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock and as described in this registration statement.

(2) Estimated solely for the purpose of calculating the registration fee (i) for the shares of common stock underlying the Series D Convertible Preferred Stock, pursuant to Rule 457(c) under the Securities Act, based upon the average of the high and low prices reported on the Nasdaq Capital Market on February 7, 2017, and (ii) for the warrants, in accordance with Rule 457(g) under the Securities Act, based upon the higher of (i) the price at which the warrants may be exercised and (ii) the average of the high and low prices for a share of the registrant's common stock as reported on the Nasdaq Capital Market on February 7, 2017.

(3) Represents shares of common stock issuable upon conversion of outstanding shares of Series D Convertible Preferred Stock of the registrant, with each share of Series D Convertible Preferred Stock having a value of $1,000 per share and a conversion price into shares of common stock currently fixed at $4.483 per share, to be offered and sold by the selling stockholders identified in this registration statement.

(4) Represents shares of common stock issuable upon exercise of certain warrants to purchase common stock, at an exercise price currently fixed at $5.40 per share, to be offered and sold by the selling stockholders identified in this registration statement.

(5) Represents shares of common stock issuable upon exercise of certain warrants to purchase common stock, at an exercise price currently fixed at $5.40 per share, to be offered and sold by the selling stockholders identified in this registration statement.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. The Selling Stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, and the Selling Stockholders are not soliciting offers to buy these securities, in any state where the offer or sale of these securities is not permitted.

SUBJECT TO COMPLETION, DATED FEBRUARY 14, 2017

PRELIMINARY PROSPECTUS

SUNSHINE HEART, INC.

206,809 Shares of Common Stock, consisting of 44,614 Shares of Common Stock Underlying 200 Shares of Series D Convertible Preferred Stock and 162,195 Shares of Common Stock issuable upon exercise of Warrants

This prospectus relates to the resale, from time to time, of (i) up to 44,614 shares of our common stock, par value $0.0001 per share (the "Common Stock"), issuable upon conversion of 200 shares of our Series D Convertible Preferred Stock, par value $0.0001 per share (the "Series D Preferred Stock"), (ii) an aggregate of 39,216 shares of our Common Stock issuable upon exercise of common stock purchase warrants issued on January 11, 2017 (the "January Warrants") and (iii) an aggregate of 122,979 shares of our Common Stock issuable upon exercise of common stock purchase warrants issued on July 20, 2016 ("July Warrants" together with the January Warrants, the "Warrants") by Sabby Healthcare Master Fund Ltd. and Sabby Volatility Warrant Master Fund Ltd., which are funds managed by Sabby Management, LLC (which we collectively refer to as "Sabby" or the "Selling Stockholders").

We are not selling any securities under this prospectus and we will not receive proceeds from the sale of Common Stock by the Selling Stockholders. However, we may receive proceeds from the cash exercise of the Warrants, which, if exercised in cash at the current applicable exercise price with respect to all of the 162,195 shares of Common Stock, would result in gross proceeds of $875,853. We sold the Series D Preferred Stock and January Warrants to Sabby under a purchase agreement (the "October Sabby Purchase Agreement") dated October 30, 2016 for gross proceeds of $0.2 million on January 11, 2017 upon the approval of our stockholders of the issuance of the shares of Common Stock upon conversion or exercise of the securities sold under the October Sabby Purchase Agreement. For a more detailed description of the Series D Preferred Stock and the January Warrants, see the section entitled "Sale of Securities to Sabby". Furthermore, we sold the July Warrants to Sabby under a purchase agreement, dated July 20, 2016 ("July Sabby Purchase Agreement"). For a more detailed description of the July Warrants, see the section "Sale of Securities to Sabby".

We will pay the expenses of registering the shares of Common Stock offered by this prospectus, but all selling and other expenses incurred by each Selling Stockholder will be paid by such Selling Stockholder. The Selling Stockholders may sell the shares of our Common Stock offered by this prospectus from time to time on terms to be determined at the time of sale through ordinary brokerage transactions or through any other means described in this prospectus under "Plan of Distribution." The prices at which the Selling Stockholders may sell shares will be determined by the prevailing market price for shares of our Common Stock or in negotiated transactions.

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Our Common Stock trades on The Nasdaq Capital Market under the ticker symbol "SSH". On February 10, 2017, the last reported sale price per share of our Common Stock was $5.44 per share. See "Description of Capital Stock — Common Stock — Listing."

Investing in our Common Stock involves a high degree of risk. Before making any investment in our Common Stock, 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.

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 date of this prospectus is , 20 .

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You should rely only on the information contained in this prospectus or any prospectus supplement or amendment thereto. We have not authorized anyone to provide you with different information.

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ABOUT THIS PROSPECTUS

This prospectus relates to the resale by the Selling Stockholders of up to 44,614 shares of our Common Stock issuable upon conversion of 200 shares of our Series D Preferred Stock, up to 39,216 shares of our Common Stock issuable upon exercise of the January Warrants and up to 122,979 shares of our Common Stock issuable upon exercise of the July Warants, in each case as described below under “Sale of Securities to Sabby” and “Description of Capital Stock.” We are not selling any shares of Common Stock under this prospectus and will not receive any proceeds from the sale of shares of Common Stock by the Selling Stockholders.

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 by the Selling Stockholders. 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. 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, 2015, filed with the SEC on March 15, 2016.

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- our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2016 filed with the SEC on May 5, 2016, for the quarter ended June 30, 2016 filed with the SEC on August 11, 2016 and for the quarter ended September 30, 2016 filed with the SEC on November 14, 2016.
- our Current Reports on Form 8-K or 8-K/A filed with the SEC on March 2, 2016, March 25, 2016, May 31, 2016, June 15, 2016, July 11, 2016, July 22, 2016, August 24, 2016, September 23, 2016, September 29, 2016, October 21, 2016, October 31, 2016, November 3, 2016, November 17, 2016, November 22, 2016, December 16, 2016, December 21, 2016, January 10, 2017, January 13, 2017, February 3, 2017 and February 10, 2017.
- the definitive proxy statement for the special meeting of stockholders held on January 9, 2017, filed with the SEC on December 8, 2016, as supplemented by the additional definitive soliciting material filed on December 21, 2016.
- our definitive proxy statement for the annual meeting of stockholders held on May 26, 2016, filed with the SEC on April 13, 2016.

- 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 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. Information contained in, or accessible through, our website is not a part of this prospectus.

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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

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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 affected 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. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and, going forward, 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.

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We qualify as an "emerging growth company" as defined in the Jumpstart our Business Startups Act of 2012 or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other requirements that are otherwise applicable generally to U.S. public companies. These provisions include an exemption from the attestation requirement in the assessment of our internal control over financial reporting by our independent auditors pursuant to section 404 (b) of the Sarbanes-Oxley Act of 2002 ("SOX"). The provisions of the JOBS Act do not preclude us from the requirement to make our own internal assessment of the effectiveness of our internal controls over financial reporting.

We may take advantage of these provisions until December 31, 2017 or such earlier time that we are no longer an emerging growth company. We will cease to be an emerging growth company if we have more than $1 billion in annual revenue, have more than $700 million in market value of our shares of Common Stock held by non-affiliates, or issue more than $1 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these reduced requirements. In addition, the JOBS Act permits emerging growth companies to take advantage of an extended transition period to comply with new or revised accounting standards applicable to U.S. public companies. We have elected to take advantage of the benefits of this extended transition period, and as a result of this election, our financial statements may not be comparable to those of companies that comply with new or revised accounting standards for U.S. public companies.

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 granted us until March 20, 2017 to evidence compliance with the $2.5 million stockholder's 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. The financial statements incorporated by reference herein have not been adjusted to reflect the reverse stock split.

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Outstanding Preferred Stock

Through February 10, 2017, 2,555.1 shares of our Series C Convertible Preferred Stock have been converted into 501,000 shares of our common stock. As of February 10, 2017, 344.9 shares of our Series C Convertible Preferred Stock remain outstanding and are currently convertible into 67,626 shares of our common stock, and 900 shares of our Series D Convertible Preferred Stock remain outstanding and are convertible into 200,760 shares of our common stock. If the effective price per share in a future offering is lower than the then price of conversion of the Series C Convertible Preferred Stock or the Series D Convertible Preferred Stock, then the price of conversion of such preferred stock shall be reduced to equal to such lower price and such preferred stock shall be issuable for additional shares of common stock in connection with such conversion price reduction. Furthermore, each holder of our Series C Convertible Preferred Stock has the right to exchange all or some of the Series C Preferred Stock for securities issued in a future offering on a $1.00 for $1.00 basis based on the outstanding stated value of the Series C Convertible Preferred Stock, along with any accrued but unpaid liquidated damages and other amounts owing thereon, and the effective price in the offering. With respect to our Series D Convertible Preferred Stock, on or after May 3, 2017, the conversion price on our Series D Convertible Preferred Stock shall become an adjustable rate equal to 80% of the average of the daily volume weighted average price of our common stock for the ten trading days immediately prior to the conversion date, but shall not be reduced below $1.26. To the extent the outstanding shares of Series C Convertible Preferred Stock or Series D Convertible Preferred Stock become exercisable for additional shares of common stock pursuant to the foregoing provisions, holders of our common stock and investors in this offering will experience further dilution.

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The Offering

Securities offered by the Selling Stockholders	206,809 shares of our Common Stock
Common stock outstanding	1,636,743 (as of February 10, 2017)
Common stock to be outstanding after this offering, assuming full conversion or exercise of Series D Preferred Stock and Warrants Registered Hereby	1,843,552
Common stock to be outstanding after this offering, assuming full conversion or exercise of all of our outstanding preferred stock and warrants	2,860,780
Use of proceeds	We will not receive any proceeds from the sale by the Selling Stockholders of the shares of Common Stock being offered by this prospectus.
NASDAQ Symbol	SSH. See “Description of Capital Stock — Common Stock — Listing” for information regarding recent delisting notices received from Nasdaq.
Risk Factors	Investing in our securities involves a high degree of risk. You should carefully review and consider the section of this prospectus entitled “Risk Factors” on page 8 of this prospectus for a discussion of factors to consider before deciding to invest in shares of our Common Stock.

Except as otherwise indicated, all information in this prospectus is based on 1,636,743 shares of Common Stock outstanding as of February 10, 2017 and excludes the shares of Common Stock being offered by this prospectus and issuable upon conversion of the Series D Preferred Stock or exercise of the Warrants and also excludes the following:

- 223,773 shares of Common Stock currently* issuable upon the conversion of outstanding shares of our Series C Convertible Preferred Stock and Series D Preferred Stock issued on November 3, 2016;
- 87,574 shares of Common Stock issuable upon the exercise of outstanding stock options, having a weighted average exercise price of $115.13 per share and 9,177 shares of common stock issuable upon the vesting of restricted stock units;
- 764,689 shares of our Common Stock issuable upon the exercise of outstanding warrants (other than the Warrants) with a weighted-average exercise price of $7.29 per share; and
- 69,425 shares of our Common Stock reserved for future issuance under our equity incentive plans.

*The conversion prices of the Series C Convertible Preferred Stock and Series D Preferred Stock are subject to adjustment as set forth in the certificate of designation for such series.

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Description of the July Sabby Purchase Agreement

On July 20, 2016, we entered into the July Sabby Purchase Agreement with the Selling Stockholders, which provided for the issuance of 3,468 shares of Series B Convertible Preferred Stock at $1,000 per share and warrants to purchase an aggregate of 122,979 shares of Common Stock, par value $0.0001 per

share. We received net proceeds of $3.2 million in connection with the closing of the July Sabby Purchase Agreement after deducting fees owned to the placement agent and other fees applicable to the offering. For a detailed description of the transactions contemplated by the July Sabby Purchase Agreement and a description of the securities issued pursuant thereto, including the July Warrants, please see "Sale of Securities to Sabby" in this prospectus.

Description of the October Sabby Purchase Agreement

On October 30, 2016, we entered into the October Sabby Purchase Agreement with the Selling Stockholders, which provides that, upon the terms and subject to the conditions and limitations set forth therein, the closing of each of the transactions contemplated by the October Sabby Purchase Agreement were to occur in two stages. At the initial closing, which took place on November 3, 2016, we sold 2,900 shares of Series C Convertible Preferred Stock, 700 shares of Series D Preferred Stock, and 705,882warrants to purchase common stock to Sabby. At the second closing, which took place January 11, 2017, we sold 200 shares of Series D Preferred Stock and 39,216 January Warrants to purchase shares of common stock to Sabby. We received net proceeds of $3.3 million in connection with the first closing on November 3, 2016, after deducting fees owed to the placement agent and other fees applicable to the offering. We received net proceeds of $0.2 million in connection with the second closing on January 11, 2017, after deducting fees owed to the placement agent and other fees applicable to the offering. We intend to use the net proceeds for working capital needs for our recently-acquired Aquadex product line and for general corporate purposes. For a detailed description of the transactions contemplated by the October Sabby Purchase Agreement and a description of the securities issued pursuant thereto, including the Series D Preferred Stock and the January Warrants, please see "Sale of Securities to Sabby" in this prospectus.

We filed the registration statement on Form S-1, of which this prospectus forms a part, to fulfill our contractual obligations under October Purchase Agreement and the Registration Rights Agreement entered into concurrently therewith to provide for the resale by the Selling Stockholders of the shares of Common Stock offered hereby and issuable upon conversion of outstanding shares of our Series D Preferred Stock or exercise of the outstanding January Warrants. We agreed to use our best efforts to cause such registration statement to be declared effective by the 90th calendar day following the issuance of the Series D Preferred Stock and the January Warrants (or the 120th day in the event of a "full review" by the SEC) and to use best efforts to keep such registration statement continuously effective until the shares of Common Stock being offered by this prospectus have been sold hereunder or pursuant to Rule 144 or may be sold without volume or manner-of-sale restrictions pursuant to Rule 144 and without the requirement for the Company to be in compliance with the current public information requirement under Rule 144.

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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, 2015 expresses substantial doubt about our ability to continue as a going concern. We will need additional funding to continue operations, which may not be available to us on favorable terms or at all.

We are an early-stage company with a history of incurring net losses. We have incurred net losses since our inception, including net losses of $26.6 million, $25.6 million, and $21.8 million for the years ended December 31, 2015, 2014, and 2013, respectively, and $12.9 million for the nine months ended September 30, 2016. As of September 30, 2016, our accumulated deficit was $166.1 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, 2015 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 expect to require additional funding to grow our Aquadex Business, which may not be available on terms favorable to us, or at all. In addition, the risk that we may not be able to continue as a going concern may make it

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more difficult to obtain necessary additional funding on terms favorable to us, or at all. We expect to seek additional financing during 2017. 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 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 expect to seek additional financing during 2017. 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. If adequate funds are not available to us on a timely basis or at all, we would likely be required to significantly reduce our operations.

