UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

Current Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **January 11, 2017**

SUNSHINE HEART, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-35312**	**68-0533453**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

12988 Valley View Road
Eden Prairie, Minnesota 55344
(Address of principal executive offices) (Zip Code)

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

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 3.02 Recent Sales of Unregistered Securities

See the disclosures under the heading "Second Closing of Securities Purchase Agreement" under Item 8.01 below, which disclosures are incorporated herein by reference.

Item 3.03 Material Modification to Rights of Security Holders.

To the extent required by Item 3.03 of Form 8-K, the information contained in Item 5.03 of this report is incorporated herein by reference.

Item 5.03 Amendment to Articles of Incorporation or Bylaws; Change in Fiscal Year.

On January 9, 2017, Sunshine Heart, Inc. (the ***"Company"***, ***"we"*** or ***"us"***) held a special meeting of stockholders (the ***"Special Meeting"***) at its offices at 12988 Valley View Road, Eden Prairie, Minnesota. At the Special Meeting, the stockholders approved the proposal to amend the Company's Fourth Amended and Restated Certificate of Incorporation, as amended (the ***"Certificate of Incorporation"***), to effect a reverse stock split of its outstanding common stock, at any time prior to the first anniversary of the approval by the stockholders, at a ratio in the range of 1-for-20 to 1-for-60, to be determined at the discretion of the Board of Directors of the Company (the ***"Board"***).

On January 9, 2017, following the Special Meeting, the Board approved a 1-for-30 reverse stock split of the Company's issued and outstanding shares of common stock (the ***"Reverse Stock Split"***). The Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment to its Fourth Amended and Restated Certificate of Incorporation (the ***"Certificate of Amendment"***) to effect the Reverse Stock Split, and the Reverse Stock Split was effective as of 5:00 p.m. Eastern Time on January 12, 2017, and the Company's common stock will begin trading on a split-adjusted basis when the market opens on January 13, 2017.

When the Reverse Stock Split becomes effective, every 30 shares of the Company's issued and outstanding common stock (and such shares held in treasury) will automatically be converted into one share of common stock, without any change in the par value per share. In addition, a proportionate

adjustment will be made to the per share exercise price and the number of shares issuable upon the conversion of the Company's outstanding shares of preferred stock and the exercise of all outstanding stock options, restricted stock units and warrants to purchase shares of common stock and the number of shares reserved for issuance pursuant to the Company's equity incentive compensation plans. Any fraction of a share of common stock that would be created as a result of the Reverse Stock Split will be rounded down to the next whole share and the stockholder will receive cash equal to the market value of the factional share, determined by multiplying such fraction by the closing sales price of the Company's common stock as reported on Nasdaq on the last trading day before the Reverse Stock Split becomes effective.

The Company's common stock will continue to trade on the Nasdaq Capital Market under the symbol "SSH." The new CUSIP number for common stock following the Reverse Stock Split will be 86782U 304.

American Stock Transfer & Trust Company, the Company's transfer agent, will act as the exchange agent for the Reverse Stock Split.

For more information about the Reverse Stock Split, see the Company's Definitive Proxy Statement on Schedule 14A (the ***"Special Meeting Proxy Statement"***), which was filed with the Securities and Exchange Commission and mailed to the Company's stockholders on or about December 8, 2016, the relevant portions of which are incorporated herein by reference. A copy of the Certificate of Amendment is attached as Exhibit 3.1 hereto and incorporated herein by reference.

Item 8.01 Other Events.

Second Closing of Securities Purchase Agreement

As previously disclosed in the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission (***"SEC"***) on October 31, 2016 (the ***"Prior Current Report"***), we entered into securities

purchase agreements (collectively, the "***Securities Purchase Agreement***") with certain institutional investors named in the signature pages thereto on October 30, 2016 which provided that the closing of the transactions contemplated thereby would occur in two stages. The initial closing occurred on November 3, 2016, and the second closing was subject to shareholder approval. Following the receipt of shareholder approval on January 9, 2017, as previously disclosed on the Company's Current Report on Form 8-K filed with the SEC on January 10, 2017, the Company consummated the second closing and completed the issuance and sale of 200 shares of Series D Convertible Preferred Stock (the ***"Series D Preferred Stock"***) at $0.17 per share and warrants (each a ***"Warrant"*** and collectively, the ***"Warrants"***) to purchase an aggregate of 1,176,471 shares of the Common Stock, at an exercise price equal to $0.18 per share, on January 11, 2017, in each case, pursuant to an exemption from the registration requirement of the Securities Act of 1933, as amended, provided in Section 4(a)(2) thereof and/or Rule 506 of Regulation D promulgated thereunder.

