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SSH Annual Report

SUNSHINE HEART

Our objective is to improve the quality of life for patients with heart failure and related conditions

Dear Shareholders,

After acquiring the Aquadex FlexFlow® system and product portfolio from Baxter International in August of 2016, we began executing a revenue growth strategy in deliberate stages. In fourth quarter of 2016, we focused on increasing utilization in the top 55 hospital accounts that provided about 80 percent of the revenue stream in 2015. Furthermore, we expanded our efforts to re-engage an additional 110 hospitals that also purchased blood sets in 2015.

By the end of 2016, there were 95 hospital accounts that have re-engaged and are purchasing the disposable blood sets on a regular basis. Through the end of first quarter 2017, a total of 115 active hospitals are ordering disposable product regularly. Our momentum is increasing as we enhance visibility in previously dormant accounts while the Aquadex business was operated under previous ownership.

Looking ahead to 2017 and beyond, the company will focus on four key areas:

- Provide better diagnostic tools that will enable healthcare professionals to improve patient selection
- Generate meaningful economic evidence to support reimbursement and drive utilization
- Expand the utilization of Aquadex in other areas of the hospital
- Expand the use of the Aquadex system in an outpatient setting

In addition to these key focus areas, we are excited about some early initiatives that involve collecting post-market clinical data by partnering with high-profile institutions to accomplish this effort. We will have more to update on this activity later in 2017. We remain confident that the initiatives in place, coupled with increasing the number of sales personnel to enhance national coverage, will provide steady growth to meet company objectives.

John Erb,
Chief Executive Officer and Chairman of the Board
April 10, 2017

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the Fiscal Year Ended: December 31, 2016

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Transition Period from to

Commission file number 001-35312

SUNSHINE HEART, INC.

(Exact name of registrant as specified in its charter)

Delaware	**68-0533453**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

12988 Valley View Road
Eden Prairie, Minnesota 55344
(Address of principal executive offices including zip code)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	The Nasdaq Stock Market LLC (Nasdaq Capital Market)

Securities registered pursuant to Section 12(g) of the Act: **None.**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K ☐

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

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

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

As of June 30, 2016, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of shares of the registrant's common stock held by non-affiliates of the registrant (based upon the June 30, 2016 closing sale price of $13.8 per share) was approximately $8.5 million.

The number of shares of the registrant's common stock, par value $0.0001 per share, outstanding as of March 1, 2017 was 1,741,745 shares.

DOCUMENTS INCORPORATED BY REFERENCE

N/A

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the ***"Securities Act"***), and Section 21E of the Securities Exchange Act of 1934, as amended (the ***"Exchange Act"***). These forward-looking statements relate to us, our business prospects and our results of operations and are subject to certain risks and uncertainties posed by many factors and events that could cause our actual business, prospects and results of operations to differ materially from those anticipated by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those described under the heading "Risk Factors" included in this Annual Report on Form 10-K. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. We undertake no obligation to revise any forward-looking statements in order to reflect events or circumstances that might subsequently arise. Readers are urged to carefully review and consider the various disclosures made by us in this report and in our other reports filed with the U.S. Securities and Exchange Commission (the ***"SEC"***) that advise interested parties of the risks and factors that may affect our business.

PART I

Item 1. Business

Overview

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

Company History

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

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

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

The Aquadex FlexFlow System

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

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

Benefits of the Aquadex FlexFlow

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

[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.

- 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 system consists of:

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

Our Market Opportunity

Heart failure is one of the leading causes of death in the United States and other developed countries. The American Heart Association estimates that 5.7 million people in the United States age 20 and over are affected by heart failure, with an estimated 870,000 new cases diagnosed each year and 670,000 emergency department visits. Congestive heart failure is the highest U.S. chronic health care expense category. [5]

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

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

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

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[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.
[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.
[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.

Medicare reimbursement. The Aquadex FlexFlow is positioned to assist hospitals with the Affordable Care Act and may offer hospitals an economic benefit for using the device on a regular basis for in-patient or out-patient usage.

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

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

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

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

Our Strategy

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

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

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

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 exceptional performance for our customers and patients.
- Alignment with Market Dynamics — Utilize existing and new data to demonstrate to hospital administrators that Aquadex FlexFlow can be a solution for 30-day readmissions and challenges with length of stay. Therefore, every Aquadex FlexFlow usage is economically advantageous driving increased demand.
- Reimbursement Opportunity — Work to build acceptance through clinical evidence and a registry to gain reimbursement coding for Aquapheresis therapy.

Sales and Marketing

As of March 1, 2017, we had 8 full-time employees in sales and marketing. During 2016, we trained our existing field personnel and hired additional sales personnel with prior experience with the Aquadex Business. Our sales force includes therapy development managers as well as field clinical engineers who provide training, technical and other support services to our customers. Since the acquisition of the Aquadex Business from Baxter in August 2016, our direct sales force has focused on reengaging hospital accounts that ordered Aquadex Blood Sets in prior years, re-educating customers on the therapy and diagnosing each hospital's use of the Aquadex FlexFlow to gain additional opportunity for increased utilization. We plan to grow the sales and marketing organization as necessary to support future growth.

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

Clinical Experience

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

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

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

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

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

Research and Development

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

Manufacturers and Suppliers

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

Intellectual Property

We have established an intellectual property portfolio through which we seek to protect our system and technology. As of December 31. 2017, our portfolio consisted of over 35 patents issued and 13 patents pending in the United States and abroad for our counterpulsation, technology. In addition, our portfolio includes over 50 exclusively and non-exclusively licensed patents with respect to ultrafiltration and the Aquadex system. Finally, Sunshine Heart has two patents pending in the neuromodulation space. Our patents and patent applications cover various aspects of both the methodology as well as the design of our discontinued C-Pulse System device and related components, our discontinued neuromodulation technology, and the Aquadex FlexFlow.

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

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

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

Competition

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

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

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

Third-Party Reimbursement

In the United States, the Aquadex FlexFlow is purchased primarily by customers, such as hospitals or other health care providers. Customers bill various third-party payers for covered Aquadex FlexFlow services provided to patients. These payers, which include federal health care programs (e.g., Medicare and Medicaid), state health care programs, private health insurance companies and

managed care organizations, would then reimburse our customers based on established payment formulas that take into account part or all of the cost associated with these devices and the related procedures performed.

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

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

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

Government Regulations

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

United States

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

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

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

510(k) Clearance. To obtain 510(k) clearance for a medical device, an applicant must submit a premarket notification to the FDA demonstrating that the device is "substantially equivalent" to a predicate device legally marketed in the United States. A device is substantially equivalent if, with respect to the predicate device, it has the same intended use and has either (i) the same technological characteristics or (ii) different technological characteristics and the information submitted demonstrates that the device is as safe and effective as a legally marketed device and does not raise different questions of safety or effectiveness. A showing of substantial

equivalence sometimes, but not always, requires clinical data. Generally, the 510(k) clearance process can exceed 90 days and may extend to a year or more.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Employees

As of March 1, 2017, we had 29 full-time employees and no part-time employees. None of our employees are covered by a collective bargaining agreement. We consider relations with our employees to be good.

Corporate Information

Sunshine Heart, Inc. was incorporated in Delaware on August 22, 2002. We began operating our business in November 1999 through Sunshine Heart Company Pty Limited, which currently is a wholly owned Australian subsidiary of Sunshine Heart, Inc. In September of 2004, Chess Depositary Instruments or CDIs representing beneficial ownership of our common stock began trading on the Australian Securities Exchange or ASX under the symbol "SHC." Initially, each CDI represented one share of our common stock. In connection with the 1-for-200 reverse stock split we affected on January 27, 2012, we changed this ratio so that each CDI represented 1/200th of a share of our common stock. Our common stock began trading on the Nasdaq Capital Market on February 16, 2012. We delisted from the ASX at the close of trading on May 6, 2013.

Our principal executive offices are located at 12988 Valley View Road, Eden Prairie, Minnesota 55344, and our telephone number is (952) 345-4200. Our website address is www.sunshineheart.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-

Q and, going forward, Current Reports on Form 8-K and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Exchange Act will be made available free of charge on our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The information on, or that may be accessed through, our website is not incorporated by reference into and should not be considered a part of this Annual Report on Form 10-K

Until December 31, 2017, we qualify as an "emerging growth company" as defined in the Jumpstart our Business Startups Act of 2012 or the JOBS Act. Furthermore, we are and will remain a "smaller reporting company" as long as our public float remains less than $75 million as of the last business day of our most recently-completed second fiscal quarter. An emerging growth company or smaller reporting company may take advantage of specified reduced reporting and other requirements that are otherwise applicable generally to U.S. public companies. These provisions include an exemption from the attestation requirement in the assessment of our internal control over financial reporting by our independent auditors pursuant to section 404 (b) of the Sarbanes-Oxley Act of 2002 ("SOX") but do not preclude us from the requirement to make our own internal assessment of the effectiveness of our internal controls over financial reporting. Furthermore, as an emerging growth company, we 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. Until such date as we no longer qualify as an emerging growth company, our financial statements may not be comparable to those of companies that comply with new or revised accounting standards for U.S. public companies.

We have elected to take advantage of the benefits of this extended transition period, which will end on December 31, 2017. Until such date, 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.

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 requested a hearing before the Nasdaq Hearings Panel (the ***"Panel"***), which occurred on November 10, 2016. On November 11, 2016, we received notice from the Staff that we no longer satisfied Nasdaq Listing Rule 5550(b) insofar as we did not expect to report stockholders' equity of at least $2.5 million upon the filing of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2016 and that the deficiency could serve as an additional basis for the delisting of the Company's common stock from The Nasdaq Capital Market. On November 21, 2016, Nasdaq informed us that the Panel had granted us continued listing on The Nasdaq Capital Market while we implement our plan to regain compliance with the minimum bid price and minimum stockholders' equity requirements. The Panel granted us until January 30, 2017 to evidence a closing bid price of $1.00 or more for a minimum of ten prior consecutive trading days. At a special meeting of our stockholders on January 9, 2017, our stockholders approved, among other things, a reverse stock split, and following such special meeting, our Board of Directors approved a 1-for-30 reverse split of our issued and outstanding shares of common stock. The reverse stock split was effective as of 5:00 p.m. Eastern Time on January 12, 2017, and our common stock began trading on a split-adjusted basis on The Nasdaq Capital Market on January 13, 2017. The reverse stock split did not change the par value of our stock or the authorized number of common or preferred shares. All share and per share amounts in this Annual Report on Form 10-K for the year ended December 31, 2016, including the financial statements and notes thereto included in Item 8 hereof, have been retroactively adjusted to reflect the reverse stock split for all periods presented.

After implementing the reverse stock split, we received confirmation from Nasdaq on February 9, 2017 that we have regained compliance with the minimum bid price rule. The Panel granted us until March 20, 2017 to evidence compliance with the $2.5 million stockholder's equity requirement. If it appears to the Nasdaq staff that we will not be able to meet the minimum stockholders' equity or any other listing standard, our common stock may be subject to delisting.

Item 1A. Risk Factors.

Our business faces many risks. We believe the risks described below are the material risks we face. However, the risks described below may not be the only risks we face. Additional unknown risks or risks that we currently consider immaterial may also impair our business operations. If any of the events or circumstances described below actually occurs, our business, financial condition or results of operations could suffer, and the trading price of our shares of common stock could decline significantly. Investors should consider the specific risk factors discussed below, together with the "Cautionary Note Regarding Forward-Looking Statements" and the other information contained in this Annual Report on Form 10-K and the other documents that we will file from time to time with the SEC.