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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

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our business. In addition, because our system has been implanted in a limited number of patients to date, all of the material risks and potential competitive disadvantages of our system are not necessarily known at this time.

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

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

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

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

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 get the Aquadex FlexFlow into 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.

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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

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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

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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 futures losses.

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

Risks 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 5, 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

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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

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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 deviation 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

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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.

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, our common stock would likely 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;

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- 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 February 10, 2017 was $5.44. 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 proposed 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 preferred stock and 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 holders of our common stock.

The number of shares of common stock issuable upon conversion of our outstanding preferred stock and exercise of outstanding warrants is significant in relation to the number of shares of our Common Stock currently outstanding. If any security holder, including the Selling Stockholders, 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.

Through February 10, 2017, shares of our Series C Convertible Preferred Stock have been converted into 501,000 shares of our common stock. As of February 10, 2017, 344.9 shares of our Series C Convertible Preferred Stock

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remain outstanding and are currently convertible into 67,626 shares of our common stock, and 900 shares of our Series D Convertible Preferred Stock remain outstanding and are convertible into 200,760 shares of our common stock. If the effective price per share in a future offering is lower than the then price of conversion of the Series C Convertible Preferred Stock or the Series D Convertible Preferred Stock, then the price of conversion of such preferred stock shall

be reduced to equal to such lower price and such preferred stock shall be issuable for additional shares of common stock in connection with such conversion price reduction. Furthermore, each holder of our Series C Convertible Preferred Stock has the right to exchange all or some of the Series C Preferred Stock for securities issued in a future offering on a $1.00 for $1.00 basis based on the outstanding stated value of the Series C Convertible Preferred Stock, along with any accrued but unpaid liquidated damages and other amounts owing thereon, and the effective price in the offering. With respect to our Series D Convertible Preferred Stock, on or after May 3, 2017, the conversion price on our Series D Convertible Preferred Stock shall become an adjustable rate equal to 80% of the average of the daily volume weighted average price of our common stock for the ten trading days immediately prior to the conversion date, but shall not be reduced below $1.26. To the extent the outstanding shares of Series C Convertible Preferred Stock or Series D Convertible Preferred Stock become exercisable for additional shares of common stock, holders of our common stock 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.

Our board of directors has approved, pursuant to this authority, the issuance of preferred stock, and we have 344.9 shares of Series C Convertible Preferred Stock and 900 shares of Series D Preferred Stock outstanding as of February 10, 2017. The rights, preferences and privileges of our Series C Convertible Preferred Stock and Series D Preferred Stock are described in our Current Report on Form 8-K filed with the SEC on October 31, 2016. As described therein, upon liquidation, dissolution or winding-up of the Company, holders of our Series C Convertible Preferred Stock and Series D Preferred Stock have the right to receive, out of the assets, whether capital or surplus, of the Company, (i) for the Series C Convertible Preferred Stock, an amount equal to the par value, plus any accrued and unpaid dividends thereon, and (ii) for the Series D Preferred Stock, an amount equal to the stated value, plus any accrued and unpaid dividends thereon and any other fees or liquidated damages then due and owing thereon, in each case, for each such share of preferred stock held by such holder before any distribution or payment shall be made to the holders of our common stock, and, following such payment, such holders are entitled to receive the same amount that a holder of common stock would receive if such preferred stock was fully converted, pari passu with all the holders of common stock.

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 February 10, 2017, we had 1,636,743 shares of common stock outstanding and 1,292,021 shares of common stock reserved pursuant to

outstanding convertible preferred stock, warrants, options or restricted stock units or under the Company's equity incentive plans.

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 September 30, 2016, we had U.S. net operating loss ("NOL") carryforwards of approximately $37.9 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 September 30, 2016, we had tax losses in the Commonwealth of Australia of approximately AU$14.7 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

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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,

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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 2/3% majority stockholder approval in order for stockholders to amend certain provisions of our certificate of incorporation or bylaws or adopt new bylaws; providing that, subject to the rights of preferred shares, the directors will be divided into three classes and the number of directors is to be fixed exclusively by our board of directors; and providing that none of our directors may be removed without cause. Section 203 of the DGCL, from which we did not elect to opt out, provides that if a holder acquires 15% or more of our stock without prior approval of our board of directors, that holder will be subject to certain restrictions on its ability to acquire us within three years. These provisions may delay or deter a change in control of us, and could limit the price that investors might be willing to pay in the future for shares of our Common Stock.

We are an "emerging growth company" under federal securities laws and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our Common Stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the external auditor attestation requirements of Section 404 of SOX, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. The JOBS Act also permits emerging growth companies to take advantage of an extended transition period to comply with new or revised accounting standards applicable to U.S. public companies. We will be an emerging growth company until December 31, 2017. 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

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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.

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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.

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SALE OF SECURITIES TO SABBY

General

On July 20, 2016, we entered into the July Sabby Purchase Agreement with the Selling Stockholders under which we agreed to issue and sell (i) 3,468 shares of Series B Convertible Preferred Stock pursuant to our shelf registration statement on Form S-3 (File No. 333-194731) filed with the SEC, declared effective on May 5, 2014 and a prospectus supplement relating to the offering filed with the SEC on July 22, 2016 and (ii) warrants to purchase an aggregate of 122,979 shares of Common Stock, pursuant to an exemption from the registration requirements of the Securities Act provided in Section 4(a)(2) thereof and/or Rule 506 of Regulation D promulgated thereunder. We received net proceeds of $3.2 million at the closing on July 26, 2016, after deducting fees owed to the placement agent and other fees applicable to the offering.

On October 30, 2016, we entered into the October Sabby Purchase Agreement with the Selling Stockholders under which we agreed to issue and sell (i) 2,900 shares of Series C Convertible Preferred Stock pursuant to our shelf registration statement on Form S-3 (File No. 333-194731) filed with the SEC, declared effective on May 5, 2014 and a prospectus supplement relating to the offering filed with the SEC on October 31, 2016 (the "October Registered Direct Offering") and (ii) 900 shares of Series D Preferred Stock and warrants to purchase an aggregate of 745,097 shares of Common Stock, pursuant to an exemption from the registration requirements of the Securities Act provided in Section 4(a)(2) thereof and/or Rule 506 of Regulation D promulgated thereunder (such sale of warrants, together with the sale of Series D Preferred Stock, the "Private Placement"). The October Sabby Purchase Agreement provides that, upon the terms and subject to the conditions and limitations set forth therein, the closing of each of the October Registered Direct Offering and the Private Placement would occur in two stages. At the initial closing, which occurred on November 3, 2016, we sold 2,900 shares of Series C Convertible Preferred Stock, 700 shares of Series D Preferred Stock and 705,882warrants to purchase Common Stock to Sabby. At the second closing, which occurred January 11, 2017, we sold 200 shares of Series D Preferred Stock and 39,216 January Warrants to Sabby. We received net proceeds of $3.3 million in connection with the first closing on November 3, 2016, after deducting fees owed to the placement agent and other fees applicable to the offering. We received net proceeds of $0.2 million at the second closing on January 11, 2017, after deducting fees owed to the placement agent and other fees applicable to the offering. The shares of Series C Convertible Preferred Stock and Series D Preferred Stock have a stated value of $1,000 and convert into Common Stock at a conversion price of $5.10 and $4.483 per share, respectively, as of February 10, 2017, and would convert into an aggregate of 268,387 shares of Common Stock. The number of shares of Common Stock issuable upon conversion or exercise of the Series C Convertible Preferred Stock, Series D Preferred Stock or the warrants sold pursuant to the October Sabby Purchase Agreement is subject to adjustment pursuant to the terms of the certificates of designation for such series and the warrants. Pursuant to the October Sabby Purchase Agreement, we are required to reserve for future issuance pursuant to the Series C Convertible Preferred Stock and Series D Preferred Stock and the warrants sold thereunder the greater of (i) 100% (300% following the receipt of stockholder approval) of the maximum aggregate number of shares of Common Stock issuable upon conversion in full of all shares of the Series C Convertible Preferred Stock and Series D Preferred Stock and upon exercise in full of all warrants and (ii) 19.9% of our then issued and outstanding shares of Common Stock.

On October 30, 2016, we entered into a Securities Exchange Agreement with the Selling Stockholders pursuant to which we agreed to issue 2,227.2 shares of Series B-1 Convertible Preferred Stock in exchange for the cancellation of the 2,227.2 shares of Series B Convertible Preferred Stock that remained outstanding at the time. All such shares of Series B-1 Convertible Preferred Stock have since been converted to Common Stock.

October Securities Purchase Agreement

The October Sabby Purchase Agreement also required us, on or before the 20th day following the first closing, to file a proxy statement with the SEC for the purposes of holding a special meeting of our stockholders to vote on a proposal to approve the issuance of the shares of Common Stock underlying the preferred stock and warrants issued or issuable in connection with the transactions contemplated by the October Sabby Purchase Agreement pursuant to the requirements of Nasdaq Listing Rule 5635(d). We further agreed to hold such meeting within 120 days of the first closing for the purpose of obtaining stockholder approval and to use reasonable best efforts to obtain such

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approval. On December 9, 2016, we provided notice of our intention to call a special meeting of our stockholders on January 9, 2017 for such approval, among other things. We obtained such stockholder approval at the special meeting on January 9, 2017.

The second closing under the October Sabby Purchase Agreement was contingent upon the satisfaction of customary closing conditions and was consummated on January 11, 2017.

The October Sabby Purchase Agreement contains other customary representations, warranties and agreements by us.

Under the October Sabby Purchase Agreement, we agreed not to contract to issue or announce the issuance or proposed issuance of any Common Stock or equivalents until 30 days from the date of the receipt of stockholder approval, except on or after the date a definitive proxy statement for a special meeting of stockholders for the purpose of obtaining stockholder approval has been filed with the SEC, we may file a primary registration statement registering for issuance and sale our debt or equity securities. We have also agreed with Sabby that until such time as Sabby no longer holds any of the warrants issued under the October Securities Purchase Agreement, we will not effect or contract to effect a "Variable Rate Transaction" as defined in the October Sabby Purchase Agreement. We also agreed to provide Sabby, if we issue any shares of Common Stock or equivalents for cash consideration, indebtedness or a combination of units, with certain exceptions (including the issuance of debt or equity securities in a public offering pursuant to an effective registration statement), within twelve (12) months after the closing date, the right to participate in up to 50% of such subsequent financing on the same terms, conditions and price provided for in the subsequent financing. If we effect a subsequent financing at any time that Sabby holds Series C Convertible Preferred Stock or any securities received upon any exchange of Series C Convertible Preferred Stock or any subsequent exchange of any securities received by Sabby pursuant to this right

(the "Exchanged Securities"), Sabby has the right to exchange all or some of the Series C Convertible Preferred Stock or Exchanged Securities then held by Sabby for any securities or units issued in a subsequent financing on a $1.00 for $1.00 basis based on the outstanding stated value of such Series C Convertible Preferred Stock, along with any accrued but unpaid liquidated damages and other amounts owing thereon, or based on the value of the Exchanged Securities based on the effective per share purchase price multiplied by the number of such Exchanged Securities, and the effective price at which such securities were sold in such subsequent financing.

Placement Agent

We entered into a placement agent engagement letter with Northland Securities, Inc. (the "Placement Agent") pursuant to which we agreed to pay the Placement Agent an aggregate cash placement fee equal to 6% of the aggregate gross proceeds raised in the transactions consummated in July and October and to issue to the Placement Agent or its designees warrant(s) to purchase shares of Common Stock equal to, in the aggregate, 6% of the common shares sold or issuable upon conversion of the Preferred Stock sold to Sabby under the July and October Sabby Purchase Agreements, generally on the same terms as the warrants sold to Sabby in the transactions with certain exceptions. Subject to certain conditions, we also have agreed to reimburse certain out-of-pocket expenses of the Placement Agent, including but not limited to legal fees. The engagement letter contains customary representations, warranties and agreements by us and customary conditions to closing. We have further agreed to indemnify the Placement Agent against certain liabilities arising out of or in connection with the transactions.

Certificate of Designation and Series D Preferred Stock

On November 1, 2016, we filed a Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock, or the Certificate of Designation, with the Secretary of State of the State of Delaware. The number of shares of Series D Preferred Stock designated is 900, and each share of our Series D Preferred Stock has a stated value equal to $1,000. As of February 10, 2017, the conversion price on the Series D Preferred Stock was $4.483 per share, subject to adjustment as described below under "—Conversion."

Beneficial Ownership Limitation

Under the terms of the Series D Preferred Stock, we cannot issue any shares of Common Stock to Sabby, and Sabby cannot convert the Series D Preferred Stock into Common Stock, to the extent it would result in ownership in excess

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of 4.99%; provided, however, that upon prior notice to us, Sabby may increase its ownership, provided that in no event will the ownership exceed 9.99%.

Voting Rights

Except as otherwise provided herein or as otherwise required by law, the Series D Preferred Stock shall have no voting rights. However, as long as any shares of Series D Preferred Stock are outstanding, we shall not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series D Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series D Preferred Stock or alter or amend the Series D Certificate of Designation, (b) authorize or create any class of stock ranking as to dividends, redemption or distribution of assets upon a liquidation senior to, or otherwise pari passau with, the Series D Preferred Stock, (c) amend our certificate of incorporation or other charter documents in any manner that materially adversely affects any rights of the holders of the Series D Preferred Stock, (d) increase the number of authorized shares of Series D Preferred Stock, or (e) enter into any agreement with respect to any of the foregoing.

Liquidation

Upon liquidation, dissolution or winding-up of the Company, each holder of Series D Preferred Stock will be entitled to receive out of the assets, whether capital or surplus, of the Company an amount equal to the stated value, plus any accrued and unpaid dividends thereon, and any other fees or liquidated damages then due and owing thereon under the Series D Certificate of Designation for each share of Series D Preferred Stock before any distribution or payment shall be made to the holders of any Common Stock and all other Common Stock equivalents of the Company other than those securities which are explicitly senior or pari passu to the Series D Preferred Stock in dividend rights or liquidation preference, and if the assets of the Company are insufficient to pay in full such amounts, then the entire assets to be distributed to the holders of Series D Preferred Stock shall be ratably distributed among such holders in accordance with the respective amounts that would be payable on such shares if all amounts payable thereon were paid in full.