Announcement of Approval of Reverse Stock Split

On January 12, 2017, the Company issued a press release announcing that the Board has approved the Reverse Stock Split. A copy of the press release is attached hereto as Exhibit 99.1, and is incorporated herein by reference.

Update of Risk Factors and Business Disclosure

The following risk factors and business section are provided to update the risk factors and business disclosure of the Company previously disclosed in periodic reports filed with the SEC, including its Annual Report on Form 10-K for the year ended December 31, 2015 and its Quarterly Reports on Form 10-Q for the quarters ended March 31, 2016, June 30, 2016 and September 30, 2016:

RISK FACTORS

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 System (the ***"Aquadex Business"*** or 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 pausing 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 limited experience with respect to 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

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 that cannot then be dedicated to other projects. Our failure to manage and coordinate the growth of the combined company successfully 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 a subsidiary of Baxter International Inc. (***"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 products 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.

We have limited 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 limited 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 will mainly compete against pharmacological therapies, diuretics, as well as a range of other specialized medical device companies with devices at varying stages of development. Some of these competitors have significantly greater financial and human resources than we do and have established reputations, as well as worldwide distribution channels and sales and marketing capabilities that are significantly larger and more established than ours. Additional competitors may enter the market, and we are likely to compete with new companies in the future. We also face competition from other medical therapies which may focus on our target market as well as competition from manufacturers of pharmaceutical and other devices that have not yet been developed. Competition from these companies could harm our business. In addition, because our system has been implanted in a limited number of patients to date, all of the material risks and potential competitive disadvantages of our system are not necessarily known at this time.

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

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

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

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

While the agency responsible for administering the Medicare program, the Centers for Medicare and Medicaid Services, has not issued a favorable national coverage determination 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, coverage can be sought 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.

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. 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.

The design, manufacture and marketing of medical devices carries a significant risk of product liability claims. Our products treats heart failure for patients who typically have serious medical issues. As a result, our exposure to product liability claims may be heightened because the people who use our products have a high risk of suffering adverse outcomes, regardless of the safety or efficacy of our system.

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 demand for our system, if approved for commercialization, injury to our reputation, diversion of management's attention from operating our business, withdrawal of study participants, significant costs of related litigation, loss of revenue or the inability to commercialize our products.

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

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

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

Approval or clearance of our products could be withdrawn, delayed or denied by the European Union, the FDA and the relevant authorities of other countries if our manufacturing facilities do not comply with their respective manufacturing requirements. The European Union imposes requirements on quality control systems of manufacturers, which are inspected and certified on a periodic basis and may be subject to additional unannounced inspections. Failure by our manufacturers to comply with these requirements could prevent us from marketing our products in the European Community. The FDA also imposes requirements through quality system requirements, or QSR, regulations, which include requirements for good manufacturing practices, or GMP. Failure by our manufacturers to comply with these requirements could prevent us from obtaining FDA approval of our products and from marketing such products in the

United States. Although the manufacturing facilities and processes that we use to manufacture our products have been inspected and certified by a worldwide testing and certification agency (also referred to as a notified body) that performs conformity assessments to European Union requirements for medical devices, they have not been inspected by the FDA. A “notified body” is a group accredited and monitored by governmental agencies that inspects manufacturing facilities and quality control systems at regular intervals and is authorized to carry out unannounced inspections. We cannot be sure that any of the facilities or processes we use will comply or continue to comply with their respective requirements on a timely basis or at all, which could delay or prevent our obtaining the approvals we need to market our products in the European Community and the United States.