Risks Related to Our Business

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

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

We have incurred operating losses since our inception and anticipate that we will continue to incur operating losses in the near-term. The report of our independent registered public accounting firm issued in connection with its audit of our financial statements for the fiscal year ended December 31, 2016 expresses substantial doubt about our ability to continue as a going concern. We 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 $15.8 million and $26.6 million for the years ended December 31, 2016, and 2015, respectively. As of December 31, 2016, our accumulated deficit was $169.0 million.

The report of our independent registered public accounting firm issued in connection with its audit of our financial statements for the fiscal year ended December 31, 2016 expresses substantial doubt about our ability to continue as a going concern. Prior to August 2016, we did not have any products approved for commercialization, generated only limited revenue from our clinical studies and had significant operating losses as we incurred costs associated with the conduct of clinical studies and our research and development programs for our C-Pulse System. We became a revenue generating company only a few months ago after acquiring the Aquadex Business in August 2016. We expect to incur additional losses in the near-term as we grow the Aquadex Business, including investments in expanding our sales and marketing capabilities, purchasing inventory, manufacturing components, and complying with the requirements related to being a U.S. public company listed on NASDAQ. To become and remain profitable, we must succeed in expanding the adoption and market acceptance of the Aquadex FlexFlow. This will require us to succeed in a range of challenging activities, including training personnel at hospitals and effectively and efficiently manufacturing, marketing and distributing the Aquadex FlexFlow and related components. There can be no assurance that we will succeed in these activities, and we may never generate revenues sufficient to achieve profitability. If we do achieve profitability, we may not be able to sustain it.

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

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

Our near-term prospects are highly dependent on the development of a single product, the Aquadex FlexFlow, and we have no other commercial products or products in active development at this time. The established market or customer base for our Aquadex FlexFlow is limited and our success depends on our ability to increase adoption of the Aquadex FlexFlow. Acceptance of our product in the marketplace by health care providers is uncertain, and our failure to achieve sufficient market acceptance will significantly limit our ability to generate revenue and be profitable. Market acceptance will require substantial marketing efforts and the expenditure of significant funds by us to inform health care providers of the benefits of using the Aquadex FlexFlow and to provide further training on its use. We may not be able to build key relationships with health care providers to drive further sales in the United States or sell the Aquadex FlexFlow outside the United States. Product orders may be cancelled, patients or customers currently using our products may cease to do so and patients or customers expected to begin using our products may not. Our ability to achieve acceptance of our Aquadex FlexFlow depends on our ability to demonstrate the safety, efficacy, ease-of-use and cost-effectiveness of the system. We may not be able to expand the adoption and market acceptance of the Aquadex FlexFlow to both the inpatient and outpatient markets and our potential sales and revenues could be harmed.

We will need to raise additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations.

We expect to seek additional financing during 2017. Changing circumstances may cause us to consume capital significantly faster than we currently anticipate and could adversely affect our ability to raise additional capital. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. If adequate funds are not available to us on a timely basis or at all, we would likely be required to significantly reduce our operations.

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

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

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

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

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

Our strategy requires us to provide a significant amount of customer service and maintenance and other technical service to our customers. To provide these services, we have begun, and will need to continue, to develop a network of distribution and a staff of employees and independent contractors in each of the areas in which we intend to operate. We cannot assure that we will be able to

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

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

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

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

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

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

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

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

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

our ability to market our Aquadex FlexFlow. Moreover, changes that result in our failure to comply with the requirements of applicable laws and regulations could result in the types of enforcement actions by the U.S. Food and Drug Administration (the "FDA") and/or other agencies as described above, all of which could impair our ability to have manufactured and to sell the affected products.

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

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

The Patient Protection and Affordable Care Act of 2010, as modified by the Health Care and Education Reconciliation Act of 2010 (collectively, the "Health Reform Laws"), provides those states that expand their Medicaid coverage to otherwise eligible state residents with incomes at or below 138% of the federal poverty level with an increased federal medical assistance percentage, effective January 1, 2014, when certain conditions are met. On June 28, 2012, the United States Supreme Court upheld the individual mandate of the Health Reform Laws but partially invalidated the expansion of Medicaid. The ruling on Medicaid expansion allows states to elect not to participate in the expansion-and to forego funding for the Medicaid expansion-without losing their existing Medicaid funding. States will be expected to pay for part of costs of Medicaid expansion beginning in 2017. In light of the current political environmental and the possibility that proposed legislation may significantly impact Medicaid funding to states, it is unclear how states will pay their share of these additional Medicaid costs and providers would be able to continue to receive reimbursement for services to all patients receiving treatment using the Aquadex FlexFlow who are currently enrolled in Medicaid.

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

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

Product defects, including lawsuits for product liability, could harm our business, results of operations and financial condition.

The design, manufacture and marketing of medical devices involve certain inherent risks. Manufacturing or design defects, unanticipated use of a product or inadequate disclosure of risks relating to the use of the product can lead to injury or other adverse events. These events could lead to recalls or safety alerts relating to a product (either voluntary or required by the FDA or similar governmental authorities in other countries), and could result, in certain cases, in the removal of a product from the market. Any recall of our Aquadex FlexFlow or any related components could result in significant costs, as well as negative publicity and damage to our reputation that could reduce demand for our products. Additionally, the C-Pulse system treats Class III and ambulatory Class IV heart failure for patients who typically have serious medical issues. As a result, our exposure to product liability claims may be heightened because the people who use this system have a high risk of suffering adverse outcomes, regardless of the safety or efficacy of our system. In addition, because this system was implanted in a limited number of patients, we cannot assure you that we are currently aware of all material risks related to use of our system or that could lead to product liability claims against us. Personal injuries relating to the use of our products could also result in product liability claims being brought against us. In some circumstances, such adverse events could also cause delays in new product approvals.

We may be held liable if any product we develop or commercialize causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or consumer use. The safety studies we must perform and the regulatory approvals required to commercialize our products will not protect us from any such liability. We carry product liability insurance with a $5 million aggregate limit. However, if there are product liability claims against us, our insurance may be insufficient to cover the expense of defending against such claims, or may be insufficient to pay or settle such claims. Furthermore, we may be unable to obtain adequate product liability insurance coverage for commercial sales of any approved product. If such insurance is insufficient to protect us, our business, results of operations and financial condition will be harmed. If any product liability claim is made against us, our reputation and future sales will be damaged, even if we have adequate insurance coverage. Even if a product liability claim against us is without merit or if we are not found liable for any damages, a product liability claim could result in decreased interest in our registry studies, decreased demand for our system, if approved for commercialization, injury to our reputation, diversion of management's attention from operating our business, withdrawal of study participants, significant costs of related litigation, loss of revenue or the inability to commercialize our products.

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

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

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

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

To market our products in the European Community, the United States and other countries, where approved, manufacturers of such products must continue to comply or ensure compliance with the relevant manufacturing requirements. Although we cannot control the manufacturers of our products, if we choose to subcontract manufacturing to a contract manufacturer, we may need to expend time, resources and effort in product manufacturing and quality control to assist with their continued compliance with these requirements. If violations of applicable requirements are noted during periodic inspections of the manufacturing facilities of our manufacturers or we fail to address issues raised by the FDA in these inspections, then we may not be able to continue to market the products manufactured in such facilities and our revenues may be materially adversely affected.

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

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

If we violate the FDC Act or other regulatory requirements at any time during or after the product development and/or approval process, we could be subject to enforcement actions by the FDA or other agencies, including: fines, injunctions, civil penalties, recalls

or seizures of products, total or partial suspension of the production of our products, withdrawal of any existing approvals or pre-market clearances of our products, refusal to approve or clear new applications or notices relating to our products, recommendations that we not be allowed to enter into government contracts and criminal prosecution. Any of the above could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

The Patient Protection and Affordable Care Act, as amended, (the "Affordable Care Act") as well as other healthcare reform, including possible repeal of the Affordable Care Act, may have a significant impact on our business. The impact of the Affordable Care Act on the health care industry is extensive and includes, among other things, the federal government assuming a larger role in the health care system, expanding healthcare coverage of United States citizens and mandating basic healthcare benefits. The Affordable Care Act contains many provisions designed to generate the revenues necessary to fund the coverage expansions and to reduce costs of Medicare and Medicaid, including imposing a 2.3% excise tax on domestic sales of many medical devices by manufacturers that began in 2013. Although a moratorium was placed on the medical device excise tax in 2016 and 2017, if it is reinstated, it may adversely affect our sales and the cost of goods sold.

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

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

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

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

Our operations are directly, or indirectly through customers, subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the Stark Law and federal False Claims Act. These laws may impact, among other things, our sales, marketing and education programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and, despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The physician self-referral laws, commonly referred to as the Stark law is a strict liability statute that generally prohibits physicians from referring Medicare patients to providers of "designated health services," with whom the physician or the physician's immediate family member has an ownership interest or compensation arrangement, unless an applicable exception applies. Moreover, many states have adopted or are considering adopting similar laws, some of which extend beyond the scope of the Stark law to prohibit the payment or receipt of remuneration for the prohibited referral of patients for designated healthcare services and physician self-referrals, regardless of the source of the payment for the patient's care. If it is determined that any of the relationships we may have with physicians violate the Stark law or similar statutes, we could become subject to civil and criminal penalties. The imposition of any such penalties could harm our business.

The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, commonly known as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing qui tam actions has increased significantly in recent years, causing greater numbers of medical device, pharmaceutical and healthcare companies to have to defend a False Claim Act action. When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Various states have also enacted laws modeled after the federal False Claims Act.

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

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

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

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

Risks Related to Our Intellectual Property

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

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

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

Our pending and future patent applications may not issue as patents or, if issued, may not issue in a form that will provide us any competitive advantage. Even if issued, existing or future patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of terms of patent protection we may have for our system. Changes in patent laws or their interpretation in the United States and other countries could also diminish the value of our intellectual property or narrow the scope of our patent protection. In addition, the legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. In order to preserve and enforce our patent and other intellectual property rights, we may need to make claims or file lawsuits against third parties. This can entail significant costs to us and divert our management's attention from our business.

Intellectual property litigation could be costly and disruptive to us.

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

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

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

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

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

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

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

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

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

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

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

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

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

financial information, provide information about our products and other patient and physician education and outreach efforts through our website, manage the administrative aspects of our business, and damage our reputation, any of which could adversely affect our business.

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

Risks Related to Our Common Stock

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

On September 21, 2016, we received notice from the Staff of Nasdaq indicating that the Staff had determined to delist our securities from The Nasdaq Capital Market due to our then continued non-compliance with the minimum bid price requirement. We timely requested a hearing before the Panel, which occurred on November 10, 2016. On November 11, 2016, we received notice from the Staff that we no longer satisfied Nasdaq Listing Rule 5550(b) insofar as we did not expect to report stockholders' equity of at least $2.5 million upon the filing of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2016 and that the deficiency could serve as an additional basis for the delisting of the Company's common stock from The Nasdaq Capital Market. On November 21, 2016, Nasdaq informed us that the Panel had granted us continued listing on The Nasdaq Capital Market while we implement our plan to regain compliance with the minimum bid price and minimum stockholders' equity requirements. The Panel granted us until January 30, 2017 to evidence a closing bid price of $1.00 or more for a minimum of ten prior consecutive trading days and until March 20, 2017 to evidence compliance with the $2.5 million stockholder's equity requirement. On December 9, 2016, we provided notice of our intention to call a special meeting of our stockholders on January 9, 2017 to, among other things, obtain stockholder approval for a reverse stock split. At a special meeting of our stockholders on January 9, 2017, our stockholders approved, among other things, a reverse stock split, and following such special meeting, our Board of Directors approved a 1-for-30 reverse split of the Company's issued and outstanding shares of common stock. The reverse stock split became effective as of 5:00 p.m. Eastern Time on January 12, 2017, and the Company's common stock began trading on a split-adjusted basis on The Nasdaq Capital Market on January 13, 2017. We received confirmation from Nasdaq on February 9, 2017 that we have regained compliance with the minimum bid price rule.