Dividends

The Series D Preferred Stock is entitled to receive dividends if any are declared on an "as converted to Common Stock" basis to and in the same form as dividends actually paid on shares of our Common Stock. No other dividends shall be paid on shares of Series D Preferred Stock.

Conversion

Series D Preferred Stock can be converted into shares of Common Stock at any time and from time to time after receipt of stockholder approval, at a conversion price of $4.483 as of February 10, 2017, subject to adjustment and for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock. If, at any time while the Series D Preferred Stock is outstanding, the Company or any subsidiary, as applicable sells or grants any option to purchase or sells or grants any right to reprice, or otherwise disposes of or issues any Common Stock or its equivalents entitling any person to acquire shares of Common Stock at an effective price per share that is lower than the then price of conversion (other than in connection with certain exempt issuances as set forth in the Series D Certificate of Designation), then the price of conversion shall be reduced to such lower price. On or after May 3, 2017, the conversion price on our Series D Convertible Preferred Stock shall become an adjustable rate equal to 80% of the average of the daily volume weighted average price of our common stock for the ten trading days immediately prior to the conversion date, but shall not be reduced below $1.26.

Redemption

Any time after the Company receives stockholder approval, if certain conditions are met and on 20 trading days' notice to the holders during which time such holders may elect to convert, the Company may redeem some or all of the Series D Preferred Stock for cash (i) if on or prior to the 90 day anniversary of the

issuance date of the Series D Preferred Stock, in an amount equal to 120% of the aggregate stated value then outstanding, (ii) if after the 90 day

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anniversary but on or before the 180 day anniversary of the issuance date, in an amount equal to 140% of the aggregate stated value then outstanding and (iii) if after the 180 day anniversary of the issuance date, in an amount equal to 150% of the aggregate stated value then outstanding, in each case, together with accrued and unpaid dividends, if any, and all liquidated damages and other amounts due on the Series D Preferred Stock, if any.

Each holder shall have the right to require us to, upon the occurrence of the triggering events listed in (iii), (v), (vii), (ix), (x) (as to changes of control approved by our board of directors) and (xi) (as to voluntary filings only) below, redeem all of the Series D Preferred Stock then held by such holder for a redemption price equal to the Triggering Redemption Amount or, upon the occurrence of the triggering events listed in (i), (ii), (iv), (vi), (viii), (x) (as to involuntary filings only), (xii), (xiii) and (xiv) below, either (a) redeem all of the Series D Preferred Stock then held by such holder for a redemption price, in shares of our Common Stock equal to the Triggering Redemption Amount divided by 75% of the average of the 10 VWAPs immediately prior to the date of election hereunder or (b) increase the dividend rate on all of the outstanding Series D Preferred Stock held by such holder to 18% per annum. "Triggering Redemption Amount" means the sum of (a) the greater of (i) 130% of the stated value and (ii) the product of (y) the VWAP on the trading day immediately preceding the date of the triggering event and (z) the stated value divided by the then conversion price, (b) all accrued but unpaid dividends thereon and (c) all liquidated damages and other costs, expenses or amounts due in respect of the Series D Preferred Stock.

Redemption of the Series D Preferred Stock can be triggered by the following events:

i. failure of a registration statement required to be filed pursuant to the Registration Rights Agreement (as defined below) (a "Required Registration Statement") to be declared effective by the SEC on or prior to the 180th day after the original date of issuance of the Series D Preferred Stock and Warrants or if we do not meet the current public information requirements under Rule 144 in respect of the securities to be registered;

ii. if the effectiveness of a Required Registration Statement lapses or the Selling Stockholders shall not otherwise be permitted to resell the securities to be registered pursuant to a Required Registration Statement for more than an aggregate of sixty (60) calendar days, which need not be consecutive calendar days, during any twelve (12) month period;

iii. we fail to deliver the Common Stock prior to the fifth Trading Day after such shares are required to be delivered upon conversion of shares of Series D Preferred Stock or we provide written notice to the applicable Selling Stockholder, including by way of public announcement, at any time, of our intention not to comply with requests for conversion of any shares of the Series D Preferred Stock;

iv. if the following have not been cured, pursuant to the Registration Rights Agreement within thirty (30) calendar days: (i) a Required Registration Statement was not filed on or prior to 45 days from the applicable closing, held on November 3, 2016, (ii) if we filed a Required Registration Statement without affording the Selling Stockholders the opportunity to review and comment on the same, (iii) if we fail to file with the SEC a request for acceleration within five trading days of the date that we are notified by the SEC that a Required Registration Statement will not be "reviewed" or will not be subject to further review, or (iv) prior to the effective date of any Required Registration Statement, we fail to respond in writing to comments made by the SEC in respect of any Required Registration Statement within ten days after the receipt of comments by or notice from the SEC that such amendment is required in order for any Required Registration Statement to be declared effective;

v. we fail for any reason to pay in full the amount of cash due pursuant to a Buy-In as described under " — Failure to Deliver Conversion Shares" below, within five calendar days after notice therefor is delivered or if we fail to pay all amounts owed as liquidated damages under the terms of the Registration Rights Agreement within five days of the date due and payable;

vi. we fail to have available a sufficient number of authorized and unreserved shares of Common Stock to issue to such Selling Stockholder upon a conversion of Series D Preferred Stock;

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vii. if we substantially fail to observe or perform any other material covenant, agreement or warranty contained in, or otherwise commit any breach of the documents in relation to the Sabby Purchase Agreement, and such failure or breach shall not, if subject to the possibility of a cure, have been cured within thirty (30) calendar days after the date on which written notice of such failure or breach shall have been delivered;

viii. any breach of the agreements delivered to the Selling Stockholders at the closing pursuant to Section 2.2(a)(v) of the Sabby Purchase Agreement;

ix. we redeem more than a de minimis number of junior securities;

x. a change of control occurs (which shall not include a transaction the primary purpose of which is financing the Company);

xi. a bankruptcy event occurs; or

xii. the electronic transfer by the Company of shares of Common Stock through the Depository Trust Company or another established clearing corporation is no longer available or is subject to a "chill".

Failure to Deliver Conversion Shares

If we fail to timely deliver shares of Common Stock upon conversion of the Series D Preferred Stock within three trading days after delivery of the notice of conversion, then the Company is obligated to pay to the holder, as liquidated damages, an amount equal to $50 per business day (increasing to $100 per business day after the third business day and increasing to $200 per business day after the sixth business day) for each $5,000 of stated value of the Series D Preferred Stock for which the Series D Preferred Stock is converted which is not timely delivered. If the Company fails to timely deliver shares of Common

Stock upon conversion of the Series D Preferred Stock to the holder, and if after the required delivery date the holder is required by its broker to purchase (in an open market transaction or otherwise) or the holder or its brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the holder of the Common Stock which the holder anticipated receiving upon such conversion (a "Buy-In"), then the Company is obligated to (A) pay in cash to the holder the amount, if any, by which (x) the holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased, minus any amounts paid to the holder by the Company as liquidated damages for late delivery of such shares, exceeds (y) the amount obtained by multiplying (1) the number of shares of Common Stock that the Company was required to deliver at the time of conversion of the Series D Preferred Stock times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the holder, either reinstate the portion of the Series D Preferred Stock and equivalent number of shares of Common Stock for which such conversion was not honored (in which case such conversion shall be deemed rescinded) or deliver to the holder the number of shares of Common Stock that would have been issued had the Company timely complied with its delivery obligations.

The July Warrants

Each July Warrant became exercisable on January 26, 2017 (the "July Warrant Initial Exercise Date") at an exercise price of $5.40 per share, subject to adjustment as provided therein, and terminates thirty-six (36) months after the July Warrant Initial Exercise Date. Under the July Securities Purchase Agreement, we agreed that so long as a Selling Stockholder holds any of the July Warrants, we will not effect a "Variable Rate Transaction" as defined in the July Securities Purchase Agreement. A holder of July Warrants will not have the right to exercise any portion of its July Warrants if the holder, together with its affiliates, would beneficially own over 4.99%; provided, however, that upon prior notice to us, the holder may increase its ownership, provided that in no event will the ownership exceed 9.99%. The exercise price and number of the shares of our Common Stock issuable upon exercising the July Warrants will be subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described therein. In addition, the July Warrants are subject to reduction of the exercise price if we subsequently issue Common Stock or equivalents at an effective price less than the current exercise price of such July Warrants.

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The January Warrants

Each January Warrant is exercisable beginning on the date of stockholder approval (the "Initial Exercise Date") at an exercise price of $5.40 per share, subject to adjustment as provided therein, and terminate five years after the Initial Exercise Date. In the event that the shares underlying the January Warrants are not subject to a registration statement at the time of exercise, the Warrants may be exercised on a cashless basis. Subject to limited exceptions, a holder of January Warrants 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%; provided, however, that upon prior notice to us, the holder may increase its ownership, provided that in no event will the ownership exceed 9.99%. The exercise price and number of the shares of our Common Stock issuable upon exercising the January Warrants will be subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described therein. In addition, the January Warrants are subject to reduction of the exercise price if we subsequently issue Common Stock or equivalents at an effective price less than the current exercise price of such January Warrants.

Registration Rights Agreement with Sabby

Concurrent with the closing of the October Sabby Purchase Agreement, we entered into a Registration Rights Agreement with Sabby (the "Registration Rights Agreement"), whereby we agreed to prepare and file a registration statement covering the resale of shares of Common Stock issuable upon conversion of the Series D Preferred Stock and the January Warrants within 45 days of each closing. We agreed to use our best efforts to cause such registration Statement to be declared effective by the 90th calendar day following each closing date (or the 120th day in the event of a "full review" by the SEC) and to use best efforts to keep such registration statement continuously effective until the shares of Common Stock being offered thereby have been sold under the registration statement or pursuant to Rule 144 or may be sold without volume or manner-of-sale restrictions pursuant to Rule 144 and without the requirement for the Company to be in compliance with the current public information requirement under Rule 144.

Before all registrable securities under the Registration Rights Agreement have been sold or may be sold under Rule 144 without volume or manner-of-sale restrictions and without the current public information requirement, if there is not an effective registration statement covering all of the registrable securities and we determine to prepare and file with the SEC a registration statement relating to an offering of our equity securities for our own account or the account of others under the Securities Act (other than on Form S-4 or Form S-8), then each holder will be entitled to certain "piggyback" registration rights allowing them to include their shares in such registration, provided, however, that we shall not be required to register any registrable securities that are eligible for resale pursuant to Rule 144 (without volume restrictions or current public information requirements) promulgated by the SEC pursuant to the Securities Act or that are the subject of a then effective registration statement that is available for resales or other dispositions by such holder.

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We are responsible for all fees and expenses incident to the performance of or compliance with the Registration Rights Agreement borne by us whether or not any registrable securities are sold pursuant to a registration statement. The Registration Rights Agreement also contains customary indemnification provisions.

We have filed the registration statement of which this prospectus forms a part pursuant to the requirements in the Registration Rights Agreement to register for resale the shares of Common Stock issuable upon conversion of the Series D Preferred Stock and the January Warrants that were issued at the second closing.

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USE OF PROCEEDS

We are not selling any securities under this prospectus and will not receive any proceeds from the sale of shares of Common Stock offered by this prospectus by the Selling Stockholders. However, we may receive proceeds from the cash exercise of the Warrants, which, if exercised in cash at the current exercise price with respect to all 162,195 shares of Common Stock, would result in gross proceeds of $875,853. We sold 3,468 shares of Series B Convertible Preferred and July Warrants to Sabby under the July Sabby Purchase Agreement on July 26, 2016 for gross proceeds of $3.2 million. Furthermore, we sold Series C Convertible Preferred Stock, Series D Convertible Preferred Stock and warrants to Sabby on November 3, 2016 for gross proceeds of $3.6 million, and sold 200 shares of Series D Preferred Stock and the January Warrants to Sabby for gross proceeds of $0.2 million on January 11, 2017, in each case, under the October Sabby Purchase Agreement.

PRICE RANGE OF COMMON STOCK AND DIVIDEND POLICY

Our Common Stock is currently listed on The Nasdaq Capital Market under the symbol "SSH." See "Description of Capital Stock — Common Stock — Listing" for information regarding recent delisting notices received from Nasdaq. Our Series C Convertible Preferred Stock and Series D Preferred Stock and Warrants are not and will not 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.

	High	Low
2015		
First Quarter	$ 207.0207	$ 114.0114
Second Quarter	$ 148.8149	$ 96.6097
Third Quarter	$ 107.0777	$ 60.006
Fourth Quarter	$ 81.9082	$ 31.8032
2016		
First Quarter	$ 41.4041	$ 16.8017
Second Quarter	$ 29.2139	$ 12.0012
Third Quarter	$ 48.6049	$ 13.2013
Fourth Quarter	$ 28.8029	$ 4.5005
2017		
First Quarter (through February 10, 2017	$ 12.0012	$ 4.96

As of February 10, 2017, the last reported sale price of our common stock on The Nasdaq Capital Market was $5.44.

As of February 7, 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.

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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 the most 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)
- 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

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

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- 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 go into 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.

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.(7) 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. (8) (9)

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:

(4) Costanzo MR, et al. J Am Coll Cardiol. 2005 Dec 6; 46(11): 2047-2051.
(5) Mozzafarian 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.
(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. https://data.medicare.gov/data/hospital-compare. Accessed June 10, 2016.2. Chen J, et al. J *Am Coll Cardiol*. 2013 Mar 12; 61(10): 1078-1088.

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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.

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.

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- 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 February 7, 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

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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.

Manufactures 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 will transfer Console manufacturing to Sunshine Heart or a qualified contract manufacturer by mid-year 2017. We will 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 5, 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.

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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 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.

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

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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.

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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;

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- 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.

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Employees

As of February 7, 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.

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DESCRIPTION OF CAPITAL STOCK

The following description of our Common Stock is a summary only and is qualified in its entirety by reference to our certificate of incorporation and bylaws, both of which are exhibits to the registration statement of which this prospectus is a part.

General

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, 30,000 of which are designated as Series A Junior Participating Preferred Stock, 344.9 of which are designated as Series C Convertible Preferred Stock and 900 of which are designated Series D Preferred Stock. Once shares of Series C Convertible Preferred Stock or Series D Preferred Stock are converted, redeemed or reacquired by us, such shares shall resume the status of authorized but unissued shares of undesignated preferred stock.

As of February 10, 2017, we had (i) 1,636,743 outstanding shares of Common Stock and (ii) 344.9 outstanding shares of Series C Convertible Preferred Stock and 900 outstanding shares of Series D Preferred Stock, which, at the conversion prices applicable to such series as of February 10, 2017, would currently convert into an aggregate of 268,387 shares of Common Stock.