To market our products in the European Community, the United States and other countries, where approved, manufacturers of such products must continue to comply or ensure compliance with the relevant manufacturing requirements. Although we cannot control the manufacturers of our products, 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 may have a significant impact on our business. The impact of the Affordable Care Act on the health care industry is extensive and includes, among other things, the federal government assuming a larger role in the health care system, expanding healthcare coverage of United States citizens and mandating basic healthcare benefits. The Affordable Care Act contains many provisions designed to generate the revenues necessary to fund the coverage expansions and to reduce costs of Medicare and Medicaid, including imposing a 2.3% excise tax on domestic sales of many medical devices by manufacturers that began in 2013. Although a moratorium was placed on the medical device excise tax in 2016 and 2017, if it is reinstated, it may adversely affect our sales and the cost of goods sold.

The Affordable Care Act includes a Hospital Readmission Reduction program and is designed to reduce payments to hospitals with excess heart failure readmissions, among other conditions. The penalty to hospitals can be significant, as much as 3% of total Medicare reimbursement. We believe the Aquadex FlexFlow can 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.

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 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 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 September 30, 2016, we owned 37 issued patents and 12 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 2020 and 2024. 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 under the 49 exclusive and 9 non-exclusive 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 files for, has filed against it, or otherwise undertakes 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.

Our pending and future patent applications may not issue as patents or, if issued, may not issue in a form that will provide us any competitive advantage. Even if issued, existing or future patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of terms of patent protection we may have for our system. Changes in patent laws or their interpretation in the United States and other countries could also diminish the value of our intellectual property or narrow the scope of our patent protection. In addition, the legal

systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. In order to preserve and enforce our patent and other intellectual property rights, we may need to make claims or file lawsuits against third parties. This can entail significant costs to us and divert our management's attention from our business.

Intellectual property litigation could be costly and disruptive to us.

In recent years, there has been significant litigation involving intellectual property rights. From time to time, third parties may assert patent, copyright, trademark and other intellectual property rights to technologies used in our business. Any claims, with or without merit, could be time-consuming, result in costly litigation, divert the efforts of our technical and management personnel or require us to pay substantial damages. If we are unsuccessful in defending ourselves against these types of claims, we may be required to do one or more of the following:

- halt use of our Aquadex Business;

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

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

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

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

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

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

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

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

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

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

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

The secure processing, storage, maintenance, and transmission of this critical information is vital to our operations and business strategy. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks

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

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

Risks Related to 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 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 our 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 has 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. There can also be no assurance that the minimum bid price per share of our common stock would remain in excess of $1.00 following the reverse stock split for a sustained period of time, or long enough to satisfy Nasdaq's continued listing requirements.

Despite our efforts, we cannot assure you that we will be able to meet these listing requirements. If it appears to the

Nasdaq staff that we will not be able to comply with the minimum bid price requirement, or if we do not meet the minimum stockholders' equity or any other listing standard, our common stock may be subject to delisting and we could face significant material adverse consequences, including:

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

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

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

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. There can be no assurance that the total market capitalization of our common stock after the proposed 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.

Because the number of authorized shares of our common stock will not be reduced proportionately, the reverse stock split will increase our board of directors' ability to issue authorized and unissued shares without further stockholder action. Without taking into account the impact of the proposed reverse stock split, the Company already has a substantial number of authorized but unissued shares of stock, the issuance of which would be dilutive to our existing stockholders and may cause a decline in the trading price of our common stock, although a large portion of such authorized but unissued shares are reserved for issuance pursuant to the conversion or exercise of convertible securities. With respect to authorized but unissued and unreserved shares, the Company 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.

In addition, the reverse stock split may increase the number of stockholders who own odd lots (less than 100 shares). Any stockholder who owns fewer than 2,000 to 6,000 shares of common stock, depending on the final ratio, prior to the reverse stock split will own fewer than 100 shares of common stock following the reverse stock split. Stockholders who hold odd lots typically experience an increase in the cost of selling their shares and may have greater difficulty in effecting sales. Furthermore, some stockholders may cease being stockholders of the Company following the reverse stock split. Any stockholder who owns fewer than 20 to 60 shares of common stock, depending on the final ratio, prior to the reverse stock split will own less than one share of common stock following the reverse stock split and therefore such stockholder will receive cash equal to the market value of such fractional share and cease being a stockholder of the Company.

The number of shares of common stock underlying our 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.

The number of shares of common stock issuable upon conversion of our preferred stock and warrants is significant in relation to the number of shares of our common stock currently outstanding. If any security holder determines to sell a substantial number of shares into the market at any given time, there may not be sufficient demand in the market to purchase the shares without a decline in the market price for our common stock. Moreover, continuous

sales into the market of a number of shares in excess of the typical trading volume for our common stock, or even the availability of such a large number of shares, could depress the trading market for our common stock over an extended period of time.