Despite our efforts, we cannot assure you that we will be able to meet the minimum stockholders' equity or other listing requirements. If it appears to the Nasdaq staff that we will not meet the minimum stockholders' equity or any other listing standard, our common stock may be subject to delisting. If our common stock is delisted, our common stock would likely trade only in the over-the-counter market. If our common stock were to trade on the over-the-counter market, selling our common stock could be more difficult because smaller quantities of shares would likely be bought and sold and transactions could be delayed, and we could face significant material adverse consequences, including:

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

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

In addition to the foregoing, if our common stock is delisted from NASDAQ and it trades on the over-the-counter market, the application of the "penny stock" rules could adversely affect the market price of our common stock and increase the transaction costs to sell those shares. The SEC has adopted regulations which generally define a "penny stock" as an equity security that has a market price of less than $5.00 per share, subject to specific exemptions. The closing price of our common stock on March 1, 2017 was $4.33. If our common stock is delisted from NASDAQ and it trades on the over-the-counter market at a price of less than $5.00 per share, our

common stock would be considered a penny stock. The SEC's penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document that provides information about penny stocks and the risks in the penny stock market. The broker-dealer must also provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and the salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. In addition, the penny stock rules generally require that before a transaction in a penny stock occurs, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's agreement to the transaction. If applicable in the future, these rules may restrict the ability of brokers-dealers to sell our common stock and may affect the ability of investors to sell their shares, until our common stock no longer is considered a penny stock.

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

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

The number of shares of common stock underlying our outstanding preferred stock and outstanding warrants is significant in relation to our currently outstanding common stock and could cause downward pressure on the market price for our common stock and conversion of such outstanding convertible securities will cause dilution to holders of our common stock.

The number of shares of common stock issuable upon conversion of our outstanding preferred stock and exercise of outstanding warrants is significant in relation to the number of shares of our common stock currently outstanding. If any security holder, including the Selling Stockholders, determines to sell a substantial number of shares into the market at any given time, there may not be sufficient demand in the market to purchase the shares without a decline in the market price for our common stock. Moreover, continuous sales into the market of a number of shares in excess of the typical trading volume for our common stock, or even the availability of such a large number of shares, could depress the trading market for our common stock over an extended period of time. Through March 1, 2017, shares of our Series C Convertible Preferred Stock have been converted into 501,000 shares of our common stock. As of March 1, 2017, 344.9 shares of our Series C Convertible Preferred Stock remain outstanding and are currently convertible into 67,627 shares of our common stock, and 900 shares of our Series D Convertible Preferred Stock remain outstanding and are convertible into 200,759 shares of our common stock. If the effective price per share in a future offering is lower than the then price of conversion of the Series C Convertible Preferred Stock or the Series D Convertible Preferred Stock, then the price of conversion of such preferred stock shall be reduced to equal to such lower price and such preferred stock shall be issuable for additional shares of common stock in connection with such conversion price reduction. Furthermore, each holder of our Series C Convertible Preferred Stock has the right to exchange all or some of the Series C Preferred Stock for securities issued in a future offering on a $1.00 for $1.00 basis based on the outstanding stated value of the Series C Convertible Preferred Stock, along with any accrued but unpaid liquidated damages and other amounts owing thereon, and the effective price in the offering. With respect to our Series D Convertible Preferred Stock, on or after May 3, 2017, the conversion price on our Series D Convertible Preferred Stock shall become an adjustable rate equal to 80% of the average of the daily volume weighted average price of our common stock for the ten trading days immediately prior to the conversion date, but shall not be reduced below $1.26. To the extent the outstanding shares of Series C Convertible Preferred Stock or Series D Convertible Preferred Stock become exercisable for additional shares of common stock, holders of our common stock will experience further dilution.

As of March 1, 2017, we have warrants to purchase 926,884 shares of common stock outstanding. Pursuant to a letter agreement dated February 15, 2017 with the holders of our Series C Convertible Preferred Stock and Series D Convertible Preferred Stock (the ***"Holders")***, who also hold certain outstanding warrants (the ***"Warrants"***), we agreed in consideration for the Holders exercising Warrants during the period beginning on February 15, 2017 to and including March 31, 2017 (the "***Exercise Period"***), that we would issue, promptly upon receipt of the cash exercise price, a common stock purchase warrant to the Holders (the ***"New Warrants"***) pursuant to Section 4(a)(2) of the Securities Act, to purchase up to a number of shares of our common stock equal to 100% of the number of shares issued pursuant to such Holder's exercise of Warrants under the letter agreement, which New Warrants shall have a term of five years from the date of issuance and an exercise price equal to consolidated closing bid price of our common stock as quoted on The Nasdaq Capital Market on the date each New Warrant is issued. The letter agreement also (i) amends the definition of "Beneficial Ownership Limitation" in the Warrants to mean, solely for purposes of any exercises of such Warrants that occurs during the Exercise Period, "9.99%" and (ii) amends the initial exercise date of the Warrants issued on November 3, 2016 and January 11, 2017 so that such Warrants are exercisable on or after the receipt of stockholder approval of such Warrants. Since such stockholder

approval was received on January 9, 2017, such Warrants became immediately exercisable on the date of the letter agreement. On February 15, 2017, following the execution of the letter agreement, the Holders exercised Warrants to purchase shares of our common stock so that, after such exercise, such holders owned, in the aggregate, 9.9% of our common stock. We received gross proceeds of $563,863 in connection with such exercise and issued the Holders New Warrants to purchase an aggregate of 104,419 shares of our common stock with a per share exercise price of $4.99. To the extent additional Warrants are exercised during the Exercise Period and we issue additional New Warrants, holders of our common stock will be further diluted and sales of any shares of common stock underlying such Warrants or the New Warrants could cause downward pressure on the market price for our common stock.

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

Our board of directors has authority, without further stockholder approval, to issue additional shares of preferred stock with such rights, preferences and privileges as our board may determine. These rights, preferences and privileges may include dividend rights, conversion rights, voting rights and liquidation rights that may be greater than the rights of our common stock.

Our board of directors has approved, pursuant to this authority, the issuance of preferred stock, and we have 344.9 shares of Series C Convertible Preferred Stock and 900 shares of Series D Convertible Preferred Stock outstanding as of March 1, 2017. The rights, preferences and privileges of our Series C Convertible Preferred Stock and Series D Convertible Preferred Stock are described in our Current Report on Form 8-K filed with the SEC on October 31, 2016. As described therein, upon liquidation, dissolution or winding-up of the Company, holders of our Series C Convertible Preferred Stock and Series D Convertible Preferred Stock have the right to receive, out of the assets, whether capital or surplus, of the Company, (i) for the Series C Convertible Preferred Stock, an amount equal to the par value, plus any accrued and unpaid dividends thereon, and (ii) for the Series D Convertible Preferred Stock, an amount equal to the stated value, plus any accrued and unpaid dividends thereon and any other fees or liquidated damages then due and owing thereon, in each case, for each such share of preferred stock held by such holder before any distribution or payment shall be made to the holders of our common stock, and, following such payment, such holders are entitled to receive the same amount that a holder of common stock would receive if such preferred stock was fully converted, pari passu with all the holders of common stock. Our board of directors may issue additional series of preferred stock in the future pursuant to this authority. As a result, the rights of holders of our capital stock will be subject to, and could be adversely affected by, the rights of holders of any stock that may be issued in the future.

We have a large number of authorized but unissued shares of stock, which could negatively impact a potential investor if they purchased our common stock.

We effected 1-for-30 reverse split of our issued and outstanding shares of common stock as of 5:00 p.m. Eastern Time on January 12, 2017, and our common stock began trading on a split-adjusted basis on The Nasdaq Capital Market on January 13, 2017.
Because the number of authorized shares of our common stock was not reduced proportionately, the reverse stock split increased our board of directors' ability to issue authorized and unissued shares without further stockholder action. As of March 1, 2017, our certificate of incorporation provides for 100,000,000 shares of authorized common stock and 40,000,000 shares of authorized preferred stock. As of March 1, 2017, we had 1,741,745 shares of common stock outstanding and 90,651 shares of common stock reserved pursuant to outstanding convertible preferred stock, warrants, options or restricted stock units or under the Company's equity incentive plans.
With respect to authorized but unissued and unreserved shares, we could also use such shares to oppose a hostile takeover attempt or delay or prevent changes in control or changes in or removal of management. The issuance of additional shares of common stock or securities convertible into common stock may have a dilutive effect on earnings per share and relative voting power and may cause a decline in the trading price of our common stock. We could use the shares that are available for future issuance in dilutive equity financing transactions, or to oppose a hostile takeover attempt or delay or prevent changes in control or changes in or removal of management, including transactions that are favored by a majority of the stockholders or in which the stockholders might otherwise receive a premium for their shares over then-current market prices or benefit in some other manner.

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

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

- future announcements concerning us, including our clinical and product development strategy, or our competitors;
- regulatory developments, disclosure regarding completed, ongoing or future clinical studies and enforcement actions bearing on advertising, marketing or sales;
- reports and recommendations of analysts and whether or not we meet the milestones and metrics set forth in such reports;

- introduction of new products;
- acquisition or loss of significant manufacturers, distributors or suppliers or an inability to obtain sufficient quantities of materials needed to manufacture our system;
- quarterly variations in operating results, which we have experienced in the past and expect to experience in the future;
- business acquisitions or divestitures;
- changes in governmental or third-party reimbursement practices;
- fluctuations of investor interest in the medical device sector; and
- fluctuations in the economy, world political events or general market conditions.

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

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

As of December 31, 2016, we had U.S. net operating loss ("NOL") carryforwards of approximately $110.6 million for U.S. income tax purposes, which expire from 2024 through 2034. To the extent these NOL carryforwards are available, we intend to use them to reduce any corporate income tax liability associated with our operations that we might have in the future. Section 382 of the U.S. Internal Revenue Code of 1986, as amended, generally imposes an annual limitation on the amount of NOL carryforwards that might be used to offset taxable income when a corporation has undergone significant changes in stock ownership. As a result, prior or future changes in ownership, including due to this offering, could put limitations on the availability of our NOL carryforwards. In addition, our ability to utilize the current NOL carryforwards might be further limited by future issuances of our common stock.