If the effective price per share in a future offering is lower than the then price of conversion of the Series C Convertible Preferred Stock or the Series D Convertible Preferred Stock, then the price of conversion of such preferred stock shall be reduced to equal to such lower price and such preferred stock shall be issuable for additional shares of common stock in connection with such conversion price reduction. Furthermore, each holder of our Series C Convertible Preferred Stock has the right to exchange all or some of the Series C Preferred Stock for securities issued in a future offering on a $1.00 for $1.00 basis based on the outstanding stated value of the Series C Convertible Preferred Stock, along with any accrued but unpaid liquidated damages and other amounts owing thereon, and the effective price in the offering. With respect to our Series D Convertible Preferred Stock, on or after May 3, 2017, the conversion price on our Series D Convertible Preferred Stock shall become an adjustable rate equal to 80% of the average of the daily volume weighted average price of our common stock for the ten trading days immediately prior to the conversion date, but shall not be reduced below $1.26. To the extent the outstanding shares of Series C Convertible Preferred Stock or Series D Convertible Preferred Stock become exercisable for additional shares of common stock pursuant to the foregoing provisions, holders of our common stock and investors in this offering will experience further dilution.

As of February 10, 2017 we also had outstanding 87,574 options to acquire shares of our Common Stock, 9,177 shares of Common Stock issuable upon the vesting of restricted stock units and a total of 926,875 warrants outstanding to purchase Common Stock, including the Warrants. 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.

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.

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

For a description of the rights, preferences and privileges of our Series C Convertible Preferred Stock and Series D Preferred Stock, which are explicitly senior in liquidation preference to our Common Stock, please see our Current Report on Form 8-K filed with the SEC on October 31, 2016.

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 2/3% of the voting power of all of the then-outstanding shares of our capital stock entitled to vote generally in the election of directors, voting together as a single class, in addition to any vote of the holders of a class or series of our stock required by law or our certificate of incorporation. Those provisions of our certificate of incorporation that may be altered only by the super-majority vote described above relate to:

- the number of directors on our board of directors, the classification of our board of directors and the terms of the members of our board of directors;
- the limitations on removal of any of our directors described below under "—Anti-Takeover Effects of Certain Provisions of 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

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- 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, including our Series C Convertible Preferred Stock and Series D Preferred Stock.

Listing

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

Description of Outstanding Warrants

As of February 10, 2017, there were warrants outstanding to purchase a total of 926,884 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 $5.40 to $210.00 per common share, with a weighted average exercise price of $6.96 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 contain a provision requiring a reduction to the exercise price in the event we issue common stock, or securities convertible into or exercisable for common stock, at a price per share lower than the warrant exercise price. 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%.

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;

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- authorizing our board of directors to issue from time to time any series of preferred stock and fix the voting powers, designation, powers, preferences and rights of the shares of such series of preferred stock;
- prohibiting stockholders from acting by written consent in lieu of a meeting;
- requiring advance notice of stockholder intention to put forth director nominees or bring up other business at a stockholders' meeting;
- prohibiting stockholders from calling a special meeting of stockholders;
- requiring a 66 2/3% super-majority stockholder approval in order for stockholders to alter, amend or repeal certain provisions of our certificate of incorporation;
- requiring a 66 2/3% super-majority stockholder approval in order for stockholders to adopt, amend or repeal our bylaws;
- providing that, subject to the rights of the holders of any series of preferred stock to elect additional directors under specified circumstances, neither the board of directors nor any individual director may be removed without cause;
- creating the possibility that our board of directors could prevent a coercive takeover of our Company due to the significant amount of authorized, but unissued shares of our Common Stock and preferred stock;
- 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 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

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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.

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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

Sabby

Concurrent with the closing of the October Sabby Purchase Agreement, we entered into a Registration Rights Agreement with Sabby, whereby we agreed to prepare and file a registration statement covering the resale of shares of Common Stock issuable upon conversion of the Series D Preferred Stock and the warrants sold thereunder within 45 days of each closing. We agreed to use our best efforts to cause such registration statement to be declared effective by the 90th calendar day following each closing date (or the 120th day in the event of a "full review" by the SEC) and to use best efforts to keep such registration statement continuously effective until the shares of Common Stock being offered thereby have been sold under the registration statement or pursuant to Rule 144 or may be sold without volume or manner-of-sale restrictions pursuant to Rule 144 and without the requirement for the Company to be in compliance with the current public information requirement under Rule 144.

Before all registrable securities under the Registration Rights Agreement have been sold or may be sold under Rule 144 without volume or manner-of-sale restrictions and without the current public information requirement, if there is not an effective registration statement covering all of the registrable securities and we determine to prepare and file with the SEC a registration statement relating to an offering of our equity securities for our own account or the account of others under the Securities Act (other than on Form S-4 or Form S-8), then each holder will be entitled to certain "piggyback" registration rights allowing them to include their shares in such registration, provided, however, that we shall not be required to register any registrable securities that are eligible for resale pursuant to Rule 144 (without volume restrictions or current public information requirements) promulgated by the SEC pursuant to the Securities Act or that are the subject of a then effective registration statement that is available for resales or other dispositions by such holder.

We are responsible for all fees and expenses incident to the performance of or compliance with the Registration Rights Agreement borne by us whether or not any registrable securities are sold pursuant to a registration statement. The Registration Rights Agreement also contains customary indemnification provisions.

We have filed the registration statement of which this prospectus forms a part pursuant to the requirements in the Registration Rights Agreement to register for resale the shares of Common Stock issuable upon conversion of the Series D Preferred Stock and the January Warrants that were issued at the second closing.

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 such 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.

EXECUTIVE OFFICER AND DIRECTOR COMPENSATION

Summary Compensation Table for 2016

The following table sets forth certain information, for the years ended December 31, 2016 and December 31, 2015, regarding compensation of our current Chief Executive Officer, our former Chief Executive Officer, the two other most highly compensated executive officers who received remuneration exceeding $100,000 during 2016 and were serving as executive officers as of December 31, 2016 and one individual for whom disclosure would have been provided but for the fact that such individual was not serving as an executive officer as of December 31, 2016 (our ***"named executive officers"***).

Name Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)(1)	Option Awards ($)(2)	Nonequity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
John L. Erb	2016	385,833	—	331,044	363,227	134,000	—	1,214,104
Chief Executive Officer & President; Chairman of the Board	2015(3)	33,519(4)	—	23,333(5)	11,669(6)	—	93,917(7)	162,438
Claudia Drayton	2016	260,000	—	39,936	43,661	60,970	6,238(8)	410,805
Chief Financial Officer; Secretary	2015(9)	240,961	—	—	365,805(10)	48,192	6,675(8)	661,633
Molly Wade	2016	228,751	50,000(11)	30,784	33,655	53,642	6,447(8)	403,279
Senior VP of Strategic Operations	2015	210,000	4,000	—	—	42,000	6,420(8)	262,420

(1) Except as otherwise noted, amounts in the Stock Awards column relate to RSUs granted under the Company's Second Amended and Restated 2011 Equity Incentive Plan (the ***"2011 Equity Incentive Plan"***). Upon vesting, the RSUs convert into shares of our common stock on a one-for-one basis. The amounts reported represent the grant date fair value of the RSUs (excluding the effect of estimated forfeitures), which is based on the closing trading price of a share of our common stock on the grant date.

(2) Except as otherwise noted, amounts in the Option Awards column relate to stock options granted under the Company's 2011 Equity Incentive Plan. The amounts reported reflect the grant date fair value of the stock options. Valuation assumptions used in determining the grant date fair value are included in Note 5 to the consolidated financial statements included in our annual report on Form 10-K for the year ended December 31, 2015.

(3) Prior to his appointment as Chief Executive Officer and President on November 23, 2015, initially on an interim basis, Mr. Erb was a non-employee director and our Chairman of the Board. As a named executive officer of the Company, compensation paid to Mr. Erb for the entire 2015 fiscal year is fully reflected in this table.

(4) Reflects the amount paid to Mr. Erb as a cash retainer for his service as Interim Chief Executive Officer and President in fiscal 2015, which commenced on November 23, 2015. During his service as Interim Chief Executive Officer and President, Mr. Erb received a monthly retainer of $26,250.

(5) Reflects RSUs granted under the 2013 Directors' Plan on the date of the 2015 annual meeting as Mr. Erb was a non-employee director on such date. Upon vesting, the RSUs convert into shares of our common stock on a one-for-one basis. The amounts reported represent the grant date fair value of the RSUs, which is based on the closing trading price of a share of our common stock on the grant date. The closing trading price of a share of our common stock on May 21, 2015 was $128.70.

(6) Reflects stock options granted under the 2013 Directors' Plan on the date of the 2015 annual meeting as Mr. Erb was a non-employee director on such date. The amounts reported represent the grant date fair value of the stock options. Valuation assumptions used in determining the grant date fair value for are included in Note 5 to the consolidated financial statements included in our annual report on Form 10-K for the year ended December 31, 2015. The grant date fair value per share of the stock options granted on May 21, 2015 was approximately $94.80.

(7) Reflects the amount paid to Mr. Erb in fiscal 2015 as a cash retainer for his service as a non-employee director and our Chairman of

the Board pursuant to our non-employee director compensation program prior to his appointment as Chief Executive Officer and President on November 23, 2015.

(8) Reflects the amount of employer match contributions made on the individual's behalf to the Company's 401(k) Plan.

(9) Amounts reported reflect that Ms. Drayton commenced employment with the Company effective January 5, 2015.

(10) Reflects stock options granted under the Company's New-Hire Equity Incentive Plan (the ***"New-Hire Plan"***) in connection with such officer's hiring. The amounts reported reflect the grant date fair value of the stock options. Valuation assumptions used in determining the grant date fair value for are included in Note 5 to the consolidated financial statements included in our annual report on Form 10-K for the year ended December 31, 2015. The grant date fair value per share of the stock options granted on January 5, 2015 was approximately $99.77.

(11) Consists of a retention bonus that was paid in fiscal 2016.

Narrative Discussion of Summary Compensation Table for 2016

Employment Agreements and Other Arrangements. Mr. Erb has a written employment agreement, and all of the named executive officers have change in control agreements, which entitle them to payments from the Company upon the happening of specified termination events. See "— Potential Payments Upon Termination or Change in Control".

Base Salaries. The initial annual base salaries of the Company's executive officers are negotiated in connection with their hiring. The Compensation Committee reviews the base salaries of the executive officers on an annual basis and generally grants salary increases following such reviews. Base salary increases are typically between 3-5% and represent a combination of a cost of living and inflation adjustment and a merit raise.

The Compensation Committee engaged Compensia in the fourth quarter of 2015 to conduct a comprehensive review of the Company's executive compensation program and to consider year-end merit increases for the Company's officers for fiscal 2016. Compensia assessed the Company's compensation program against a peer group consisting of 16 companies similar to the Company based on industry, market capitalization and revenue. Compensia's comparison of the Company's target total compensation with peer group target pay levels indicated that our salaries and total target cash compensation were in the 75th percentile among private companies and in the bottom 25th percentile among public companies, although in the latter, the market range is narrow. In determining base salaries for 2016, Mr. Erb recommended base salaries for the Company's executive officers to the Compensation Committee taking into account the findings in the report prepared by Compensia, and the Compensation Committee approved a general increase in base salaries of the executive officers of 4% for fiscal 2016.

Equity Compensation. The Compensation Committee engaged Grant Thornton in 2013 to conduct a comprehensive review of the Company's executive compensation program. Grant Thornton assessed our compensation program against a peer group consisting of 21 companies similar to the Company based on industry, market capitalization, revenue and assets. Grant Thornton's comparison of the Company's target total compensation with peer group target pay levels indicated that our salaries were competitive to the median of the peer group; that target total cash compensation was, on average, 14% below the median of the peer group; and that target total compensation was, on average, 2% below the median of the peer group. Grant Thornton's comparison of the Company's current total compensation with peer group pay levels indicated that while current total compensation was, on average, 10% above the median of the peer group, this finding was misleading, given that executive equity holdings were below market. Based on the foregoing, Grant Thornton made several

recommendations with respect to the Company's executive compensation program, including that the Company utilize RSU awards; that the Company grant equity awards at or above historic levels to ensure each executive officer moves to a competitive ownership position for a start-up, high-growth firm; and that the Company adopt a new-hire program to facilitate recruitment of executive talent. In light of the foregoing and other factors deemed relevant by the Compensation Committee, in 2013 the Committee recommended, and the Board approved, the New-Hire Plan. The Company also began utilizing RSU awards.

As noted above, the Compensation Committee engaged Compensia in the fourth quarter of 2015 to review the Company's executive compensation program. Compensia's report indicated that stock options and restricted stock grants were the most used equity vehicle among companies in the peer group for long-term compensation. Further Compensia recommended that the Company continue to focus on competitive initial total potential ownership for

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each executive officer with smaller, periodic refresh grants. The Compensation Committee approved equity compensation awards to the Company's named executive officers, other than Mr. Erb, in the form of incentive stock options and restricted stock unit awards on January 15, 2016. Mr. Erb was granted stock options and a restricted stock unit award in March 2016.

Nonequity Incentive Plan Compensation. Nonequity incentive plan compensation is based on the achievement of corporate performance goals, and then subject to adjustment following an evaluation of departmental and individual performance.

In 2015 and 2016, each of the Company's executive officers had a target bonus, set forth as a percentage of annual base salary. In fiscal 2016, the Compensation Committee determined to increase target bonuses to 35% of base salary for each of the named executive officers other than Mr. Erb. The earned bonus was based on the achievement of corporate performance objectives defined and weighted by the Compensation Committee, in consultation with our Chief Executive Officer, and primarily related to the Company's clinical studies, financing activities and integration of the Aquadex Business. The Committee assessed the Company's achievement of those objectives at year end, and calculated a total weighted average performance to objectives of 80% and 67% for 2015 and 2016, respectively. The amounts of the earned bonuses for the named executive officers varied in 2016, based on Mr. Erb's evaluation of departmental and individual performance. The Compensation Committee further awarded retention bonuses of $50,000 to each of Ms. Drayton and Ms. Wade in December 2016, payable on July 15, 2017, so long as such officers remain with the Company through June 30, 2017 and the Company receives a minimum of $5 million in equity financing by such date.

The following table sets forth target and earned non-equity incentive plan compensation for 2015 and 2016.