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 ultimate ownership (subject to the relevant tests in Australian tax law) of more than 50% between the loss year and the income year in which the loss is claimed.

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

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

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

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

In connection with the effectiveness of our registration statement on Form 10, as of February 14, 2012, we became subject to the periodic reporting requirements of the Exchange Act. Although we were previously listed on the Australian Securities Exchange and had been required to file financial information and make certain other filings with the Australian Securities Exchange, our status as a U.S. reporting company under the Exchange Act has caused us, and will continue to cause us, to incur additional legal, accounting and other expenses that we did not previously incur, including costs related to compliance with the requirements of SOX and the listing requirements of The Nasdaq Capital Market. We expect these rules and regulations will continue to increase our legal and financial compliance costs and make some activities more time-consuming and costly, and these activities may increase general and administrative expenses and divert management's time and attention away from revenue-generating activities. Furthermore, now that we are a revenue-generating company following the acquisition of the Aquadex Business in August 2016, our costs to comply with regulations applicable to U.S. reporting

companies may further increase. We also expect these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers.

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

In connection with becoming a company required to file reports with the SEC, we are required to comply with the internal control evaluation and certification requirements of Section 404 of SOX. Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of SOX until the date we are no longer an "emerging growth company" as defined in the JOBS Act or a "smaller reporting company" as defined by applicable SEC rules. We will no longer qualify as an "emerging growth company" on or before December 31, 2017, although we will remain a "smaller reporting company" as long as our public float remains less than $75 million as of the last business day of our most recently-completed second fiscal quarter.

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

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

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

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

Certain provisions of our certificate of incorporation and bylaws may have the effect of deterring takeovers, such as those provisions authorizing our board of directors to issue, from time to time, any series of preferred stock and fix the designation, powers, preferences and rights of the shares of such series of preferred stock; prohibiting stockholders from acting by written consent in lieu of a meeting; requiring advance notice of stockholder intention to put forth director nominees or bring up other business at a stockholders' meeting; prohibiting stockholders from calling a special meeting of stockholders; requiring a 66 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 could be an emerging growth company until December 31, 2017, although we could lose that status sooner if our revenues exceed $1 billion, if we issue more than $1 billion in non-convertible debt in a three-year period, or if the market value of our common stock held by non-affiliates exceeds $700 million as of any June 30 before that time, in which case we would no longer be an emerging growth company as of the following December 31. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline or be more volatile.

As explained above, Section 102(b)(1) of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. An emerging growth company can delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period, and as a result of this election, our financial statements may not be comparable to those of companies that comply with public company effective dates for new or revised accounting standards for U.S. public companies.

If we receive the approval of our stockholders for, and effect, a reverse stock split in the range proposed by our board of directors, we may have a large number of authorized but unissued shares of stock, which could negatively impact a potential investor if they purchased our common stock.

Our certificate of incorporation provides for 100,000,000 shares of authorized common stock and 40,000,000 shares of authorized preferred stock. As of December 9, 2016, we had 23,290,801 shares of common stock outstanding and 63,524,472 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. 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. 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.

Our board of directors has recommended, and we are seeking approval of our stockholders, of a reverse stock split in the range of 1-to-20 to 1-to-60. Because the number of authorized shares of our common stock will not be reduced proportionately, the reverse stock split will increase our board of directors' ability to issue authorized and unissued shares without further stockholder action. Without taking into account the impact of the proposed reverse stock split, we already have a substantial number of authorized but unissued shares of stock, the issuance of which would be dilutive to our stockholders and may cause a decline in the trading price of our common stock, although a large portion of such authorized but unissued shares are reserved for issuance pursuant to the conversion or exercise of outstanding convertible securities.

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.