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

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

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

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

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

In connection with the effectiveness of our registration statement on Form 10, as of February 14, 2012, we became subject to the periodic reporting requirements of the Exchange Act. Although we were previously listed on the Australian Securities Exchange and had been required to file financial information and make certain other filings with the Australian Securities Exchange, our status as a U.S. reporting company under the Exchange Act has caused us, and will continue to cause us, to incur additional legal, accounting and other expenses that we did not previously incur, including costs related to compliance with the requirements of SOX and the listing requirements of The Nasdaq Capital Market. We expect these rules and regulations will continue to increase our legal and financial compliance costs and make some activities more time-consuming and costly, and these activities may increase general and administrative expenses and divert management's time and attention away from revenue-generating activities. Furthermore, now that we are a revenue-generating company following the acquisition of the Aquadex Business in August 2016, our costs to comply with regulations applicable to U.S. reporting companies may further increase. We also expect these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers.

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

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

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

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

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

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

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

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

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the external auditor attestation requirements of Section 404

of SOX, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. The JOBS Act also permits emerging growth companies to take advantage of an extended transition period to comply with new or revised accounting standards applicable to U.S. public companies. We will be an emerging growth company until December 31, 2017. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline or be more volatile.

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

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

We lease a 23,000 square foot facility located in Eden Prairie, Minnesota. The lease period commenced December 1, 2011 and extends through March 31, 2019. This facility serves as our corporate headquarters and houses substantially all of our functional areas. Monthly rent and common area maintenance charges for our headquarters total approximately $23,000. The lease contains provisions for annual inflationary adjustments.

We believe that our current facilities are suitable and adequate to meet our current needs, and that suitable additional or substitute space will be available as needed to accommodate expansion of our operations.

Item 3. Legal Proceedings.

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

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information. Commencing February 16, 2012, our shares of common stock began trading on NASDAQ under the symbol "SSH." See "Risk Factors—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" under Part I, Item 1A of this Annual Report on Form 10-K.

The following table sets forth, for the periods indicated, the high and low closing prices for our common stock as reported on NASDAQ in U.S. Dollars. Effective January 13, 2017, we effected a 1-for-30 reverse split of our issued and outstanding shares of common stock. All share and per share amounts presented below have been retroactively adjusted to reflect the reverse stock split for all periods presented.

	High	Low
2015		
First Quarter	$207.0207	$114.0114
Second Quarter	$148.8149	$96.6097
Third Quarter	$107.0777	$59.706
Fourth Quarter	$81.9082	$31.8032
2016		
First Quarter	$41.4041	$16.8017
Second Quarter	$29.2139	$12.0012
Third Quarter	$48.6049	$13.2013
Fourth Quarter	$28.8029	$4.5005
2017		
First Quarter (through March 1, 2017	$12.0012	$4.25

Stockholders of Record. As of March 1, 2017, we had 1,741,745 shares of common stock issued and outstanding, and there were 226 holders of record of our common stock.

Dividends. We have not historically paid cash dividends on our capital stock. We intend to retain our future earnings, if any, to finance the expansion and growth of our business, and we do not expect to pay cash dividends on our common stock in the foreseeable future. Payment of future cash dividends, if any, will be at the sole discretion of our board of directors after taking into account various factors, including our financial condition, earnings, capital requirements of our operating subsidiaries, covenants associated with any debt obligations, legal requirements, regulatory constraints and other factors deemed relevant by our board of directors. Moreover, if we determine to pay any dividends in the future, there can be no assurance that we will continue to pay such dividends.

Item 6. Selected Financial Data.

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read together with our audited financial statements and related notes which are included elsewhere in this Annual Report on Form 10-K. Our actual results could differ materially from those anticipated in the forward-looking statements included in this discussion as a result of certain factors, including, but not limited to, those discussed in "Risk Factors" included elsewhere in this Annual Report on Form 10-K.

Overview

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

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

In August 2016, we acquired the Aquadex Business from a subsidiary of Baxter International, Inc. (***"Baxter"***), a global leader in the hospital products and dialysis markets.

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

Recent Developments

Nasdaq Compliance
On September 21, 2016, we received notice from the Listing Qualifications Staff (the ***"Staff")*** of The Nasdaq Stock Market LLC ***("Nasdaq")*** indicating that the Staff had determined to delist our securities from The Nasdaq Capital Market due to our then continued non-compliance with the minimum bid price requirement. We timely requested a hearing before the Nasdaq Hearings Panel (the ***"Panel"),*** which occurred on November 10, 2016. On November 11, 2016, we received notice from the Staff that we no longer satisfied Nasdaq Listing Rule 5550(b) insofar as we did not expect to report stockholders' equity of at least $2.5 million upon the filing of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2016 and that the deficiency could serve as an additional basis for the delisting of the Company's common stock from The Nasdaq Capital Market. On November 21, 2016, Nasdaq informed us that the Panel had granted us continued listing on The Nasdaq Capital Market while we implement our plan to regain compliance with the minimum bid price and minimum stockholders' equity requirements. The Panel granted us until January 30, 2017 to evidence a closing bid price of $1.00 or more for a minimum of ten prior consecutive trading days. After implementing the reverse stock split described below, we received confirmation from Nasdaq on February 9, 2017 that we have regained compliance with the minimum bid price rule. The Panel granted us until March 20, 2017 to evidence compliance with the $2.5 million stockholder's equity requirement. If it appears to the Nasdaq staff that we will not be able to meet the minimum stockholders' equity or any other listing standard, our common stock may be subject to delisting.

Reverse Stock Split
At a special meeting of our stockholders on January 9, 2017, our stockholders approved, among other things, a reverse stock split, and following such special meeting, our Board of Directors approved a 1-for-30 reverse split of our issued and outstanding shares of common stock. The reverse stock split was effective as of 5:00 p.m. Eastern Time on January 12, 2017, and our common stock began trading on a split-adjusted basis on The Nasdaq Capital Market on January 13, 2017. The reverse stock split did not change the par value of our stock or the authorized number of common or preferred shares. All share and per share amounts in this Annual Report on Form 10-K for the year ended December 31, 2016, including the financial statements and notes thereto included in Item 8 hereof, have been retroactively adjusted to reflect the reverse stock split for all periods presented.

Warrant Exercise Agreement
On February 15, 2017, we entered into a letter agreement with the institutional investors ("the Investors") that hold the majority of our outstanding warrants, to incent the cash exercise of these warrants on or before March 31, 2017 (the "Exercise Period"). These warrants, if exercised in full, would yield gross proceeds of approximately $4.65 million to the Company. In exchange for any such exercise, we agreed to provide the Investors a replacement warrant (the "Replacement Warrants") to purchase the same number of shares of common stock as were issued upon exercise of the exercised warrants, with an exercise price equal to the consolidated closing bid price of our common stock on the date of issuance. The agreement also (i) amends the definition of "Beneficial Ownership Limitation" in the existing warrants to mean, solely for purposes of any exercises of warrants that occur during the Exercise Period, "9.99%" and (ii) amends the Initial Exercise Date of the existing warrants issued on November 3, 2016 and January 11, 2017 so that such warrants are exercisable on or after the receipt of stockholder approval. Since such stockholder approval was received on January 9, 2017, such warrants were immediately exercisable as of the date of the agreement. The Replacement Warrants will be in the same form as the exercised warrants except the exercise price will not be subject to reduction for subsequent equity and (ii) the Replacement Warrants will not allow the Investor to demand that we purchase the Replacement Warrants in the event of a fundamental transaction involving the Company. Concurrent with the signing of the agreement, the Investors exercised warrants to purchase 104,419 shares of common stock for cash proceeds of approximately $564,000, and we issued such Investors Replacement Warrants to purchase 104,419 shares of common stock.

Critical Accounting Policies and Estimates

We have adopted various accounting policies to prepare the condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States. (U.S. GAAP). The preparation of the condensed consolidated financial statements, in conformity with U.S. GAAP, requires us to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Our estimates and assumptions, including those related to stock-based compensation, valuation of equity and debt securities, and income tax reserves are updated as appropriate, which in most cases is quarterly. We base our estimates on historical experience, valuations, or various assumptions that are believed to be reasonable under the circumstances.

Revenue Recognition
We recognize revenue from product sales when earned. Specifically, revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the price is fixed or determinable, and collectability is reasonably assured. Revenue is not recognized until title and risk of loss have transferred to the customer. The shipping terms for our revenue arrangements are FOB shipping point.

Accounts Receivable
Our accounts receivable have terms that require payment in 30 days. We did not establish an allowance for doubtful accounts at December 31, 2016 as we have not experienced any write offs or a deterioration in the aging of our receivables to date and do not expect to experience in the future.

Inventories
Inventories represent primarily finished goods purchased from our supplier and are recorded as the lower of cost or market using the first-in-first out method.

Intangible assets
Our intangible assets as of December 31, 2016 consist of $3.1 million for customer relationships, $1.1 million for developed technology, and $0.4 million for trademarks and tradenames. All intangible assets are estimated to have a useful life of 5-7 years. We review our definite-lived intangible assets for impairment when impairment indicators exist. When impairment indicators exist, we determine if the carrying value of the intangible assets exceeds the related undiscounted cash flows. In cases where the carrying value exceeds the undiscounted cash flows, the carrying value is written down to its fair value, generally using a discounted cash flow analysis. No impairments have been identified or recorded in the periods presented.

Goodwill
Goodwill is the cost of an acquisition in excess of the fair value of acquired assets and liabilities and is recorded as an asset on our balance sheet. Goodwill is not subject to amortization but must be tested for impairment at least annually. This test requires us to assign goodwill to an appropriate reporting unit and to determine if the implied fair value of the reporting unit's goodwill is less than its carrying amount.

We evaluate goodwill for impairment annually on November 1st of each calendar year, or to the extent events or conditions indicate a risk of possible impairment during the interim periods prior to our annual impairment test. Generally, the evaluation of goodwill for impairment involves a two-step test, although under certain circumstance an initial qualitative evaluation may be sufficient to conclude that goodwill is not impaired without conducting the quantitative test.

Step 1 involves comparing the estimated fair value of each respective reporting unit to its carrying value, including goodwill. If the estimated fair value exceeds the carrying value, the reporting unit's goodwill is not considered impaired. If the carrying value exceeds the estimated fair value, step 2 must be performed to determine whether goodwill is impaired and, if so, the amount of the impairment. Step 2 involves calculating an implied fair value of goodwill by performing a hypothetical allocation of the estimated fair value of the reporting unit determined in step 1 to the respective tangible and intangible net assets of the reporting unit. The remaining implied goodwill is then compared to the actual carrying amount of the goodwill for the reporting unit. To the extent the carrying amount of goodwill exceeds the implied goodwill, the difference is the amount of the goodwill impairment. No impairments have been identified or recorded in the periods presented.

Contingent consideration
In connection with our purchase of the Aquadex Business, we have an obligation to pay additional consideration that is contingent upon the occurrence of certain future events. Contingent consideration is recognized at the acquisition date at the estimated fair value of the contingent milestone payments. The fair value of the contingent consideration is remeasured to its estimated fair value at the end of each reporting period, with changes recorded to earnings.

Common stock warrant liability
We record common stock warrant liability at fair value at the date of issuance using primarily a Monte Carlo valuation model. The fair value is remeasured to its estimated fair value at the end of each reporting period with changes recorded to earnings.

Stock-Based Compensation
We recognize all share-based payments to employees and directors, including grants of stock options, restricted stock units (RSUs), warrants and common stock awards in the income statement as an operating expense based on their fair values over the requisite service period.

We compute the estimated fair values of stock options and warrants using the Black-Scholes option pricing model. Market price at the date of grant is used to calculate the fair value of restricted stock units and common stock awards.