	2015			2016		
	Target		Earned (as adjusted)	Target		Earned
Name	% of Base Salary	$	$	% of Base Salary	$	$
John L. Erb(1)	—	—	—	50	200,000	134,000
Claudia Drayton	25	60,240	48,192	35	91,000	60,970
Molly Wade	25	52,500	42,000	35	80,063	53,642

(1) Mr. Erb was a non-employee director for a portion of fiscal 2015. He was not entitled to non-equity incentive plan compensation as our Interim Chief Executive Officer and President during the remainder of fiscal 2015.

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Outstanding Equity Awards at Fiscal Year-End

The following table sets forth certain information concerning equity awards held by our named executive officers that were outstanding as of December 31, 2016.

	Option Awards(1)				Stock Awards	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested ($)	Market Value of Shares or Units of Stock That Have Not Vested ($) (4)
John L. Erb	1,800(1)	—	248.10	09/11/2022		
	92(1)	—	167.10	05/28/2024		
	123(1)	—	128.70	05/20/2025		
	—	17,800(2)	27.30	03/16/2026		
					8,080(3)	84,849
Claudia Drayton	1,833(5)	1,833(5)	134.40	01/05/2025		
	480(2)	1,440(2)	31.20	01/15/2026		
					—	—
Molly Wade (2)	923	243	330.00	10/27/2023		
	503	330	148.50	08/01/2024		
	370	1,110	31.20	01/15/2026		

	—	—

(1) Consists of stock options granted under the 2013 Directors' Plan. 1/12th of the shares underlying the awards vests monthly, commencing on the one-month anniversary of the grant date, so that all of the shares are vested on the one-year anniversary of the grant date.

(2) Consists of stock options granted under the Second Amended and Restated 2011 Equity Incentive Plan (the ***"2011 Plan"***). The underlying shares generally vest as follows: 25% of the shares vest on the one-year anniversary of the grant date; the remaining shares vest in 36 equal consecutive monthly increments thereafter, so that all of the shares will be vested on the four-year anniversary of the grant date.

(3) Consists of RSUs granted under the 2011 Plan. The RSUs vest in 36 consecutive monthly increments, commencing on the one-month anniversary of the grant date, so that all of the underlying shares will be vested on the three-year anniversary of the grant date.

(4) Based on the closing price of our common stock on Nasdaq on December 30, 2016, which was $10.5011.

(5) Consists of stock options granted under the New-Hire Plan. The underlying shares generally vest as follows: 25% of the shares vest on the one-year anniversary of the grant date; the remaining shares vest in 36 equal consecutive monthly increments thereafter, so that all of the shares will be vested on the four-year anniversary of the grant date.

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Potential Payments Upon Termination or Change in Control

Equity Compensation Plans

Equity awards have been issued to the named executive officers under the 2011 Equity Incentive Plan and the New-Hire Plan. A termination or change in control may affect the vesting and/or exercisability of awards issued under the equity compensation plans, as further discussed below.

Second Amended and Restated 2011 Equity Incentive Plan

Under the 2011 Equity Incentive Plan, the Board or the Compensation Committee may accelerate the exercisability or vesting of an award at any time, including immediately prior to a participant's termination or change of control.

Stock Options. Generally, if a participant's continuous service terminates:

- other than for cause or upon the participant's death or disability, the participant may exercise his or her option (to the extent the option was vested as of the date of termination) within such period of time ending on the earlier of (i) the date three months following the termination or (ii) the expiration of the term of the option. If the option is not exercised within such period, it will terminate.

- upon the participant's disability, the participant may exercise his or her option (to the extent the option was vested as of the date of termination) within such period of time ending on the earlier of (i) the date 12 months following the termination or (ii) the expiration of the term of the option. If the option is not exercised within such period, it will terminate.

- as a result of the participant's death, or if the participant dies within the period during which the option may be exercised after the termination of the participant's continuous service for a reason other than cause, the option may be exercised (to the extent the option was vested as of the date of death) by the participant's estate within the period ending on the earlier of (i) the date 18 months following the date of death or (ii) the expiration of the term of the option. If the option is not exercised within such period, it will terminate.

- for cause, the option will terminate upon the date of termination, and the participant will be prohibited from exercising his or her option from and after such time.

In addition, if the participant is a member of senior management, and if a change in control occurs and as of, or within six months after, the effective time of the change in control, the participant's continuous service terminates due to (i) an involuntary termination, which is not for cause or due to death or disability, or (ii) a resignation for good reason, 25% of the unvested portion of the option as of the date of termination will vest and become exercisable immediately upon such termination.

RSUs. Upon termination of a participant's continuous service for any reason, any unvested RSUs will be immediately canceled and forfeited, provided that the Compensation Committee may accelerate the vesting of all or a portion of the award in connection with such termination.

New-Hire Equity Incentive Plan

Under the New-Hire Plan, the Board or the Compensation Committee may accelerate the exercisability or vesting of an award at any time, including immediately prior to a participant's termination or change of control.

Stock Options. Generally, if a participant's continuous service terminates:

- for any reason other than the participant's death or disability, the participant may exercise his or her option (to the extent the option was vested as of the date of termination) within such period of time ending on the earlier of (i) the date three months following the termination or (ii) the expiration of the term of the option. If the option is not exercised within such period, it will terminate.

- upon the participant's disability, the participant may exercise his or her option (to the extent the option was vested as of the date of termination) within such period of time ending on the earlier of (i) the date 12 months following the termination or (ii) the expiration of the term of the option. If the option is not exercised within such period, it will terminate.

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- as a result of the participant's death, or if the participant dies within the period (if any) specified in the award agreement during which the option may be exercised after the termination of the participant's continuous service for a reason other than death, the option may be exercised (to the extent the option was vested as of the date of death) by the participant's estate within the period ending on the earlier of (i) the date 12 months following the date of death or (ii) the expiration of the term of the option. If the option is not exercised within such period, it will terminate.

Change in Control Agreements

The Company has entered into change in control agreements with the named executive officers who are currently executive officers of the Company, other than Mr. Erb, that require us to provide compensation to the officer in the event of a change in control. Each agreement has a term that runs from its effective date through the later of: (i) the five-year anniversary of the effective date, subject to automatic extension for successive two-year periods until notice of non-renewal is given by either party at least 60 days prior to the end of the then-effective term; or (ii) if a change in control occurs on or prior to the end of the then-effective term, then the one-year anniversary of the effective date of such change in control.

The change in control agreements provide that, if: (x) a change in control occurs during the term of the officer's agreement; and (y) the officer's employment terminates anytime during the one-year period after the effective date of the change in control; and (z) such termination is involuntary at the Company's initiative without cause or is due to the officer's voluntary resignation for good reason, then the Company will: (i) pay in a lump sum the officer's salary for 12 months and any other earned but unpaid compensation; (ii) pay in a lump sum an amount equal to the incentive bonus payment received by the officer for the fiscal year immediately preceding the fiscal year in which the termination occurs; and (iii) provide healthcare benefits to the officer and the officer's family until the earlier of (A) the date 12 months after the officer's termination and (B) the date the officer is, and/or the officer's covered dependents are, eligible to receive group medical and/or dental insurance coverage by a subsequent employer.

The Company is also obligated to make the foregoing payments and to provide the foregoing healthcare benefits in the event (i) the officer's employment terminates (A) due to a voluntary resignation for good reason or (B) due to an involuntary termination by the Company without cause, and (ii) a change in control occurs within 90 days after the termination date and during the term of the agreement.

In addition to the payments described above, each change in control agreement provides that if a change in control occurs while the officer is actively employed by the Company and during the term of the agreement, such change in control will cause the immediate acceleration of the vesting of 100% of any unvested portion of any stock option awards held by the officer on the effective date of such change in control.

The Company is not obligated to make the payments described above unless: (i) the officer signs a full release of any and all claims in favor of the Company; (ii) all applicable consideration periods and rescission periods have expired; and (iii) as of the dates the Company provides any payments to the named executive officer, the officer is in strict compliance with the terms of the applicable change in control agreement and any proprietary information agreement the officer has entered into with the Company.

Employment Agreement — Mr. Erb

On March 1, 2016, we entered into an executive employment agreement with Mr. Erb regarding his employment as our Chief Executive Officer and President.

The agreement has an initial term (the ***"Initial Term"***) of twelve (12) months beginning on March 1, 2016 and automatically renews for an additional twelve (12) month period at the end of the Initial Term and each anniversary thereafter provided that at least ninety (90) days prior to the expiration of the Initial Term or any renewal term the Board does not notify Mr. Erb of its intention not to renew the employment period.

The agreement entitles Mr. Erb to, among other benefits, the following compensation:

- an annual base salary of at least $400,000, reviewed at least annually;
- initial equity grants of an option to purchase 17,800 shares of common stock and 11,866 restricted stock units, in each case, granted in accordance with the terms and conditions of the Company's Second Amended and Restated 2011 Equity Incentive Plan;

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- an opportunity to receive additional annual equity awards as determined by the Compensation Committee based on Mr. Erb's performance and commensurate with grants made to chief executive officers in the Company's compensation peer group;
- an opportunity for Mr. Erb to receive an annual performance bonus in an amount of up to 50% of Mr. Erb's annual base salary for such fiscal year based upon achievement of certain performance goals to be established by the Board;
- participation in welfare benefit plans, practices, policies and programs provided by the Company and its affiliated companies (including, without limitation, medical, prescription, dental, disability, employee life, group life, accidental death and travel accident insurance plans and programs) to the extent available generally or to other senior executive officers of the Company;
- prompt reimbursement for all reasonable expenses incurred by Mr. Erb in accordance with the plans, practices, policies and programs of the Company; and
- 22 days paid time off, to accrue and to be used in accordance with the Company's policies and practices in effect from time to time, as well as all recognized Company holidays.

In connection with the equity grant contemplated by the agreement, Mr. Erb received an option to purchase 17,800 shares of the Company's common stock at an exercise price of $27.30 per share and an award of 11,866 restricted stock units, both of which were issued on March 16, 2016.

The agreement also includes a "claw-back" provision providing for the recoupment of unearned incentive compensation if the Board, or an appropriate committee thereof, determines that Mr. Erb engaged in any fraud, negligence, or intentional misconduct that caused or significantly contributed to the Company having to restate all or a portion of its financial statements, or if the Company is required to seek reimbursement by applicable laws or regulations, the Board or committee may require reimbursement of any bonus or incentive compensation paid to Mr. Erb.

Upon termination of Mr. Erb's employment, Mr. Erb may be entitled to certain payments and benefits, depending on the reason for his termination. In the event Mr. Erb resigns his employment without good reason, the Company terminates Mr. Erb's employment for cause, or Mr. Erb's employment terminates as a result of his death or disability, Mr. Erb is entitled to receive the Unconditional Entitlements, but not the Conditional Benefits (each as defined below). In the event Mr. Erb resigns with good reason or the Company terminates Mr. Erb's employment for reason other than cause, Mr. Erb is entitled to receive the Unconditional Entitlements, as well as the Conditional Benefits, provided that Mr. Erb signs and delivers to the Company, and does not revoke, a general release of claims in favor of the Company and certain related parties.

The ***"Unconditional Entitlements"*** include the following: (i) any annual base salary earned, but unpaid, for services rendered to the Company on or prior to the date on which the employment period ends; (ii) in the event Mr. Erb's employment terminates after the end of a fiscal year but before payment of the annual bonus payable for his services rendered in that fiscal year, the annual bonus that would have been payable to Mr. Erb for such completed fiscal year, provided that such termination is not due to the Company's termination of Mr. Erb for cause or Mr. Erb's resignation without good reason; and (iii) certain other benefits contemplated by the agreement.

The ***"Conditional Benefits"*** include the following: (i) a lump sum amount equal to one times Mr. Erb's annual base salary as of the termination date; (ii) continued medical coverage for 12 months following the termination date; (iii) continued vesting of equity awards for 12 months following the termination date; and (iv) a pro-rata annual bonus for the year in which the termination date occurs, determined on the basis of an assumed full-year target bonus and the number of days in the applicable fiscal year occurring on or before the termination date.

Director Compensation

Our non-employee directors receive a mix of cash and share-based compensation. The compensation mix is intended to encourage non-employee directors to continue Board service, further align the interests of the Board and stockholders, and attract new non-employee directors with outstanding qualifications. Directors who are employees or officers of the Company do not receive any additional compensation for Board service.

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2016 Compensation Program

The Compensation Committee engaged Grant Thornton in 2013 to conduct an analysis of the Company's non-employee director compensation. Grant Thornton assessed the compensation program against a peer group consisting of 22 companies similar to the Company based on industry, market capitalization, revenue and assets. The market data indicated that the Company's average total compensation for 2012 was at the 25th percentile of the peer group; and while the annual retainers for non-employee directors were competitive, the lack of annual equity compensation was a competitive shortfall to the Company's peer organizations.

In light of the market data and other factors deemed relevant by the Compensation Committee, the Committee determined to maintain the annual retainers at then-current levels, but to provide annual equity grants at competitive market levels, as opposed to discretionary grants from time to time.

For 2016, the Compensation Committee determined not to engage a compensation consultant to perform a comprehensive review with respect to the Company's non-employee director compensation program and made no changes to the existing program in 2016.

The following table sets forth the compensation program for non-employee directors in 2016:

	2016 ($)
Annual Cash Retainer:	55,000
Annual Equity Award ($ value):	35,000

Annual cash retainers are payable in equal quarterly installments, in arrears on the last day of each quarter in which the service occurs.

Annual equity awards are granted on the date of the annual meeting of stockholders. One-third of the award is issued in the form of a stock option, and two-thirds of the award is issued in the form of restricted stock units (***"RSUs"***). In each case, 1/12th of the shares underlying the awards vests monthly, commencing on the one-month anniversary of the grant date, so that all of the underlying shares are vested on the one-year anniversary of the grant date.

The Company does not provide any perquisites to directors.

2016 Compensation Table

The table below sets forth the compensation of each non-employee director in 2016.

Name	Fees Earned or Paid in Cash ($)(1)	Stock Awards ($)(2)	Option Awards ($)(3)	Total ($)
Paul R. Buckman (4)	46,597	23,333	11,669	81,599
Jon W. Salveson	55,000	23,333	11,669	90,002
Gregory D. Waller	55,000	23,333	11,669	90,002

Warren S. Watson	55,000	23,333	11,669	90,002
Total	**211,597**	**93,332**	**46,676**	351,605

(1) Reflects cash retainers.

(2) Reflects RSUs granted on the date of the 2016 annual meeting under the 2013 Non-Employee Directors' Equity Incentive Plan (the "2013 Directors' Plan"). Upon vesting, the RSUs convert into shares of our common stock on a one-for-one basis. The amounts reported represent the grant date fair value of the RSUs, which is based on the closing trading price of a share of our common stock on the grant date. The closing trading price of a share of our common stock on May 26, 2016 was $21.3021.