BUSINESS

Overview

We are an early-stage medical device company focused on developing and commercializing a product portfolio to treat moderate to severe heart failure and related conditions. 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, manufacturing and commercializing the C-Pulse® Heart Assist System for treatment of Class III and ambulatory Class IV heart failure. The C-Pulse System utilizes the known concept of counterpulsation applied in an extra-aortic approach to assist the left ventricle by reducing the workload required to pump blood throughout the body, while increasing blood flow to the coronary arteries. Specifically, we were in the process of pursuing regulatory approvals necessary to sell the system in the United States. We completed enrollment of our North American feasibility clinical study in the first half of 2011. In November 2011, we announced the preliminary results of the six-month follow-up period for the feasibility study and we submitted the clinical data to the FDA. In March 2012, the FDA notified us that it had completed its review of the C-Pulse System feasibility study data and concluded we met the applicable agency requirements, and further indicated that we could move forward with an investigational device exemption (***"IDE"***) application. In October 2012, we announced the results of the 12-month follow-up period for the feasibility study. In November 2012, the FDA provided us with

unconditional approval to initiate a pivotal study and we commenced enrollment in our COUNTER HF™ study in September 2013. The COUNTER HF study was designed to enroll 388 patients randomized 1:1 to treatment (C-Pulse implantation) versus optimal medical therapy, at up to 40 participating hospitals and clinics. The primary efficacy endpoint of the study was defined as freedom from worsening heart failure resulting in hospitalization, Left Ventricular Assist Device (***"LVAD"***) implantation, cardiac transplantation or heart failure related death. In February 2015, we announced that we had received unconditional approval from the FDA to conduct an interim analysis of COUNTER HF, which could have reduced the overall duration of the trial. In March 2015, we announced that COUNTER HF had reached a pre-determined pausing point and we temporarily suspended enrollment in accordance with the study protocol. In May 2015, we announced that the FDA approved resumption of patient enrollment into the study and we began the process of reactivating clinical sites and of resuming enrollment of patients into the study.

We obtained CE Mark for the C-Pulse System in July 2012. In order to gain additional clinical data and support reimbursement in Europe, we initiated a 50-patient post-market study in Europe to evaluate endpoints similar to those for our U.S. pivotal study. We commenced enrollment in our OPTIONS HF study in the second quarter of 2013.

As we evaluated the pace of enrollment into our pivotal and post market studies, we determined that enrolling these studies would take much longer than anticipated as a result of the invasiveness of the implant procedure and requirements imposed by the trial design. As a result, in March 2016, we announced that we were no longer enrolling patients into the COUNTER HF and OPTIONS HF studies and that we planned to pursue a new strategic direction. Specifically, on March 3, 2016, we announced that we were working with our investigators to develop the specifics of our revised clinical and product development strategy to pursue two high level objectives: (i) pursuing a shorter clinical trial to generate incremental data to further demonstrate the clinical benefits of C-Pulse therapy to support the U.S. regulatory approval of a fully implantable device, including making relatively minor modifications to the current C-Pulse device; and (ii) in the longer term, focusing additional resources on accelerating development of a fully-implantable system, which we ultimately believe will benefit our business and prospects.

In July 2016, we announced that we were moving forward with a therapeutic strategy focused on a fully implantable system utilizing neuromodulation rather than counterpulsation. We changed our strategy after we discovered that the primary mechanism of action providing the clinical benefit was a neuromodulatory effect due to the counterpulsation balloon's placement on the ascending aorta and the activation with each expansion of the aortic and possibly carotid baroreceptors.

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 pausing 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.

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
- 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.

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

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 nicely to assist hospitals with the Affordable Care Act and can offer hospitals an economic benefit for using the device on a regular basis for in-patient or out-patient usage.

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

1) **Inpatient Care** — Given to a patient admitted to a hospital, extended care facility, nursing home or other facility. Long term care is the range of services typically provided at skilled nursing, intermediate-care, personal care or eldercare facilities.

2) **Outpatient Care** — Any health care service provided to a patient who is not admitted to a facility. Outpatient care can be provided in a doctor's office, clinic, or hospital outpatient department.

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

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

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 pausing 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 drive 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.
- 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

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. 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 compelling 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 2016, our portfolio consisted of over 35 patents issued and 17 patents pending in the United States and abroad for our counterpulsation, technology. In addition, our portfolio includes over 50 exclusive and non-exclusive 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 the C-Pulse System device and related components, our 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. Indirect competitors, such as Baxter’s Prismaflex is an ultrafiltration system, although it is a filter-based device that is intended for continuous renal replacement therapy for patients weighing 20kg or more with acute renal failure and/or fluid overload. Customers don’t consider Prismaflex as a direct competitor to the Aquadex FlexFlow.