Stock-based compensation expense is based on awards ultimately expected to vest and is reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Equity instruments issued to non-employees include RSUs, warrants or options to purchase shares of our common stock. These RSUs, warrants or options are either fully-vested and exercisable at the date of grant or vest over a certain period during which services are provided. We expense the fair market value of fully vested awards at the time of grant, and of unvested awards over the period in which the related services are received. Unvested awards are remeasured to fair value until they vest.

Earnings per share
We compute basic earnings per share based on the net loss allocable to common stockholders for each period divided by the weighted average number of common shares outstanding. The net loss allocable to common stockholders reflects an increase for net deemed dividends of $1.9 million to preferred shareholders provided in connection with the 2016 Series B and B-1 convertible preferred stock offering. Diluted earnings per share is computed based on the net loss allocable to common stockholders for each period divided by the weighted average number of common shares outstanding, increased by the number of additional shares that would have been outstanding had the potentially dilutive common shares been issued, and reduced by the number of shares the Company could have repurchased from the proceeds from issuance of the potentially dilutive shares. Potentially dilutive shares of common stock include warrants, stock options and other stock-based awards granted under stock-based compensation plans. These potentially dilutive shares were excluded from the computation of loss per share as their effect was antidilutive due to our net loss in each of those periods.

Going Concern
Our financial statements have been prepared and presented on a basis assuming we continue as a going concern. During the years ended December 31, 2016 and 2015, we incurred losses from operations and net cash outflows from operating activities as disclosed in the consolidated statements of operations and cash flows, respectively.

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. 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 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.

We expect to require additional funding to grow our Aquadex Business in 2017, 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. Our directors, after due consideration, believe that we will be able to raise new capital as required to fund our business plan. Should future capital raising be unsuccessful, we may not be able to continue as a going concern. Furthermore, our ability to continue as a going concern is subject to our ability to develop and successfully commercialize the product being developed. If we are unable to obtain such funding of an amount and timing necessary to meet our future operational plans, or to successfully commercialize our intellectual property, we may be unable to continue as a going concern. No adjustments have been made relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should we not continue as a going concern.

Accounting Standards Applicable to Emerging Growth Companies
We qualify as an “emerging growth company” pursuant to the provisions of the JOBS Act, enacted on April 5, 2012. Section 102(b)(1) of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. An emerging growth company can delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended

transition period, and as a result of this election, our financial statements may not be comparable to those of companies that comply with public company effective dates for new or revised accounting standards for U.S. public companies.

Internal Controls and Procedures

Our independent registered public accounting firm is not yet required to formally attest to the effectiveness of our internal control over financial reporting, and will not be required to do so for as long as we are an "emerging growth company" pursuant to the provisions of the JOBS Act. However, management is subject to Section 404(a) of the Sarbanes-Oxley Act of 2002 and is required to report annually on effectiveness of our internal control over financial reporting.

Recent Accounting Pronouncements

In April 2015, the Financial Accounting Standards Board (FASB) issued amended guidance concerning debt issuance costs in relation to a recognized debt liability to require it be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This guidance was effective for the Company's interim and annual reporting periods beginning January 1, 2016. In connection with the adoption of this standard, we reclassified $120,000 of debt issuance costs that were previously reported as current assets and other assets on the December 31, 2015 balance sheet, to an offset to current and long-term debt.

In May 2014, August 2015, March 2016, April 2016 and May 2016, the FASB issued amended revenue recognition guidance to clarify the principles for recognizing revenue from contracts with customers. The guidance requires an entity to recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which an entity expects to be entitled in exchange for those goods or services. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. The standard allows the Company to transition to the new model using either a full or modified retrospective approach, and early adoption is not permitted. This guidance will be effective for the Company's interim and annual periods beginning January 1, 2018. We are currently evaluating the impact that this standard will have on our business practices, financial condition, results of operations and disclosures.

In August 2014, the FASB amended guidance relating to the presentation and disclosure of the uncertainties of an entity's ability to continue as a going concern. This guidance explicitly requires management of a company to evaluate whether there is substantial doubt about a company's ability to continue as a going concern and to provide related footnote disclosure in certain circumstances. This guidance was effective for our annual reporting period ending on December 31, 2016, and annual and interim periods thereafter. The adoption of this standard did not have a material impact on our going concern evaluations or disclosures.

In November 2015, the FASB issued amended guidance concerning the classification of deferred taxes on the balance sheet to require that deferred tax assets and deferred tax liabilities be presented as noncurrent in a classified balance sheet. The amendment is effective for our annual and interim reporting periods beginning January 1, 2017, with early adoption permitted. The adoption of this standard will not have an impact on our consolidated financial statements as all deferred tax assets are fully reserved.

In February 2016, the FASB issued updated guidance to improve financial reporting about leasing transactions. This guidance will require organizations that lease assets to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. This guidance is effective for the Company's annual reporting period beginning January 1, 2020, and for interim periods beginning January 1, 2021. We are evaluating the impact that the adoption of this standard will have, if any, on our financial statements and disclosures.

Financial Overview

Until August 2016, our activities had consisted principally of raising capital, performing research and development and conducting pre-clinical and clinical studies. In August 2016, we acquired our commercial product line, the Aquadex FlexFlow, and transitioned our activities to commercializing the Aquadex FlexFlow. At December 31, 2016, we had an accumulated deficit of $169.0 million and we expect to incur losses for the near future while we continue to ramp up sales of the Aquadex Business. To date, we have been funded primarily by various equity and debt financings. Although we believe that we will be able to successfully fund our operations, there can be no assurance that we will be able to do so or that we will ever operate profitably.

Results of Operations

Net Sales
(dollars in thousands)

Year Ended December 31, 2016	Year Ended December 31, 2015	Increase (Decrease)	% Change
$ 1,289	$ 59	$ 1,230	N/A%

On August 5, 2016, we completed the acquisition of the Aquadex Business from Baxter. The Aquadex Business generated revenues of $1.23 million from the date of acquisition through December 31, 2016. Revenue is generated mainly from the sale of disposable blood filters and catheters used in conjunction with our Aquadex consoles. We estimate that there are over 500 installed Aquadex consoles around the United States. We had no commercial sales prior to the acquisition of the Aquadex Business.

On March 3, 2016, we announced that we were no longer enrolling patients in our two clinical studies for our now discontinued C-Pulse System. Prior to this announcement, all of our revenue was generated by sales of the C-Pulse System to hospitals and clinics in conjunction with our U.S. clinical study. The C-Pulse System was not approved for commercial sale, however, the FDA had assigned the C-Pulse System to a Category B designation, making it eligible for reimbursement at certain U.S. sites when implanted in connection with our clinical studies. During the year ended December 31, 2016, we received reimbursement and recognized revenue of $59,000 for one implant that was performed before the announcement that we were no longer enrolling patients in the study. Since we terminated enrollment in these clinical studies, we do not expect to generate revenue from our clinical studies in the foreseeable future.

On September 29, 2016, we announced a strategic refocus of our near term strategy to fully focus the Company's resources on our recently acquired Aquadex Business. As such, we expect our Aquadex revenue to grow in the upcoming quarters as we drive increased utilization of disposable sales within our installed base.

Costs and Expenses
Our costs and expenses were as follows:

(dollars in thousands)	Year Ended December 31, 2016	Year Ended December 31, 2015	Increase (Decrease)	% Change
Cost of goods sold	$ 713	$ -	$ 713	N/A
Selling, general and administrative	$ 8,129	$ 8,345	$ (216)	(2.6)%
Research and development	$ 8,109	$ 17,672	$ (9,563)	(54.1)%

Cost of Goods Sold
In connection with the acquisition of the Aquadex Business, we entered into a manufacturing and supply agreement with Baxter. Cost of sales reflects the agreed-upon price paid to Baxter for the manufacturing of the disposables and consoles. This acquisition closed on August 5, 2016. Prior to that date, we did not have commercial sales or related product costs.

Selling, General and Administrative
The changes in selling, general and administrative expense reflect primarily the impact of our transition from a research and development stage company to a commercially focused organization. As a result, we incurred $1.1 million of incremental expenses related to the commercialization of the Aquadex FlexFlow, which we acquired from Baxter in August of 2016. In addition, during the year, we incurred $0.9 million in transaction fees (accounting, audit, valuation and legal fees) in connection with the acquisition of the Aquadex Business. These increases were offset by efficiencies achieved as a result of ongoing consolidation and streamlining activities in our administrative functions, and by lower stock-based compensation costs.
As we continue to ramp up our sales organization we expect that our commercial expenses will continue to increase in future quarters, and that general and administrative expenses will continue to decrease.

Research and Development
The decrease in research and development expense resulted primarily from our decision to stop enrollment in our two clinical studies for our now discontinued C-Pulse System, which was announced on March 3, 2016. In July 2016, we announced that we were moving forward with a therapeutic strategy utilizing neuromodulation rather than counterpulsation. Further, on September 29, 2016, we announced a strategic refocus of our near term strategy that includes halting clinical evaluations of the neuromodulation technology to fully focus the Company's resources on our recently acquired Aquadex system. As a result, we expect that our research and development expenditures will continue to decrease in future quarters.

Other Income (Expense)
The following is a summary of other income (expense)

(dollars in thousands)	Year Ended December 31, 2016	Year Ended December 31, 2015	Increase (Decrease)	% Change
Interest expense	$ (504)	$ (743)	$ (239)	(32.2)%
Loss on early retirement of long term debt	(500)	-	500	N/A
Change in fair value of warrant liability	818	-	646	N/A

Interest Expense
We incurred interest expense in connection with our prior debt facility with Silicon Valley Bank. On August 4, 2016, we repaid all amounts outstanding under this loan facility, totaling $5.5 million.

Loss on early retirement of debt
On August 4, 2016, we repaid all amounts outstanding under our prior term loan with Silicon Valley Bank, totaling $5.5 million. In connection with the repayment of this debt, we incurred a $0.5 million loss, including the accelerated write-off of unamortized warrants and debt issuance costs.

Change in fair value of warrant liability
In connection with financings completed on July 26, 2016 and November 3, 2016, we issued warrants that are classified as liabilities on our balance sheet as of December 31, 2016. These warrants must be marked to market at each reporting period, with the changes in fair value recorded on our statement of operations. As of December 31, 2016 these warrants had experienced a net decrease in value of $818,000 since their issuance in July and November of 2016. There were no warrants outstanding that were classified as liabilities and required to be measured at fair value during the year ended December 31, 2015.

Income tax benefit, net

(dollars in thousands)	Year Ended December 31, 2016	Year Ended December 31, 2015	Increase (Decrease)	% Change
Income tax benefit, net	$ 54	$ 124	$ (70)	(56.5)%

Our income tax benefit for the year ended December 31, 2016 and 2015 resulted mainly from research and development tax credits in Australia. We have substantially reduced research and development expenditures in Australia, so future research and development tax credits refunds, if any, are expected to decrease. We have not recognized any income tax benefit in our statement of operations related to our U.S. operating losses, as all tax benefits are fully reserved.

We generate minimal amounts of income tax expense in connection with activities incurred by our Irish subsidiary.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations primarily through cash on hand and a series of equity and debt issuances.