(3) Reflects stock options granted on the date of the 2016 annual meeting under the 2013 Directors' Plan. The amounts reported represent the grant date fair value of the stock options. Valuation assumptions used in determining the grant date fair value are included in Note 5 to the consolidated financial statements included in our annual report on Form 10-K for the year ended December 31, 2015. The grant date fair value per share of the stock options granted on May 26, 2016 was approximately $15.46.

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(4) Mr. Buckman resigned from the Board on November 5, 2016.

As a named executive officer of the Company, compensation paid to Mr. Erb for the 2015 and 2016 fiscal years is fully reflected under "Named Executive Officer Compensation Tables—Summary Compensation Table for 2016**"**.

As of December 31, 2016, each non-employee director had the following number of shares underlying outstanding options (both vested and unvested) and RSUs, respectively: Mr. Buckman, 1,435 and 0; Mr. Salveson, 1,819 and 457; Mr. Waller, 1,439 and 457; Mr. Watson, 1,819 and 457.

Compensation Committee Interlocks and Insider Participation

For fiscal 2016 through the 2016 annual meeting, the Compensation Committee consisted of Messrs. Buckman and Waller and, thereafter and until Mr. Buckman's resignation in November 2016, of Messrs. Buckman, Watson and Salveson. The Board determined not to fill the vacancy on the Compensation Committee following the departure of Mr. Buckman from the Board in November 2016. As a result, from and after Mr. Buckman's departure from the Board, the Committee had two, as opposed to three, members. All members of the Committee during 2016 were independent directors and, none of them is or has been an employee or officer of ours. During 2016, none of our executive officers served on the compensation committee (or equivalent) or the board of directors of another entity whose executive officer(s) served on the Committee or the Board.

Related Party Transactions

We give careful attention to related person transactions because they may present the potential for conflicts of interest. Under SEC rules, a related person transaction is any transaction or series of transactions in which: the Company or a subsidiary is a participant; the amount involved exceeds $120,000; and a related person has a direct or indirect material interest. A "related person" is a director, executive officer, nominee for director or a more than 5% stockholder, and any immediate family member of the foregoing.

To identify related person transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. We maintain a written policy for the review, approval or ratification of related person transactions, and our Audit Committee reviews all related person transactions identified by us. The Committee approves or ratifies only those related person transactions that are determined by it to be, under all of the circumstances, in the best interests of the Company and its stockholders. The Committee affirmatively determined that none of the related person transactions below constituted a conflict of interest.

Scott Erb, Senior Manager of Operations, is the son of John Erb, our Chief Executive Officer, President and Chairman of the Board. In 2016, Scott Erb was paid $88,028 in salary and bonus and received an option to purchase 166 shares of our common stock.

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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 February 10, 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 February 10, 2017, there were 1,636,743 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	7,388	7,085	14,473	1%
Jon W. Salveson	1,050	1,876	2,926	*
Gregory D. Waller	1,169	1,496	2,665	*
Warren S. Watson	1,050	1,876	2,926	*
Claudia Drayton	739	2,622	3,361	*
Eric Lovett	—	1,083	1,083	*

Molly Wade	907	1,983	2,890	*
All directors and executive officers as a group (7 persons)	12,303	18,021	30,324	2%
Sabby Management, LLC 10 Mountainview Road, Suite 205 Upper Saddle River, NJ 07458	52,135	1,136,465(3)	1,188,600	4.99(4)%

* 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 February 10, 2017.

(2) Based on 1,636,743 shares outstanding as of February 10, 2017.

(3) Includes (1) 286,092 shares of common stock issuable upon exercise of warrants to purchase shares of common stock held by Sabby Volatility Warrant Master Fund, Ltd., (2) 581,987 shares of common stock issuable upon exercise of warrants to purchase shares of common stock held by Sabby Healthcare Master Fund, Ltd., (3) 5,058 shares of Common Stock issuable upon conversion of outstanding shares of Series C Convertible Preferred Stock held by Sabby Volatility Warrant Master Fund, Ltd., (4) 62,568 shares of Common Stock issuable upon conversion of outstanding shares of Series C Convertible Preferred Stock held by Sabby Healthcare Master Fund, Ltd., (5) 66,028 shares of Common Stock issuable upon conversion of outstanding shares of Series D Convertible Preferred Stock held by Sabby Volatility Warrant Master Fund, Ltd. and (6) 134,732 shares of Common Stock issuable upon conversion of outstanding shares of Series D Convertible Preferred Stock held by Sabby Healthcare Master Fund, Ltd., that are, in each case,

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convertible or exercisable within 60 days of February 10, 2017. The conversion prices of our Series C Convertible Preferred Stock and Series D Convertible Preferred Stock are subject to adjustment as described under “Prospectus Summary—Recent Developments—Outstanding Preferred Stock”.

(4) The percentage in this table reflects that Sabby Management, LLC may not convert the preferred stock or exercise the warrants described in footnote (3) above to the extent such conversion or exercise would cause Sabby Management, LLC, together with its affiliates, to beneficially own a number of shares of common stock that would exceed 4.99% of our then outstanding common stock following such exercise; provided, however, that upon prior notice to us, such holder may increase its ownership, provided that in no event will the ownership exceed 9.99%.

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PLAN OF DISTRIBUTION

Each Selling Stockholder of the securities and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the principal trading market or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or at prices then prevailing or related to the then current market price or at negotiated prices. The offering price of the shares from time to time will be determined by the Selling Stockholders and, at the time of the determination, may be higher or lower than the market price of our Common Stock. A Selling Stockholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- in transactions through broker-dealers that agree with the Selling Stockholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The Selling Stockholders may also sell securities under Rule 144 or any other exemption from registration under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the Selling Stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholders (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

In connection with the sale of the securities or interests therein, the Selling Stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The Selling Stockholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

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The Selling Stockholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Stockholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the securities. The Company has agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

The Company agreed to keep this prospectus effective until the earlier of (i) the date on which the securities may be resold by the Selling Stockholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, without the requirement for the Company to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect or (ii) all of the securities have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the Common Stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the Common Stock by the Selling Stockholders or any other person. We will make copies of this prospectus available to the Selling Stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

We will not receive any proceeds from the sale of the shares by the Selling Stockholders.

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SELLING STOCKHOLDERS

The shares of Common Stock being offered by the Selling Stockholders are those issuable to the Selling Stockholders upon conversion of the Series D Preferred Stock and exercise of the Warrants. For additional information regarding the issuances of those shares of Series D Preferred Stock and Warrants, see "Sale of Securities to Sabby". We are registering the shares of Common Stock in order to permit the Selling Stockholders to offer the shares for resale from time to time. Except for the ownership of shares of Common Stock, preferred stock and warrants, the Selling Stockholders have not had any material relationship with us within the past three years.

The table below lists the Selling Stockholders and other information regarding the beneficial ownership of the shares of Common Stock by each of the Selling Stockholders. The following table sets forth the number of shares of our Common Stock beneficially owned by each Selling Stockholder as of February 10, 2017 and after giving effect to the sale of the shares of Common Stock offered by the Selling Stockholders pursuant to this prospectus, assuming all such shares are sold, except as otherwise referenced below.

The Selling Stockholders may sell all, some or none of the shares of Common Stock subject to this prospectus. See "Plan of Distribution."

Name of Selling Stockholder	Number of shares of Common Stock Beneficially Owned Prior to Offering	Number of shares of Common Stock Offered Upon Exercise of Series D Preferred Stock(2)(6)	Number of shares of Common Stock Offered Upon Exercise of Warrants(2)	Beneficial Ownership After Offering(1)	
				Number of Shares	Ownership Percentage(1)
Sabby Volatility Warrant Master Fund, Ltd. (3)	379,040(4)	14,723	53,893	310,424(4)	19.0%(6)
Sabby Healthcare Master Fund, Ltd.(3)	809,560(5)	29,891	108,302	671,367(5)	41.0%(6)

(1) Based upon 1,636,743 shares of Common Stock issued and outstanding as of February 10, 2017. Beneficial ownership is determined in accordance with Rule 13d-3 under the Securities Act, and includes any shares as to which the Selling Stockholder has sole or shared voting power or investment power, and also any shares which the Selling Stockholder has the right to acquire within 60 days of the date hereof, whether through the exercise or conversion of any stock option, convertible security, warrant or other right. The indication herein that shares are beneficially owned is not an admission on the part of the Selling Stockholder that he, she or it is a direct or indirect beneficial owner of those shares.

(2) The actual number of shares of Common Stock offered hereby and included in the registration statement of which this prospectus forms a part includes, in accordance with Rule 416 under the Securities Act, such indeterminate number of additional shares of our Common Stock as may become issuable in connection with any proportionate adjustment for any stock splits, stock combinations, stock dividends, recapitalizations or similar events with respect to common stock.

(3) Sabby Management, LLC is the investment manager of Sabby Healthcare Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. and shares voting and investment power with respect to these shares in this capacity. As manager of Sabby Management, LLC, Hal Mintz also shares voting and investment power on behalf of each Selling Stockholder. Each of Sabby Management, LLC and Hal Mintz disclaims beneficial ownership over the securities listed except to the extent of their pecuniary

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interest therein. The address of principal business office of each of Sabby Healthcare Master Fund, Ltd., Sabby Volatility Warrant Master Fund, Ltd., Sabby Management, LLC and Hal Mintz is 10 Mountainview Road, Suite 205, Upper Saddle River, New Jersey 07458. Neither Sabby Healthcare Master Fund, Ltd. nor Sabby Volatility Warrant Master Fund, Ltd. is a registered broker-dealer or an affiliate of a registered broker-dealer.

(4) Includes 21,862 shares of common stock and the following shares of common stock underlying convertible securities that are convertible or exercisable within 60 days of February 10, 2017: (1) 286,092 shares of common stock issuable upon exercise of warrants to purchase shares of common stock held by Sabby Volatility Warrant Master Fund, Ltd., (2) 5,058 shares of Common Stock issuable upon conversion of outstanding shares of Series C Convertible Preferred Stock held by Sabby Volatility Warrant Master Fund, Ltd. and (3) 66,028 shares of Common Stock issuable upon conversion of outstanding shares of Series D Convertible Preferred Stock held by Sabby Volatility Warrant Master Fund, Ltd. The conversion prices of our Series C Convertible Preferred Stock and Series D Convertible Preferred Stock are subject to adjustment.

(5) Includes 30,273 shares of common stock and the following shares of common stock underlying convertible securities that are convertible or exercisable within 60 days of February 10, 2017: (1) 581,987 shares of common stock issuable upon exercise of warrants to purchase shares of common stock held by Sabby Healthcare Master Fund, Ltd., (2) 62,568 shares of Common Stock issuable upon conversion of outstanding shares of Series C Convertible Preferred Stock held by Sabby Healthcare Master Fund, Ltd. and (3) 134,732 shares of Common Stock issuable upon conversion of outstanding shares of Series D Convertible Preferred Stock held by Sabby Healthcare Master Fund, Ltd. The conversion prices of our Series C Convertible Preferred Stock and Series D Convertible Preferred Stock are subject to adjustment.

(6) Includes the shares of Common Stock identified in footnotes (4) and (5) above issuable upon conversion or exercise of certain preferred stock and warrants. The percentages in this table do not reflect that the Selling Stockholder may not convert such preferred stock or exercise such warrants to the extent such conversion or exercise would cause such Selling Stockholder, together with its affiliates and attribution parties, to beneficially own a number of shares of Common Stock which would exceed 4.99% of our then outstanding Common Stock following such exercise; provided, however, that upon prior notice to us, the Selling Stockholder may increase its ownership, provided that in no event will the ownership exceed 9.99%.

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LEGAL MATTERS

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

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, 2015, 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.

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PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the estimated costs and expenses to be incurred in connection with the issuance and distribution of the securities registered under this Registration Statement. All amounts are estimates except the Securities and Exchange Commission registration fee.

	Amount to be Paid
SEC registration fee	$ 137.35
Legal fees and expenses	$ 10,000
Accountant's fees and expenses	$ 20,000
Printing and miscellaneous expenses	$ 5,000
Total	$ 35,137.35

Item 14. Indemnification of Directors and Officers.

Our certificate of incorporation and bylaws provide that each person who was or is made a party or is threatened to be made a party to or is otherwise involved (including, without limitation, as a witness) in any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he or she is or was a director or an officer of Sunshine Heart, Inc. or is or was serving at our request as a director, officer, or trustee of another corporation, or of a partnership, joint venture, trust or other enterprise, including service with respect to an employee benefit plan, whether the basis of such proceeding is alleged action in an official capacity as a director, officer or trustee or in any other capacity while serving as a director, officer or trustee, shall be indemnified and held harmless by us to the fullest extent authorized by the Delaware General Corporation Law, as amended (the **"**DGCL**"**), against all expense, liability and loss (including attorneys' fees, judgments, fines, ERISA excise taxes or penalties and amounts paid in settlement) reasonably incurred or suffered by such.

Section 145 of the DGCL permits a corporation to indemnify any director or officer of the corporation against expenses (including attorney's fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with any action, suit or proceeding brought by reason of the fact that such person is or was a director or officer of the corporation, if such person acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, and, with respect to any criminal action or proceeding, if he or she had no reason to believe his or her conduct was unlawful. In a derivative action, (i.e., one brought by or on behalf of the corporation), indemnification may be provided only for expenses actually and reasonably incurred by any director or officer in connection with the defense or settlement of such an action or suit if such person acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, except that no indemnification shall be provided if such person shall have been adjudged to be liable to the corporation, unless and only to the extent that the court in which the action or suit was brought shall determine that the defendant is fairly and reasonably entitled to indemnity for such expenses despite such adjudication of liability.

Pursuant to Section 102(b)(7) of the DGCL, our certificate of incorporation eliminates the liability of a director to us or our stockholders for monetary damages for such a breach of fiduciary duty as a director, except for liabilities arising:

- from any breach of the director's duty of loyalty to us or our stockholders;
- from acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;

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- under Section 174 of the DGCL; and
- from any transaction from which the director derived an improper personal benefit.

We carry insurance policies insuring our directors and officers against certain liabilities that they may incur in their capacities as directors and officers.

The Company has entered into indemnification agreements with each of its directors and executive officers. Pursuant to the indemnification agreements, the Company agrees to hold harmless and indemnify its directors and executive officers to the fullest extent authorized or permitted by the provisions of the Company's certificate of incorporation and bylaws and the DGCL, including for any amounts that such director or officer becomes obligated to pay because of any claim to which such director or officer is made or threatened to be made a party, witness or participant, by reason of such director's or officer's service as a director, officer, employee or other agent of the Company.