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 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, coverage can be sought 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 (i.e., C-Pulse) will require regulatory approval prior to commercialization.

United States

The FDC Act and the FDA’s implementing regulations govern medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post market surveillance. Medical devices and their manufacturers are also subject to inspection by the FDA. The FDC Act, supplemented by other federal and state laws, also provides civil and criminal penalties for violations of its provisions. We manufacture and market medical devices that are regulated by the FDA, comparable state agencies and regulatory bodies in other countries.

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

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

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

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

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

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

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

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

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

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

- changes in governmental regulations or administrative actions;
- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or efficacy; or
- the FDA concludes that the trial design is inadequate to demonstrate safety and efficacy.

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

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

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

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

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

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

The QSR requires a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of marketed devices, and includes extensive requirements with respect to quality management and organization, device design, buildings, equipment, purchase and handling of components, production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing and record keeping. The FDA enforces the QSR through periodic announced and unannounced inspections that may include the manufacturing facilities of subcontractors. If the FDA believes that we or any of our contract manufacturers or regulated suppliers is not in compliance with these requirements, it can shut down our manufacturing operations, require recall of our products, refuse to clear or approve new marketing applications, institute legal proceedings to detain or seize products, enjoin future violations or assess civil and criminal penalties against us or our officers or other employees. Any such action by the FDA would have a material adverse effect on our business.

Employees

As of December 9, 2016, we had 28 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.

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.

On September 30, 2011, we filed a Form 10 registration statement with the SEC, which was declared effective on February 14, 2012. The Form 10 registered our common stock under the Exchange Act. Our common stock began trading on The Nasdaq Capital Market on February 16, 2012.

On February 5, 2013, we received conditional approval from the ASX to delist from the official list of the ASX. The delisting occurred at the close of trading on May 6, 2013.

Our principal executive offices are located at 12988 Valley View Road, Eden Prairie, Minnesota 55344, and our telephone number is (952) 345-4200. Our website address is www.sunshineheart.com. 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 report.

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

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
3.1	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation, as amended, of Sunshine Heart, Inc.
99.1	Press release dated January 12, 2017

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: January 13, 2017

SUNSHINE HEART, INC.

By: /S/ CLAUDIA DRAYTON
Name: Claudia Drayton
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
3.1	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation, as amended, of Sunshine Heart, Inc.
99.1	Press release dated January 12, 2017

Exhibit 3.1

CERTIFICATE OF AMENDMENT
TO THE
FOURTH AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
SUNSHINE HEART, INC.

Sunshine Heart, Inc., a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the ***"Corporation"***), does hereby certify:

FIRST: That the Board of Directors of the Corporation duly adopted resolutions to amend its Fourth Amended and Restated Certificate of Incorporation as follows, declaring said amendment to be advisable and calling for submission of said resolution to a vote of the stockholders of said Corporation;

SECOND: That thereafter, at a meeting duly called and held upon notice in accordance with Section 222 of the General Corporation Law of the State of Delaware, the stockholders of the Corporation duly voted a majority of the outstanding stock of the Corporation entitled to vote thereon in favor of adoption of said amendment; and

THIRD: That said amendment being duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware, the Fourth Amended and Restated Certificate of Incorporation of Sunshine Heart, Inc., as previously amended, is hereby amended as follows:

Paragraph A of ARTICLE IV, AUTHORIZED STOCK AND RELATIVE RIGHTS, as amended to date, is hereby deleted in its entirety and replaced by the following:

"The Corporation is authorized to issue two classes of stock to be designated, respectively, ***"Common Stock"*** and ***"Preferred Stock"***. The total number of shares that the Corporation is authorized to issue is One Hundred Forty Million (140,000,000) shares, each with a par value of $0.0001 per share. One Hundred Million (100,000,000) shares shall be Common Stock and Forty Million (40,000,000) shares shall be Preferred Stock. Upon the filing and effectiveness (the ***"Effective Time"***) pursuant to the General Corporation Law of the State of Delaware (the ***"DGCL"***) of this Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Corporation, as previously amended (the ***"Restated Certificate"***), each thirty (30) shares of the Corporation's Common Stock issued and outstanding immediately prior to the Effective Time shall, automatically and without any action on the part of the Corporation or respective holders thereof, be combined and converted into one (1) validly issued, fully paid and non-assessable share of Common Stock; provided, however, that the Corporation shall issue no fractional shares as a result of the actions set forth herein but shall instead pay to the holder of such fractional share a sum in cash equal to such fraction multiplied by the closing sales price of the Common Stock as reported on The Nasdaq Capital Market on the last trading day before the Effective Time."