On July 26, 2016, pursuant to a Securities Purchase Agreement dated July 20, 2016, we completed an equity financing with an institutional investor of shares of Series B Convertible Preferred Stock and warrants for gross cash proceeds of approximately $3.5 million in a registered direct offering and simultaneous private placement. Also, on October 30, 2016, we entered into securities purchase agreement with an institutional investor for shares of Series C Convertible Preferred Stock, Series D Convertible Preferred Stock and warrants with an aggregate purchase price of $3.8 million in a registered direct offering and simultaneous private placement. The first closing occurred on November 3, 2016, whereby we received $3.6 million in gross proceeds and issued and sold shares of Series C Convertible Preferred Stock, shares of Series D Convertible Preferred Stock and warrants. At the second closing, which was subject to receipt of shareholder approval of the transactions, we received $0.2 million in gross proceeds and issued and sold shares of Series D Convertible Preferred Stock and warrants. Also on October 30, 2017, we entered into a securities exchange agreement with the holders of our Series B Convertible Preferred Stock pursuant to which we agreed to issue such holders shares of our Series B-1 Convertible Preferred Stock in exchange for the cancellation of all shares of Series B Convertible Preferred Stock held by such holders in reliance on an exemption from registration provided by Section 3(a)(9) of the Securities Act.

Subsequent to year-end, in February 2017, we entered into an agreement with the holder of the majority of our outstanding warrants to incent their exercise of warrants for cash on or before March 31, 2017 (the “Exercise Period”). If all such warrants are exercised for

cash, we will receive approximately $4.65 million in proceeds from the exercise. In exchange for any such exercise, we agreed to provide the Investors a replacement warrant (the "Replacement Warrants") to purchase the same number of shares of common stock as were issued upon exercise of the exercised warrants, with an exercise price equal to the consolidated closing bid price of our common stock on the date of issuance. The Replacement Warrants will be in the same form as the exercised warrants except the exercise price will not be subject to reduction for subsequent equity and (ii) the Replacement Warrants will not allow the Investor to demand that we purchase the Replacement Warrants in the event of a fundamental transaction involving the Company. Concurrent with the signing of the agreement, the Investors exercised warrants to purchase 104,419 shares of common stock for cash proceeds of approximately $564,000, and we issued such Investors Replacement Warrants to purchase 104,419 shares of common stock

During 2015, we entered into a loan agreement with Silicon Valley Bank for proceeds of up to $10.0 million. On August 4, 2016, we repaid all amounts outstanding under this loan facility, totaling $5.5 million, and entered into a new loan agreement with Silicon Valley Bank for proceeds of up to $5.0 million, including a $1.0 million revolving line of credit and a $4.0 million term loan. The term loan expired unused on November 30, 2016. The revolving line of credit expires on March 31, 2021. We had no borrowings outstanding under the Silicon Valley Bank facility as of December 31, 2016.

In 2014, we entered into a sales agreement with Cowen and Company, LLC (***"Cowen"***), allowing Cowen to sell from time to time, shares of our common stock having an aggregate offering price of up to $40.0 million, through an "at the market" equity offering program (the ***"Sales Agreement"***). We pay Cowen a commission of up to 3.0% of the gross proceeds from the sale of any shares pursuant to the Sales Agreement. In 2015, we sold 41,879 shares of common stock for net proceeds of $7.1 million after stock issuance costs of $0.2 million. There were no issuances of common stock under this facility during 2016. As of March 01, 2017, we had a total of $32.6 million available for future sales under the Sales Agreement.

As of December 31, 2016 and 2015, cash and cash equivalents were $1.3 million and $23.1 million, respectively. Prior to our acquisition of the Aquadex FlexFlow in August 2016, we did not have a product approved for commercial sale and focused our resources on developing, manufacturing and commercializing our C-Pulse System. In September 2016, we announced a strategic refocus of our near-term strategy that includes halting all clinical evaluations to fully focus our resources on our recently acquired Aquadex Business, taking actions to reduce our cash burn in connection with such strategic refocus and reviewing potential strategic alliances and financing alternatives. Our business strategy and ability to fund our operations in the future 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. We believe that our cash on hand and proceeds from the warrant exercises will fund our operations until mid-2017, and expect to seek additional financing during 2017.

The sale of additional equity, debt, or convertible debt securities and the conversion or exercise of our outstanding convertible securities may result in dilution to our stockholders. If we raise additional funds through the issuance of debt, convertible debt or enter into credit facilities, these securities and debt holders could have rights senior to those of our common stock, and this debt could contain covenants that would restrict our operations and would require us to use cash for debt service rather than our operations. We may require additional capital beyond our currently forecasted amounts. Although we have successfully financed our operations through equity and debt financings to date, any such required additional capital may not be available to us on acceptable terms, or at all.

Cash Flows from Operating Activities

Net cash used in operating activities was $16.3 million and $23.0 million in 2016 and 2015, respectively. The net cash used in each of these periods primarily reflects the net loss for those periods, offset in part by stock-based compensation, depreciation and amortization expense, amortization of debt discount and financing fees, loss on retirement of long-term debt, and the effects of changes in operating assets and liabilities.

Cash Flows from Investing Activities

Net cash used in investing activities was $4.1 million and $0.2 million in 2016 and 2015, respectively. In 2016, we paid $4.0 million for the acquisition of the Aquadex Business. Other uses of cash relate to the purchase of laboratory and office equipment.

Cash Flows from Financing Activities

Net cash (used in) provided by financing activities was $(1.4) million and $15.1 million in 2016 and 2015, respectively. Net cash used during 2016 is attributable to repayments of the principal amounts outstanding on our debt facility with Silicon Valley Bank, offset by net proceeds from the issuance of preferred stock in July and November of 2016. Net cash provided by financing activities in 2015 was attributable to debt borrowings and proceeds from sales of our common stock.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2016, which represent material expected or contractually committed future obligations:

(Dollars in thousands)		Payments Due by Period				
		Less than 1 year	1-3 years	3-5 years	More than 5 years	Total
Operating Leases		$ 207,689	$ 253,415	$ -	$ -	$ 461,104
	Total	$ 207,689	$ 253,415	$ -	$ -	$ 461,104

We lease a 23,000 square foot facility located in Eden Prairie, Minnesota. The lease period commenced December 1, 2011 and extends through March 31, 2019. This facility serves as our corporate headquarters and houses substantially all of our functional areas. Monthly rent and common area maintenance charges for our headquarters total approximately $23,000. The lease contains provisions for annual inflationary adjustments. Rent expense is being recorded on a straight line basis over the term of the lease.

We lease office equipment under non-cancelable operating leases that expire at various times through February 2019.

Capital Resource Requirements

As of December 31, 2015, we did not have any material commitments for capital expenditures.

Off-Balance Sheet Arrangements

In April 2015, we amended our lease agreement for our office space leased in Eden Prairie, Minnesota, to extend it for an additional thirty-six months beyond its original expiration date. This amended lease agreement expires March 31, 2019.

On August 5, 2016, we entered into an asset purchase agreement for the Aquadex Business with Baxter, whereby we agreed that if we dispose of any of the acquired assets for a price that exceeds $4.0 million within three years of the closing, we will pay Baxter 40% of the amount of such excess; and if shares of our common stock cease to be publicly traded on the Nasdaq Capital Market, Baxter has the option to require us to repurchase, in cash, all or any part of the common shares held by Baxter at a price equal to their fair market value, as determined by a third-party appraiser.

In connection with the acquisition of the Aquadex Business, we entered into a manufacturing and supply agreement with Baxter that will expire within a period not to exceed 18 months from the close of the transaction. Upon termination of this agreement, we have an obligation to purchase from Baxter the remaining Aquadex inventory. We estimate that this inventory will consist mainly of raw materials priced at cost, and that this amount will not exceed $2.5 million.

Except as disclosed above, we have no off-balance sheet transactions, arrangements, obligations (including contingent obligations), or other relationships with unconsolidated entities or other persons that have, or may have, a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not Applicable

Item 8. Financial Statements and Supplementary Data.

Report of Independent Registered Public Accounting Firm

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders
Sunshine Heart, Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of Sunshine Heart, Inc. and Subsidiaries (the Company) as of December 31, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, shareholders' equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Sunshine Heart, Inc. and Subsidiaries at December 31, 2016 and 2015, and the consolidated results of their operations and their cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 of the consolidated financial statements, the Company has recurring losses from operations and an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not contain any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young LLP
Minneapolis, Minnesota
March 8, 2017

SUNSHINE HEART, INC. AND SUBSIDIARIES
Consolidated Balance Sheets

(In thousands, except share and per share amounts)	December 31, 2016	December 31, 2015
ASSETS		
Current assets		
Cash and cash equivalents	$ 1,323	$ 23,113
Accounts receivable	282	—
Inventory	677	—
Other current assets	137	479
Total current assets	2,419	23,592
Property, plant and equipment, net	540	535
Intangible assets, net	4,302	—
Goodwill	189	—
Other assets	21	323
TOTAL ASSETS	$ 7,471	$ 24,450
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Current portion of long-term debt	$ —	$ 3,798
Accounts payable and accrued expenses	2,351	2,832
Accrued compensation	909	1,368
Total current liabilities	3,260	7,998
Long-term debt, net of discount and financing fees	—	3,881
Common stock warrant liability	1,843	—
Other liabilities	126	400
Total liabilities	5,229	12,279
Commitments and contingencies	—	—
Temporary Stockholders' Equity		
Series D convertible preferred stock as of December 31, 2016 and December 31, 2015, par value $0.0001 per share; authorized 900 and 0 shares, respectively, issued and outstanding 700 and 0, respectively	485	—
Stockholders' equity		
Series A junior participating preferred stock as of December 31, 2016 and December 31, 2015, par value $0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Series B-1 convertible preferred stock as of December 31, 2016 and December 31, 2015, par value $0.0001 per share; authorized 1,824.4 and 0 shares, respectively, issued and outstanding 1,824.4 and 0, respectively	—	—
Series C convertible preferred stock as of December 31, 2016 and December 31, 2015, par value $0.0001 per share; authorized 2,900 and 0 shares, respectively, issued and outstanding 2,900 and 0, respectively	—	—
Preferred stock as of December 31, 2016 and December 31, 2015, par value $0.0001 per share; authorized 39,964,375.6 and 39,970,000 shares, respectively, none outstanding	—	—
Common stock as of December 31, 2016 and December 31, 2015, par value $0.0001 per share; authorized 100,000,000 shares, issued and outstanding 777,238 and 611,483, respectively	—	—
Additional paid-in capital	169,496	164,107
Accumulated other comprehensive income:		
Foreign currency translation adjustment	1,235	1,246
Accumulated deficit	(168,974)	(153,182)
Total stockholders' equity	1,757	12,171
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 7,471	$ 24,450

See notes to the consolidated financial statements

SUNSHINE HEART, INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except per share amounts)

	Year Ended December 31,	
	2016	**2015**
Net sales	**$** 1,289	$ 59
Costs and Expenses:		
Cost of goods sold	713	—
Selling, general and administrative	8,129	8,345
Research and development	8,109	17,672
Total costs and expenses	16,951	26,017
Loss from operations	(15,662)	(25,958)
Other income (expense):		
Interest expense	(504)	(743)
Loss on early retirement of long-term debt	(500)	—
Other income (expense), net	2	(6)
Change in fair value of warrant liability	818	—
Total other income (expense)	(184)	(749)
Loss before income taxes	(15,846)	(26,707)
Income tax benefit, net	54	124
Net loss	$ (15,792)	$ (26,583)
Basic and diluted loss per share	$ (27.06)	$ (44.01)
Weighted average shares outstanding – basic and diluted	654	604
Other comprehensive income:		
Foreign currency translation adjustments	$ (11)	$ (26)
Total comprehensive loss	$ (15,803)	$ (26,609)