There are certain exceptions from the Company's obligation to indemnify its directors and executive officers pursuant to the indemnification agreements, including for "short-swing" profit claims under Section 16(b) of the Exchange Act, losses that result from conduct that is established by a final judgment as knowingly fraudulent or deliberately dishonest or that constituted willful misconduct, or that constituted a breach of the duty of loyalty to the Company or resulted in any improper personal profit or advantage, where payment is actually made to a director or officer under an insurance policy, indemnity clause, bylaw or agreement, except in respect of any excess beyond payment under such insurance, clause, bylaw or agreement, for indemnification which is not lawful, or in connection with any proceeding initiated by such director or officer, or any proceeding against the Company or its directors, officers, employees or other agents, unless (i) such indemnification is expressly required to be made by law, (ii) the proceeding was authorized by the board of directors of the Company, (iii) such indemnification is provided by the Company, in its sole discretion, pursuant to the powers vested in the Company under the DGCL, or (iv) the proceeding is initiated to enforce a claim for indemnification pursuant to the indemnification agreement.

All agreements and obligations of the Company contained in the indemnification agreements shall continue during the period when the director or officer who is a party to an indemnification agreement is a director, officer, employee or other agent of the Company (or is or is serving at the request of the Company as a director, officer, employee or other agent of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise) and shall continue thereafter so long as such director or officer shall be subject to any possible claim or threatened, pending or completed action, suit or proceeding, whether civil, criminal, arbitrational, administrative or investigative. In addition, the indemnification agreements provide for partial indemnification and advance of expenses.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to our directors, officers or controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the Securities and Exchange Commission this indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

Item 15. Recent Sales of Unregistered Securities.

The following sets forth information regarding all unregistered securities sold by the registrant in the three years preceding the date of this registration statement. This information has been retroactively adjusted to reflect the reverse stock split for all periods presented:

- On February 18, 2015, the registrant entered into a loan agreement with Silicon Valley Bank under which the registrant issued to Silicon Valley Bank and its affiliate, Life Science Loans, LLC, warrants to purchase shares of its common stock equal to 6% of a $6.0 million term loan divided by the lower of (i) the closing price for a share of the registrant's common stock as reported on the Nasdaq Capital Market for the date on which such term loan advance was made to the registrant, and (ii) the average of the closing prices for a share of the registrant's common stock reported for the ten trading days ending on the date of such term loan advance. The warrants were exercisable immediately with a term of ten years. Additionally, upon

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Silicon Valley Bank funding the $2.0 million term loan available until June 30, 2015, the warrants automatically became exercisable for an additional number of shares equal to 6% of such term loan divided by the lower of (i) the closing price for a share of the registrant's common stock as reported on the Nasdaq Capital Market for the date such term loan advance, and (ii) the average of the closing prices for a share of the registrant's common stock reported or the ten trading date ending on the date of such term loan advance. The warrants were issued under an exemption from the registration requirements of the Securities Act provided in Section 4(a)(2) of the Securities Act and/or Regulation D.

- On July 20, 2016, the registrant entered into a securities purchase agreement with Sabby Healthcare Master Fund Ltd. and Sabby Volatility Warrant Master Fund Ltd. (collectively, Sabby) under which the registrant issued and sold, on July 26, 2016, 3,468 shares of Series B Convertible Preferred Stock at $1,000 per share directly to Sabby in a registered direct offering. In a concurrent private placement, the registrant issued warrants to purchase an aggregate of 122,979 shares of its common stock to Sabby. Each warrant was exercisable beginning on the six month anniversary of the date of issuance at an exercise price of $5.40 per share, subject to adjustment as provided therein and for 36 months from the initial exercise date, but not thereafter. Northland Securities, Inc. acted as placement agent and the registrant issued Northland Securities, Inc. and its designees warrants to purchase an aggregate of 7,379 shares of common stock. The Northland warrants were exercisable beginning immediately upon the closing at an exercise price of $40.50 per share, subject to adjustment as provided there in, and for 5 years thereafter. Subject to limited exceptions, a holder will not have the right to exercise any portion of its warrant if the holder, together with its affiliates, would beneficially own over 4.99% of the number of shares of the registrant's common stock outstanding immediately after giving effect to such exercise; provided, however, that upon not less than 61 days' prior notice, the holder may increase the limitation, provided that in no event will the limitation exceed 9.99%. The warrants were issued under an exemption from the registration requirements of the Securities Act provided in Section 4(a)(2) of the Securities Act and/or Regulation D.

- On August 5, 2016, the registrant entered into and consummated the transactions contemplated by an asset purchase agreement with Gambro UF Solutions, Inc. (the **"**Seller**"**), pursuant to which the registrant acquired certain assets exclusively related to the production and sale of Seller's Aquadex™ FlexFlow product for consideration consisting of $4.0 million paid in cash and 33,333 shares of the registrant's common stock. The shares of common stock were issued to Seller under an exemption from the registration requirement of the Securities Act provided in Section 4(a)(2) of the Securities Act and/or Regulation D.

- On October 30, 2016, the registrant entered into a securities exchange agreement with Sabby, as holder of the registrant's Series B Convertible Preferred Stock pursuant to which the registrant agreed to issue Sabby 2,227.2 shares of Series B-1 Convertible Preferred Stock in exchange for the cancellation of all shares of Series B Convertible Preferred Stock held by Sabby in reliance on an exemption from registration provided by Section 3(a)(9) of the Securities Act, and consummated such exchange on November 3, 2016.

- On October 30, 2016, the registrant entered into securities purchase agreements with Sabby under which it agreed to issue and sell 2,900 shares of Series C Convertible Preferred Stock at $1,000 per share directly to Sabby in a registered direct offering. In a concurrent private placement, the registrant agreed to issue and sell 900 shares of Series D Convertible Preferred Stock at $1,000 per share directly to Sabby and warrants to purchase an aggregate of 745,097 shares of common stock to Sabby. The registered direct offering closed on November 3, 2016, and the registrant concurrently sold 700 shares of the Series D Convertible Preferred Stock and warrants to purchase 705,882 shares of common stock. The remaining 200 shares of Series D Convertible Preferred Stock and warrants to purchase 39,216 shares of common stock were issued and sold at a second closing on January 11, 2017. The Series D Convertible Preferred Stock has a stated value of $1,000 per share and a conversion price of $4.483 subject to adjustment and may be converted to shares of common stock at any time following the receipt of stockholder approval of such issuance upon conversion. Each warrant will be exercisable beginning on the day that is the later of the date stockholder approval of the issuance of common stock underlying such warrants is obtained or the six month anniversary of the date of issuance at an exercise price of $5.40 per share, subject to adjustment as provided therein, and terminate five years thereafter. Northland Securities, Inc. acted as placement agent and the registrant issued Northland Securities, Inc. and its designees warrants to purchase an aggregate of 42,352

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shares of common stock with an exercise price of $6.30 per share. Subject to limited exceptions, a holder of Series D Convertible Preferred Stock or warrants will not have the right to convert or exercise if the holder, together with its affiliates, would beneficially own over 4.99% of the number of shares of the registrant's common stock outstanding immediately after giving effect to such exercise; provided, however, that upon not less than 61 days' prior notice, the holder may increase the limitation, provided that in no event will the limitation exceed 9.99%. The Series D Convertible Preferred Stock and the warrants were issued pursuant to an exemption from the registration requirement of the Securities Act provided in Section 4(a)(2) of the Securities Act and/or Regulation D.

Item 16. Exhibits and Financial Statement Schedules.

The following exhibits are included as part of this Form S-1.

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing			
2.1	Asset Purchase Agreement between Sunshine Heart, Inc. and Gambro UF Solutions, Inc. dated August 5, 2016.	8-K	001-35312	August 8, 2016	2.1		
3.1	Fourth Amended and Restated Certificate of Incorporation	10	001-35312	February 1, 2012	3.1		
3.2	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	January 13, 2017	3.1		
3.3	Amended and Restated Bylaws	10	001-35312	September 30, 2011	3.2		
3.4	Form of Certificate of Designation of Series A Junior Participating Preferred Stock	8-K	001-35312	June 14,2013	3.1		
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock.	8-K	001-35312	July 25, 2016	3.1		
3.6	Certificate of Designation of Preferences, Rights and Limitations of Series B-1 Convertible Preferred Stock.	8-K	001-35312	November 3, 2016	3.1		
3.7	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock.	8-K	001-35312	November 3, 2016	3.2		
3.8	Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock.	8-K	001-35312	November 3, 2016	3.3		

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Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing			
4.1	Warrant to Purchase Stock, dated February 18, 2015, issued to Silicon Valley Bank	8-K	001-35312	February 19, 2015	4.1		
4.2	Warrant to Purchase Stock, dated February 18, 2015, issued to Life Science Loans, LLC	8-K	001-35312	February 19, 2015	4.2		
4.3	Form of Series B Convertible Preferred Stock Certificate.	8-K	001-35312	July 22, 2016	4.1		
4.4	Form of Common Stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated July 20, 2016, among the Company and the purchasers signatory thereto.	8-K	001-35312	July 22, 2016	4.3		
4.5	Form of Common Stock Purchase Warrant issued to Northland Securities, Inc.	8-K	001-35312	July 22, 2016	4.3		
4.6	Registration Rights Agreement between Sunshine Heart, Inc. and Gambro UF Solutions, Inc. dated August 5, 2016	8-K	001-35312	August 8, 2016	4.1		
4.7	Form of Common Stock Purchase	8-K	001-35312	October 31, 2016	4.1		

	Warrant issued pursuant to the Securities Purchase Agreement, dated October 30, 2016, among the Company and the purchasers signatory thereto.						
5.1	Opinion of Honigman Miller Schwartz and Cohn LLP					X	
10.1	Securities Purchase Agreement, dated July 20, 2016 among the Company and the purchasers signatory thereto.	8-K	001-35312	July 22, 2016	10.1		
10.2	Patent License Agreement between Sunshine Heart, Inc. and Gambro UF Solutions, Inc. dated August 5, 2016.	8-K	001-35312	August 8, 2016	10.1		
10.3	Loan and Security Agreement between Sunshine Heart, Inc. and Silicon Valley Bank dated August 5, 2016.	8-K	001-35312	August 8, 2016	10.2		
10.4	Amended and Restated 2002 Stock Plan†	10	001-35312	December 16, 2011	10.2		

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Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing	Exhibit Number		
10.5	Form of Notice of Stock Option Grant and Option Agreement for Amended and Restated 2002 Stock Plan†	10	001-35312	September 30, 2011	10.3		
10.6	Second Amended and Restated 2011 Equity Incentive Plan, as amended†	14A	001-35312	July 27, 2012	App. A		
10.7	Form of Stock Option Grant Notice and Option Agreement for 2011 Equity Incentive Plan †	10	001-35312	September 30, 2011	10.5		
10.8	Form of Stock Option Grant Notice and Option Agreement (Senior Management) for 2011 Equity Incentive Plan†	10	001-35312	September 30, 2011	10.6		
10.9	Form of Stock Option Grant Notice and Option Agreement (Director) for 2011 Equity Incentive Plan†	8-K	001-35312	September 18, 2012	10.1		
10.10	Form of Stock Grant Notice and Award Agreement for 2011 Equity Incentive Plan†	8-K	001-35312	September 10, 2013	10.1		
10.11	Form of Restricted Stock Unit Grant Notice and Agreement for 2011 Equity Incentive Plan†	8-K	001-35312	September 10, 2013	10.2		
10.12	2013 Non-Employee Directors' Equity Incentive Plan†	14A	001-35312	April 5, 2013	App. A		
10.13	Form of Stock Option Grant Notice and Option Agreement for 2013 Non-Employee Directors' Equity Incentive Plan†	10-K	001-35312	March 20, 2014	10.10		
10.14	Form of Restricted Stock Unit Award Grant Notice and Agreement for 2013 Non-	10-K	001-35312	March 20, 2014	10.11		

	Employee Directors' Equity Incentive Plan†						
10.15	New-Hire Equity Incentive Plan†	10-Q	001-35312	August 8, 2013	10.1		
10.16	First Amendment to New-Hire Equity Incentive Plan†	10-Q	001-35312	November 12, 2013	10.1		
10.17	Second Amendment to New-Hire Equity Incentive Plan†	10-Q	333-202904	March 20, 2015	10.1		
10.18	Form of Stock Option Grant Notice and Option Agreement for New-Hire Equity Incentive Plan†	10-K	001-35312	March 20, 2014	10.14		

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Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing			
10.19	Form of Indemnity Agreement for the Company's executive officers and directors†	10	001-35312	September 30, 2011	10.1		
10.20	Form of Change in Control Agreement for the Company's executive officers†	10-K	001-35312	March 20, 2015	10.16		
10.21	Non-Employee Director Compensation Policy†	10-Q	001-35312	August 8, 2013	10.2		
10.22	Executive Employment Agreement dated February 6, 2013 by and between the Company and David A. Rosa†	8-K	001-35312	February 6, 2013	10.1		
10.23	License, Supply & Manufacturing Agreement dated April 26, 2010 by and between the Company and DSM PTG, Inc.#	10	001-35312	February 14, 2012	10.17		
10.24	Lease Agreement dated October 21, 2011 by and between the Company and Silver Prairie Crossroads, LLC	10	001-35312	December 16, 2011	10.18		
10.25	Sales Agreement dated March 21, 2014 by and between the Company and Cowen and Company, LLC	S-3	333-194731	March 21, 2014	1.2		
10.26	Loan and Security Agreement between the Company and Silicon Valley Bank dated February 18, 2015	8-K	001-35312	February 19, 2015	10.1		
10.27	First Amendment to Loan and Security Agreement between the Company and Silicon Valley Bank dated December 8, 2015	8-K	001-35312	December 9, 2015	99.1		
10.28	Second Amendment to Lease, dated as of April 20, 2015, by and between the Company and Capital Partners Industrial Fund I, LLLP dba Prairie Crossroads Business Center	8-K	001-35312	April 23, 2015	10.1		
10.29	Termination and Release Agreement dated January 1, 2015 by and between the Company and William S. Peters†	10-Q	001-35312	May 7, 2015	10.2		
10.30	Separation and Release Agreement dated June 19, 2015	10-Q	001-35312	August 5, 2015	10.2		

	by and between the Company and Kimberly A. Oleson†						

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Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing			
10.31	Separation and Release Agreement between the Company and David A. Rosa, dated November 30, 2015†	8-K	001-35312	November 30, 2015	99.1		
10.32	Executive Employment Agreement between Sunshine Heart, Inc. and John L. Erb, dated March 1, 2016†	8-K	001-35312	March 2, 2016	10.1		
10.33	Separation and Release Agreement by and between Sunshine Heart, Inc. and Brian J. Brown, dated February 3, 2016†	10-Q	001-35312	May 5, 2015	10.2		
10.34	Separation and Release Agreement by and between Sunshine Heart, Inc. and Debra Kridner, dated January 24, 2016†	10-Q	001-35312	May 5, 2016	10.3		
10.35	Third Amendment to the Sunshine Heart, Inc. New-Hire Equity Incentive Plan †	S-8	333-210215	March 15, 2016	99.1		
10.36	Claudia Drayton Retention Bonus Letter, dated as of December 12, 2016	8-K	001-35312	December 16, 2016	10.1		
21	List of Subsidiaries	10-K	001-35312	March 15, 2016	21		
23.1	Consent of Independent Registered Public Accounting Firm					X	
23.2	Consent of Honigman Miller Schwartz & Cohn LLP					Included in Exhibit 5.1	
24.1	Power of Attorney					Included in signature page	

†Indicates management compensatory plan, contract or arrangement.
#Confidential treatment has been granted with respect to certain portions of this exhibit, which portions have been omitted and filed separately with the Securities and Exchange Commission as part of an application for confidential treatment pursuant to the Securities and Exchange Act of 1934, as amended.