FOURTH: The Effective Time of said amendment will be January 12, 2017 at 5:00 p.m. Eastern Time.

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to be signed by its Chief Executive Officer this 11th day of January, 2017.

SUNSHINE HEART, INC.

By: /s/ JOHN L. ERB
John L. Erb, Chief Executive Officer

Sunshine Heart Announces 1-for-30 Reverse Stock Split

Eden Prairie, MN: January 12, 2017: (GLOBE NEWSWIRE) Sunshine Heart, Inc. today announced a 1-for-30 reverse split of its common stock, effective at 5:00 pm Eastern time today. Beginning tomorrow, January 13, 2017, the Company's common stock will trade on The Nasdaq Capital Market on a split adjusted basis.

At Sunshine Heart's special meeting of stockholders on January 9, 2017, the Company's stockholders authorized the Board of Directors to amend the Fourth Amended and Restated Certificate of Incorporation, as amended, of the Company to effect a reverse stock split at a ratio in the range of 1-for-20 to 1-for-60, as determined at the discretion of the Company's Board of Directors.

Upon effectiveness, the reverse stock split will cause a reduction in the number of shares of common stock outstanding and issuable upon the conversion of the Company's outstanding shares of preferred stock and the exercise of its outstanding stock options and warrants in proportion to the ratio of the reverse split, and will cause a proportionate increase in the conversion and exercise prices of such preferred stock, stock options and warrants. The number of shares of common stock issuable upon the exercise or vesting of outstanding stock options and warrants will be rounded down to the nearest whole share.

The Company's common stock will continue to trade on the Nasdaq Capital Market under the symbol "SSH." The new CUSIP number for the common stock following the reverse split is 86782U 304.

The number of authorized shares of the Company's common stock will remain at 100,000,000, while the number of outstanding shares will be reduced from approximately 25.3 million to 0.8 million. No fractional shares will be issued following the reverse stock split.

Additional information about the reverse stock split can be found in the Company's definitive proxy statement filed with the Securities and Exchange Commission on December 8, 2016, a copy of which is also available on the Company's website under the Investors page.

About Sunshine Heart

Sunshine Heart, Inc. (Nasdaq:SSH) is an early-stage medical device company focused on developing a product portfolio to treat moderate to severe heart failure and related conditions. The Company's commercial product, the Aquadex 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. Our objective is to improve the quality of life for heart failure patients and slow the disease progression. Sunshine Heart is a Delaware corporation headquartered in Minneapolis with wholly owned subsidiaries in Australia and Ireland. The Company has been listed on the NASDAQ Capital Market since February 2012.

Forward-Looking Statements

Certain statements in this release are forward-looking statements that are based on management's beliefs,

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assumptions, expectations, and information currently available to management. All statements that address future operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation, clinical and pre-clinical study designs and activities, expected timing for initiation, enrollment and completion of clinical trials, research and development activities, ultimate clinical outcomes and benefits of our products to patients, design and development of future studies, site activations, patient enrollment in studies, timing of regulatory filings and approvals, regulatory acceptance of our filings, our expectations with respect to product development and commercialization efforts, market and physician acceptance of our products, intellectual property protection, our ability to integrate acquired businesses, our expectations regarding anticipated synergies with and benefits from acquired businesses, potentially competitive product offerings, the Company's ability to receive an extension from Nasdaq. The risk factors described in our filings with the SEC could cause actual events to adversely differ from the expectations indicated in these forward-looking statements. Management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on forward-looking statements because they speak only as of the date when made. Sunshine Heart does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Sunshine Heart may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including without limitation, the possibility that regulatory authorities do not accept our application or approve the marketing of our therapy, the possibility we may be unable to raise the funds necessary for the development and commercialization of our therapy and other risks and uncertainties described in our filings with the SEC. We do not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

For further information, please contact:

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