See notes to the consolidated financial statements

SUNSHINE HEART, INC. AND SUBSIDIARIES

Consolidated Statements of Stockholders' Equity
(In thousands, except share amounts)

In thousands	Outstanding Shares	Common Stock	Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Equity
Balance December 31, 2014	**566,088**	**$ —**	**$ 154,542**	**$ 1,272**	**$ (126,599)**	**$ 29,215**
Net loss	—	—	—	—	(26,583)	(26,583)
Foreign currency translation adjustment	—	—	—	(26)	—	(26)
Stock based compensation, net	3,516	—	2,510	—	—	2,510
Issuance of common stock, net	41,879	—	7,055	—	—	7,055
Balance December 31, 2015	**611,483**	**$ —**	**$ 164,107**	**$ 1,246**	**$ (153,182)**	**$ 12,171**
Net loss	—	—	—	—	(15,792)	(15,792)
Foreign currency translation adjustment	—	—	—	(11)	—	(11)
Stock based compensation, net	9,448	—	949	—	—	949
Issuance of preferred stock, net	—	—	4,440	—	—	4,440
Issuance of common stock for acquisition	33,334	—	—	—	—	—
Conversion of preferred stock into common stock	122,973	—	—	—	—	—
Balance December 31, 2016	**777,238**	**$ —**	**$ 169, 496**	**$ 1,235**	**$ (168,974)**	**$ 1,757**

See notes to the consolidated financial statements

SUNSHINE HEART, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows
(In thousands)

In thousands	For the years ended December 31, 2016	2015
Operating Activities		
Net loss	$ (15,792)	$ (26,583)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	697	325
Stock based compensation expense, net	949	2,154
Amortization of debt discount and financing fees	187	263
Loss on retirement of long-term debt	500	—
Change in fair value of warrant liability	(818)	—
Changes in assets and liabilities:		
Accounts receivable	(282)	59
Inventory	(677)	—
Other current assets	342	(181)
Other assets and liabilities	(464)	(92)
Accounts payable and accrued expenses	(934)	1,066
Net cash used in operations	(16,292)	(22,989)
Investing activities:		
Purchase of property and equipment	(117)	(199)
Purchase of Aquadex product line	(4,000)	—
Net cash used in investing activities	(4,117)	(199)
Financing activities:		
Net proceeds from the sale of preferred stock, common stock and warrants	6,636	7,055
Proceeds from borrowings on long-term debt	—	8,000
Repayments of long-term debt	(8,000)	—
Net cash provided by (used in) financing activities	(1,364)	15,055
Effect of exchange rate changes on cash	(17)	(47)
Net decrease in cash and cash equivalents	(21,790)	(8,180)
Cash and cash equivalents—beginning of period	23,113	31,293
Cash and cash equivalents—end of period	$ 1,323	$ 23,113
Supplemental schedule of non-cash activities		
Warrants issued in connection with debt financing	$ —	$ 355
Financing fees on debt	$ —	$ 400
Common stock issued for business acquisition	$ 950	$ —
Supplemental cash flow information		
Interest paid on debt borrowings	$ 840	$ 388
Cash paid for income taxes	$ 47	$ —

See notes to the consolidated financial statements

SUNSHINE HEART, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

Note 1—Nature of Business and Significant Accounting Policies

Nature of Business

Sunshine Heart, Inc. (the "Company") is an early-stage medical device company focused commercializing the Aquadex FlexFlow® System. The Company's commercial product, the Aquadex FlexFlow System (Aquadex) 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. Sunshine Heart is a Delaware corporation headquartered in Minneapolis with wholly owned subsidiaries in Australia. Ireland and Delaware. The Company has been listed on the NASDAQ Capital Market since February 2012.

Prior to July 2016, the Company was focused on developing the C-Pulse® Heart Assist System for treatment of Class III and ambulatory Class IV heart failure. The C-Pulse System utilized the known concept of counterpulsation applied to the aorta. In March 2016, the Company announced that it was no longer enrolling patients into its two clinical studies for the C-Pulse System and that it planned to pursue a new strategic direction. In July 2016, the Company announced that it was moving forward with a therapeutic strategy utilizing neuromodulation rather than counterpulsation. In August 2016, the Company acquired the Aquadex business from a subsidiary of Baxter International, Inc. ("Baxter"), a global leader in the hospital products and dialysis markets. On September 29, 2016, the Company announced a strategic refocus of its near-term strategy that included halting clinical evaluations of its neuromodulation technology to fully focus its resources on its recently acquired Aquadex business, taking actions to reduce its cash burn in connection with such strategic refocus, and reviewing potential strategic alliances and financing alternatives.

The Company's board of directors and stockholders approved a 1-for-30 reverse split of the Company's outstanding common stock that became effective after trading on January 12, 2017. The reverse stock split did not change the par value of the Company's stock or the number of common or preferred shares authorized by the Company's Fourth Amended and Restated Certificate of Incorporation, as amended. All share and per share amounts have been retroactively adjusted to reflect the split for all periods presented.

Going Concern

The Company's financial statements have been prepared and presented on a basis assuming it continues as a going concern. During the years ended December 31, 2016 and 2015, the Company incurred losses from operations and net cash outflows from operating activities as disclosed in the consolidated statements of operations and cash flows, respectively. At December 31, 2016, the Company had an accumulated deficit of $169.0 million and it expects to incur losses for the foreseeable future. To date, the Company has been funded by debt and equity financings, and although the Company believes that it will be able to successfully fund its operations, there can be no assurance that it will be able to do so or that it will ever operate profitably.

The Company became a revenue generating company after acquiring the Aquadex Business in August 2016. The Company expects to incur additional losses in the near-term as it grows the Aquadex Business, including investments in expanding its sales and marketing capabilities, purchasing inventory, manufacturing components, and complying with the requirements related to being a U.S. public company. To become and remain profitable, the Company must succeed in expanding the adoption and market acceptance of the Aquadex FlexFlow. This will require the Company to succeed in training personnel at hospitals and effectively and efficiently manufacturing, marketing and distributing the Aquadex FlexFlow and related components. There can be no assurance that the Company will succeed in these activities, and it may never generate revenues sufficient to achieve profitability.

The Company expects to require additional funding to grow its Aquadex Business in 2017, which may not be available on terms favorable to the Company, or at all. The Company's ability to continue as a going concern is dependent on the Company's ability to raise additional capital based on the achievement of commercial milestones. Should future capital raising be unsuccessful, the Company may not be able to continue as a going concern. Furthermore, the ability of the Company to continue as a going concern is subject to the ability of the Company to successfully commercialize its Aquadex products. If the Company is unable to obtain such funding of an amount and timing necessary to meet its future operational plans, or to successfully commercialize its products, the Company may be unable to continue as a going concern. No adjustments have been made relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company not continue as a going concern.

Basis of Presentation

The accompanying consolidated financial statements include the accounts of Sunshine Heart, Inc. and its wholly owned subsidiaries, Sunshine Heart Company Pty Limited and Sunshine Heart Ireland Limited. All inter-company accounts and transactions between consolidated entities have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts and disclosures in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and term deposits with original maturities of three months or less. The carrying value of these instruments approximate fair value. The balances, at times, may exceed federally insured limits. The Company has not experienced any losses on its cash and cash equivalents.

Accounts Receivable

Accounts receivable are unsecured, are recorded at net realizable value, and do not bear interest. The Company makes judgments as to its ability to collect outstanding receivables based upon significant patterns of uncollectability, historical experience, and managements' evaluation of specific accounts and will provide an allowance for credit losses when collection becomes doubtful. The Company performs credit evaluations of its customers' financial condition on an as-needed basis. Payment is generally due 30 days from the invoice date and accounts past 30 days are individually analyzed for collectability. When all collection efforts have been exhausted, the account is written off against the related allowance. To date the Company has not experienced any write-offs or significant deterioration of its accounts receivable aging, and therefore, no allowance for doubtful accounts was considered necessary as of December 31, 2016 or 2015.

Inventories

Inventories primarily represent finished goods purchased from the Company's supplier and are recorded as the lower of cost or market using the first-in-first out method.

Other Current Assets

Other current assets represent prepayments and deposits made by the Company.

Property, Plant and Equipment

Property and equipment is stated at cost less accumulated depreciation. Depreciation is computed based upon the estimated useful lives of the respective assets. Leasehold improvements and capital lease assets are amortized using the straight-line method over the shorter of the lease term or the estimated useful life of the assets. Repairs and maintenance costs are expensed as incurred. The cost and accumulated depreciation of property, plant and equipment retired, or otherwise disposed of are removed from the related accounts, and any residual values are charged to expense. Depreciation expense has been calculated using the following estimated useful lives:

Office furniture and equipment	5-15 years
Computer software and equipment	3-4 years
Laboratory and research equipment	3-15 years
Production equipment	3-7 years
Leasehold improvements and capital lease asset	3-5 years

Depreciation expense and amortization of the capital lease asset was $419,000, and $325,000 for the years ended December 31, 2016, and 2015, respectively.

Property and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. If the impairment tests indicate that the carrying value of the asset, or asset group is greater than the expected undiscounted cash flows to be generated by such asset or asset group further analysis is performed to determine the fair value of the asset or asset group. To the extent the fair value of the asset or asset group is less than its carrying

value, an impairment loss is recognized equal to the amount the fair value of the asset or asset group exceeds its carrying amount. The Company generally measures fair value by considering sale prices for similar assets or asset groups, or by discounting estimated future cash flows from such assets or asset groups using an appropriate discount rate. Assets to be disposed of are carried at the lower of their carrying value or fair value less costs to sell. Considerable management judgment is necessary to estimate the fair value of assets or asset groups, and accordingly, actual results could vary significantly from such estimates. There have been no impairment losses recognized for the years ended December 31, 2016 or 2015.

Other Assets

Other assets consisted primarily of deferred financing fees, net of amortization, recorded in connection with the term loan with Silicon Valley Bank. Upon repayment of the term loans, the Company was required to make a final payment to Silicon Valley Bank equal to 5.0% of the original principal amount. As further described in Note 4, this final payment fee was paid to the bank in August 2016 in connection with the repayment of all outstanding borrowings.

Intangible assets

The Company's intangible assets consist of customer relationships, developed technology, and trademarks and tradenames. All intangible assets recognized by the Company result from the acquisition of the Aquadex business. All intangible assets are estimated to have a useful life of 5-7 years. The Company reviews its definite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable through the estimated undiscounted future cash flows derived from such assets. In cases where the carrying value exceeds the undiscounted cash flows, the carrying value is written down to its fair value, using a discounted cash flow analysis. No impairments have been identified or recorded in 2016.

Amortization expense was $278,000 and $0 for the years ended December 31, 2016 and 2015, respectively.

Goodwill

Goodwill is the cost of an acquisition in excess of the fair value of acquired assets and liabilities and is recorded as an asset on the balance sheet. Goodwill is not subject to amortization but must be tested for impairment at least annually. This test requires the Company to determine if the implied fair value of the goodwill is less than its carrying amount.

The Company evaluates goodwill for impairment annually on November 1st of each calendar year, or to the extent events or conditions indicate a risk of possible impairment during the interim periods prior to its annual impairment test. Generally, the evaluation of goodwill for impairment involves a two-step test, although under certain circumstance an initial qualitative evaluation may be sufficient to conclude that goodwill is not impaired without conducting the quantitative test.