Item 17. Undertakings.

1. The undersigned registrant hereby undertakes that, for the purpose of determining any liability under the Securities Act of 1933, as amended, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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2. The undersigned registrant hereby undertakes to remove from registration by means of a post-effective amendment any of the securities being registered that remain unsold at the termination of the offering.

3. The undersigned registrant hereby undertakes that, for the purposes of determining liability to any purchaser:

If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was

made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

4. Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, may be permitted to directors, officers and controlling persons of the undersigned registrant according the foregoing provisions, or otherwise, the undersigned registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933, as amended, and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Eden Prairie, State of Minnesota, on this 14th day of February, 2017.

SUNSHINE HEART, INC.

By: /s/ John L. Erb
John L. Erb
Chief Executive Officer and
Chairman of the Board

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below, hereby constitutes and appoints John L. Erb and Claudia Drayton, or either of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to the registration statement, including post-effective amendments, and registration statements filed pursuant to Rule 462 under the Securities Act of 1933, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, and does hereby grant unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the foregoing, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ John L. Erb John L. Erb	Chief Executive Officer and Chairman of the Board	February 14, 2017
/s/ Claudia Drayton Claudia Drayton	Chief Financial Officer	February 14, 2017
/s/ Gregory Waller Gregory Waller	Director	February 14, 2017
/s/ Jon W. Salveson Jon W. Salveson	Director	February 14, 2017
/s/ Warren Watson Warren Watson	Director	February 14, 2017
/s/ Steve Brandt Steve Brandt	Director	February 14, 2017
/s/ Matthew Likens Matthew Likens	Director	February 14, 2017

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EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing			
2.1	Asset Purchase Agreement between Sunshine Heart, Inc. and Gambro UF Solutions, Inc. dated August 5, 2016.	8-K	001-35312	August 8, 2016	2.1		
3.1	Fourth Amended and Restated Certificate of Incorporation	10	001-35312	February 1, 2012	3.1		
3.2	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	January 13, 2017	3.1		
3.3	Amended and Restated Bylaws	10	001-35312	September 30, 2011	3.2		
3.4	Form of Certificate of Designation of Series A Junior Participating Preferred Stock	8-K	001-35312	June 14,2013	3.1		
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock.	8-K	001-35312	July 25, 2016	3.1		
3.6	Certificate of Designation of Preferences, Rights and Limitations of Series B-1 Convertible Preferred Stock.	8-K	001-35312	November 3, 2016	3.1		
3.7	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock.	8-K	001-35312	November 3, 2016	3.2		
3.8	Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock.	8-K	001-35312	November 3, 2016	3.3		
4.1	Warrant to Purchase Stock, dated February 18, 2015, issued to Silicon Valley Bank	8-K	001-35312	February 19, 2015	4.1		
4.2	Warrant to Purchase Stock, dated February 18, 2015, issued to Life Science Loans, LLC	8-K	001-35312	February 19, 2015	4.2		
4.3	Form of Series B Convertible Preferred Stock Certificate.	8-K	001-35312	July 22, 2016	4.1		
4.4	Form of Common Stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated July 20, 2016, among the Company and the purchasers signatory thereto.	8-K	001-35312	July 22, 2016	4.3		
4.5	Form of Common Stock Purchase Warrant issued to Northland Securities, Inc.	8-K	001-35312	July 22, 2016	4.3		
4.6	Registration Rights Agreement between Sunshine Heart, Inc. and	8-K	001-35312	August 8, 2016	4.1		

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	Gambro UF Solutions, Inc. dated August 5, 2016						
4.7	Form of Common Stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated October 30, 2016, among the Company and the purchasers signatory thereto.	8-K	001-35312	October 31, 2016	4.1		
5.1	Opinion of Honigman Miller Schwartz and Cohn LLP					X	
10.1	Securities Purchase Agreement, dated July 20, 2016 among the Company and the purchasers signatory thereto.	8-K	001-35312	July 22, 2016	10.1		
10.2	Patent License Agreement between Sunshine Heart, Inc. and Gambro UF Solutions, Inc. dated August 5, 2016.	8-K	001-35312	August 8, 2016	10.1		
10.3	Loan and Security Agreement between Sunshine Heart, Inc. and Silicon Valley Bank dated August 5, 2016.	8-K	001-35312	August 8, 2016	10.2		
10.4	Amended and Restated 2002 Stock Plan†	10	001-35312	December 16, 2011	10.2		
10.5	Form of Notice of Stock Option Grant and Option Agreement for Amended and Restated 2002 Stock Plan†	10	001-35312	September 30, 2011	10.3		
10.6	Second Amended and Restated 2011 Equity Incentive Plan, as amended†	14A	001-35312	July 27, 2012	App. A		
10.7	Form of Stock Option Grant Notice and Option Agreement for 2011 Equity Incentive Plan †	10	001-35312	September 30, 2011	10.5		

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Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing	Exhibit Number		
10.8	Form of Stock Option Grant Notice and Option Agreement (Senior Management) for 2011 Equity Incentive Plan†	10	001-35312	September 30, 2011	10.6		
10.9	Form of Stock Option Grant Notice and Option Agreement (Director) for 2011 Equity Incentive Plan†	8-K	001-35312	September 18, 2012	10.1		
10.10	Form of Stock Grant Notice and Award Agreement for 2011 Equity Incentive Plan†	8-K	001-35312	September 10, 2013	10.1		
10.11	Form of Restricted Stock Unit Grant Notice and Agreement for 2011 Equity Incentive Plan†	8-K	001-35312	September 10, 2013	10.2		
10.12	2013 Non-Employee Directors' Equity Incentive Plan†	14A	001-35312	April 5, 2013	App. A		
10.13	Form of Stock Option Grant Notice and Option Agreement for 2013 Non-Employee Directors' Equity Incentive Plan†	10-K	001-35312	March 20, 2014	10.10		

10.14	Form of Restricted Stock Unit Award Grant Notice and Agreement for 2013 Non-Employee Directors' Equity Incentive Plan†	10-K	001-35312	March 20, 2014	10.11		
10.15	New-Hire Equity Incentive Plan†	10-Q	001-35312	August 8, 2013	10.1		
10.16	First Amendment to New-Hire Equity Incentive Plan†	10-Q	001-35312	November 12, 2013	10.1		
10.17	Second Amendment to New-Hire Equity Incentive Plan†	10-Q	333-202904	March 20, 2015	10.1		
10.18	Form of Stock Option Grant Notice and Option Agreement for New-Hire Equity Incentive Plan†	10-K	001-35312	March 20, 2014	10.14		
10.19	Form of Indemnity Agreement for the Company's executive officers and directors†	10	001-35312	September 30, 2011	10.1		
10.20	Form of Change in Control Agreement for the Company's executive officers†	10-K	001-35312	March 20, 2015	10.16		
10.21	Non-Employee Director Compensation Policy†	10-Q	001-35312	August 8, 2013	10.2		
10.22	Executive Employment Agreement	8-K	001-35312	February 6, 2013	10.1		

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Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing	Exhibit Number		
	dated February 6, 2013 by and between the Company and David A. Rosa†						
10.23	License, Supply & Manufacturing Agreement dated April 26, 2010 by and between the Company and DSM PTG, Inc.#	10	001-35312	February 14, 2012	10.17		
10.24	Lease Agreement dated October 21, 2011 by and between the Company and Silver Prairie Crossroads, LLC	10	001-35312	December 16, 2011	10.18		
10.25	Sales Agreement dated March 21, 2014 by and between the Company and Cowen and Company, LLC	S-3	333-194731	March 21, 2014	1.2		
10.26	Loan and Security Agreement between the Company and Silicon Valley Bank dated February 18, 2015	8-K	001-35312	February 19, 2015	10.1		
10.27	First Amendment to Loan and Security Agreement between the Company and Silicon Valley Bank dated December 8, 2015	8-K	001-35312	December 9, 2015	99.1		
10.28	Second Amendment to Lease, dated as of April 20, 2015, by and between the Company and Capital Partners Industrial Fund I, LLLP dba Prairie Crossroads Business Center	8-K	001-35312	April 23, 2015	10.1		
10.29	Termination and Release Agreement dated January 1, 2015	10-Q	001-35312	May 7, 2015	10.2		

	by and between the Company and William S. Peters†						
10.30	Separation and Release Agreement dated June 19, 2015 by and between the Company and Kimberly A. Oleson†	10-Q	001-35312	August 5, 2015	10.2		
10.31	Separation and Release Agreement between the Company and David A. Rosa, dated November 30, 2015†	8-K	001-35312	November 30, 2015	99.1		
10.32	Executive Employment Agreement between Sunshine Heart, Inc. and John L. Erb, dated March 1, 2016†	8-K	001-35312	March 2, 2016	10.1		
10.33	Separation and Release Agreement by and between Sunshine	10-Q	001-35312	May 5, 2015	10.2		

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Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing			
	Heart, Inc. and Brian J. Brown, dated February 3, 2016†						
10.34	Separation and Release Agreement by and between Sunshine Heart, Inc. and Debra Kridner, dated January 24, 2016†	10-Q	001-35312	May 5, 2016	10.3		
10.35	Third Amendment to the Sunshine Heart, Inc. New-Hire Equity Incentive Plan †	S-8	333-210215	March 15, 2016	99.1		
10.36	Claudia Drayton Retention Bonus Letter, dated as of December 12, 2016	8-K	001-35312	December 16, 2016	10.1		
21	List of Subsidiaries	10-K	001-35312	March 15, 2016	21		
23.1	Consent of Independent Registered Public Accounting Firm					X	
23.2	Consent of Honigman Miller Schwartz & Cohn LLP					Included in Exhibit 5.1	
24.1	Power of Attorney					Included in signature page	

†Indicates management compensatory plan, contract or arrangement.
#Confidential treatment has been granted with respect to certain portions of this exhibit, which portions have been omitted and filed separately with the Securities and Exchange Commission as part of an application for confidential treatment pursuant to the Securities and Exchange Act of 1934, as amended.

Exhibit 5.1

HONIGMAN

Honigman Miller Schwartz and Cohn LLP
Attorneys and Counselors

(269) 337-7700
Fax: (269) 337-7701

February 14, 2017

Sunshine Heart, Inc.
12988 Valley View Road
Eden Prairie, Minnesota 55344

Re: Registration Statement on Form S-1

Ladies and Gentlemen:

We have acted as counsel to Sunshine Heart, Inc., a Delaware corporation (the "***Company***"), in connection with preparing and filing with the Securities and Exchange Commission (the "***Commission***") pursuant to the Securities Act of 1933, as amended (the "***Securities Act***"), a Registration Statement on Form S-1 (such registration statement as amended or supplemented from time to time, the "***Registration Statement***"), in connection with the registration under the Securities Act of an aggregate of 206,809 shares of the Company's common stock, par value $0.0001 per share ("***Common Stock***"), of which (i) 44,614 shares are issuable upon conversion of 200 shares of Series D Convertible Preferred Stock of the Company (the "***Preferred Stock***") and (ii) 162,195 shares are issuable upon the exercise of common stock purchase warrants (the "***Warrants***"). The Preferred Stock and the Warrants were issued pursuant to that certain Securities Purchase Agreement dated October 30, 2016 (the ***"Securities Purchase Agreement"***), by and among the Company, Sabby Healthcare Master Fund Ltd. and Sabby Volatility Warrant Fund Ltd.

For the purpose of rendering this opinion, we examined originals or copies of such documents as we deemed relevant. In conducting our examination, we assumed, without investigation, the genuineness of all signatures, the correctness of all certificates, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted as certified or photostatic copies, and the authenticity of the originals of such copies, and the accuracy and completeness of all records made available to us by the Company. As to certain factual matters, we have relied upon a certificate of officers of the Company and have not independently sought to verify such matters. In addition, in rendering this opinion, we have assumed that the Preferred Stock will be converted and the Warrants will be exercised in the manner and on the terms identified or referred to in the Registration Statement, including all supplements and amendments thereto.

Our opinions are limited solely to matters set forth herein. The law covered by the opinions expressed herein is limited to the federal law of the United States, New York law applicable to contracts and Delaware corporate law.

Based upon our examination of such documents and other matters as we deem relevant, we are of the opinion that the 206,809 shares of Common Stock have been duly authorized by the Company and upon conversion of the Preferred Stock in accordance with its terms or exercise of the Warrants in accordance with their terms, as applicable, will be validly issued, fully paid and non-assessable.

We hereby consent to the filing of this opinion as Exhibit 5.1 to the Registration Statement and to the reference to our firm under the caption "Legal Matters" in the Registration Statement. In giving such consent, we do not admit that we are within the category of persons whose consent is required by Section 7 of the Securities Act or the rules and regulations promulgated thereunder by the Commission.

Very truly yours,

/s/ Honigman Miller Schwartz and Cohn LLP

HONIGMAN MILLER SCHWARTZ AND COHN LLP

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption “Experts” in this Registration Statement (Form S-1) and related Prospectus of Sunshine Heart, Inc. and to the incorporation by reference therein of our report dated March 15, 2016, with respect to the consolidated financial statements of Sunshine Heart, Inc. and subsidiaries included in its Annual Report (Form 10-K) for the year ended December 31, 2015, filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP
Minneapolis, Minnesota
February 14, 2017