Step 1 involves comparing the estimated fair value of each respective reporting unit to its carrying value, including goodwill. The Company has one reporting unit. If the estimated fair value exceeds the carrying value, the reporting unit's goodwill is not considered impaired. If the carrying value exceeds the estimated fair value, step 2 must be performed to determine whether goodwill is impaired and, if so, the amount of the impairment. Step 2 involves calculating an implied fair value of goodwill by performing a hypothetical allocation of the estimated fair value of the reporting unit determined in step 1 to the respective tangible and intangible net assets of the reporting unit. The remaining implied goodwill is then compared to the actual carrying amount of the goodwill for the reporting unit. To the extent the carrying amount of goodwill exceeds the implied goodwill, the difference is the amount of the goodwill impairment. No impairments have been identified or recorded in 2016.

Contingent consideration

In connection with the Company's purchase of the Aquadex Business, the Company has an obligation to pay additional consideration that is contingent upon the occurrence of certain future events. Contingent consideration is recognized at the acquisition date at the estimated fair value of the contingent milestone payments. The fair value of the contingent consideration is remeasured to its estimated fair value at the end of each reporting period, with changes recorded to earnings.

Common stock warrant liability

The Company records its common stock warrant liability at fair value at the date of issuance using primarily a Monte Carlo valuation model. The fair value is remeasured to its estimated fair value at the end of each reporting period with changes recorded to earnings.

Revenue Recognition

The Company recognizes revenues from product sales when earned. Specifically, revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the price is fixed or determinable, and collectability is reasonably assured. Revenue is not recognized until title and risk of loss have transferred to the customer. The shipping terms for the Company's revenue arrangements are FOB shipping point.

Foreign Currency Translation

Sales and expenses denominated in foreign currencies are translated at average exchange rates in effect throughout the year. Assets and liabilities of foreign operations are translated at period-end exchange rates with the impacts of foreign currency translation recognized to cumulative translation adjustment, a component of *accumulated other comprehensive income*. Foreign currency transactions gains and losses are included in *other expense, net* in the consolidated statements of operations and other comprehensive loss.

Stock-Based Compensation

The Company recognizes all share-based payments to employees and directors, including grants of stock options, restricted stock units (RSUs) and common stock awards in the income statement as an operating expense, based on their fair value. The Company's stock awards use a graded vesting schedule. The Company recognizes the option expense over the requisite service period, which is generally the vesting period.

The Company computes the estimated fair values of stock options and certain of its warrants using the Black-Scholes option pricing model. The closing market price of the Company's common stock at the date of grant is used to calculate the fair value of restricted stock units and common stock awards.

Stock-based compensation expense is based on awards ultimately expected to vest and is reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Equity instruments issued to non-employees include RSUs, warrants or options to purchase shares of the Company's common stock. These RSUs, warrants or options are either fully-vested and exercisable at the date of grant or vest over a certain period during which services are provided. The Company expenses the fair market value of fully vested awards at the time of grant, and of unvested awards over the period in which the related services are received. Unvested awards are remeasured to fair value until they vest.

See Note 6 for further information regarding the assumptions used to calculate the fair value of share-based compensation.

Income Taxes

Deferred income taxes are provided on a liability method whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carryforwards. Deferred tax liabilities are recognized for taxable temporary differences, which are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment.

Earnings per share

Basic earnings per share is computed based on the net loss allocable to common stockholders for each period divided by the weighted average number of common shares outstanding. The net loss allocable to common stockholders for 2016 reflects a $1.9 million increase for the net deemed dividend to preferred shareholders provided in connection with the 2016 Series B and B-1 offering (see Note 5). Diluted earnings per share is computed based on the net loss allocable to common stockholders for each period divided by the weighted average number of common shares outstanding, increased by the number of additional shares that would have been outstanding had the potentially dilutive common shares been issued, and reduced by the number of shares the Company could have repurchased from the proceeds from issuance of the potentially dilutive shares. Potentially dilutive shares of common stock include warrants, stock options and other stock-based awards granted under stock-based compensation plans.

The following table sets forth the potential shares of common stock that are not included in the calculation of diluted net loss per share because to do so would be anti-dilutive as of the end of each period presented:

	December 31,	
	2016	2015
Stock options	87,870	66,435
Restricted stock units	10,356	378
Warrants to purchase common stock	885,601	9,930
Series B, C and D convertible preferred stock	1,063,615	—
Total	2,047,442	76,743

Research and Development

Research and development expenses consist primarily of development personnel and non-employee contractor costs incurred in connection with the discontinued C-Pulse System clinical studies, and of enhancement of existing products and services, quality assurance and testing incurred in connection with the recently acquired Aquadex Business.

Recent Accounting Pronouncements

In April 2015, the Financial Accounting Standards Board (FASB) issued amended guidance concerning debt issuance costs in relation to a recognized debt liability to require it be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This guidance is effective for the Company's interim and annual reporting periods beginning January 1, 2016. In connection with the adoption of this standard, the Company reclassified $120,000 of debt issuance costs that were previously reported as current assets and other assets on the December 31, 2015 balance sheet, to an offset to current and long-term debt.

In May 2014, August 2015, March 2016, April 2016 and May 2016, the FASB issued amended revenue recognition guidance to clarify the principles for recognizing revenue from contracts with customers. The guidance requires an entity to recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which an entity expects to be entitled in exchange for those goods or services. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. The standard allows the Company to transition to the new model using either a full or modified retrospective approach, and early adoption is not permitted. This guidance will be effective for the Company's interim and annual periods beginning January 1, 2018. The Company is currently evaluating the impact that this standard will have on its business practices, financial condition, results of operations and disclosures.

In August 2014, the FASB amended guidance relating to the presentation and disclosure of the uncertainties of an entity's ability to continue as a going concern. This guidance explicitly requires management of a company to evaluate whether there is substantial doubt about a company's ability to continue as a going concern and to provide related footnote disclosure in certain circumstances. This guidance was effective for the Company's annual reporting period ending on December 31, 2016, and annual and interim periods thereafter. The adoption of this standard did not have a material impact on the Company's going concern evaluations or disclosures.

In November 2015, the FASB issued amended guidance concerning the classification of deferred taxes on the balance sheet to require that deferred tax assets and deferred tax liabilities be presented as noncurrent in a classified balance sheet. The amendment is effective for our annual and interim reporting periods beginning January 1, 2017, with early adoption permitted. The adoption of this standard will not have an impact on the Company's consolidated financial statements as all deferred tax assets are fully reserved.

In February 2016, the FASB issued updated guidance to improve financial reporting about leasing transactions. This guidance will require organizations that lease assets to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. This guidance is effective for the Company's annual reporting period ending December 31, 2020, and for annual and interim periods thereafter. The Company is evaluating the impact that the adoption of this standard will have, if any, on its financial statements and disclosures.

The Company evaluates events through the date the financial statements are filed for events requiring adjustment to or disclosure in the financial statements.

Note 2 – Aquadex Acquisition

On August 5, 2016, the Company completed the acquisition of certain assets used in the production and sale of the Aquadex product line from Baxter. The acquisition of these assets meets the criteria for the purchase of a business, and has been accounted for in accordance with Accounting Standards Codification (ASC) 805, *Business Combinations*, with identifiable assets acquired and liabilities assumed recorded at their estimated fair values on the acquisition date. A valuation of the assets and liabilities from the business acquisition was performed utilizing cost, income and market approaches resulting in $5.1 million allocated to identifiable net assets.

In connection with the acquisition of the Aquadex Business, the Company entered into a manufacturing and supply agreement with Baxter whereby Baxter will manufacture and supply all of the Company's finished goods for a period of up to 18 months from the close of the transaction. During the year ended December 31, 2016, the Company recorded $1.2 million of revenue from the sale of Aquadex products. The Company completed the acquisition in order to strengthen its presence in the heart failure market.

Purchase Consideration: Total purchase consideration for the Aquadex business is as follows:

(in thousands)		
Cash consideration	$	4,000
Common stock consideration		950
Fair value of contingent consideration		126
Total purchase consideration	$	5,076

- *Common Stock Consideration:* The common stock consideration consisted of 33,334 shares of the Company's common stock, worth $0.95 million based on the closing market value of $0.95 per share on August 5, 2016.

- *Contingent Consideration:* In connection with the acquisition of the Aquadex product line, the Company agreed to pay the Seller 40% of any proceeds in excess of $4.0 million related to the sale or disposal of the Aquadex assets within three years of the close of the transaction. The fair value of this contingent consideration was calculated based on the estimated likelihood of occurrence of this event in the timeframe provided by the agreement.

Purchase price consideration does not include expenses of $0.9 million for accounting, audit, legal, and valuation services that were incurred as part of the transaction and were expensed as incurred as general and administrative expense in the accompanying statement of operations.

The acquisition was recorded by recognizing the assets acquired at their estimated fair value at the acquisition date. The excess of the cost of the acquisition over the fair value of the assets acquired was recorded as goodwill. The fair values were based on management's analysis, including work performed by third-party valuation specialists. The following presents the amounts recognized for the assets acquired on August 5, 2016 (in thousands):

Capital lease asset	$	307
Intangible assets		4,580
Total identifiable assets acquired		4,887
Goodwill		189
Total purchase consideration	$	5,076

The goodwill is primarily attributable to new and/or future customer relationships that were not acquired in the transaction. All recorded goodwill is expected to be deductible for tax purposes. The fair value of the capital lease asset utilized a combination of the cost and market approaches, depending on the characteristics of the asset classification.

Pro Forma Condensed Combined Financial Information (Unaudited)

The following unaudited pro forma combined financial information summarizes the results of operations for the periods indicated as if the acquisition of Aquadex had been completed on of January 1, 2015. Pro forma information reflects adjustments that are expected to have a continuing impact on our results of operations and are directly attributable to the acquisition. The unaudited pro forma results include adjustments to reflect, among other things, direct transaction costs relating to the acquisition, the difference in intangible asset amortization to be incurred based on the preliminary values of each identifiable intangible asset, and the difference in depreciation expense to be incurred based on preliminary value of the capital lease asset. The pro forma amounts do not purport to be indicative of

the results that would have actually been obtained if the acquisition had occurred as of January 1, 2015 or that may be obtained in the future, and do not reflect future synergies, integration costs, or other such costs or savings.

$ in thousands, except per share amounts	Twelve Months Ended December 31,	
	2016	2015
Pro forma net sales	$ 3,160	$ 4,225
Pro forma net loss from operations	(15,340)	(39,836)
Pro forma basic and diluted net loss per share	$ (23.93)	$ (65.95)

Note 3—Property, Plant and Equipment

Property, plant and equipment were as follows:

(Dollars in thousands)	December 31, 2016	December 31, 2015
Office Furniture & Fixtures	$ 280	$ 269
Leasehold Improvements	145	145
Software	124	121
Production Equipment	968	837
Computer Equipment	245	273
Capital Lease Asset	307	—
Total	2,069	1,645
Accumulated Depreciation	(1,529)	(1,110)
	$ 540	$ 535

Note 4—Intangible Assets

Intangible assets were as follows:

(Dollars in thousands)	December 31, 2016	December 31, 2015
Customer Relationships	$ 3,090	$ —
Developed Technology	1,050	—
Trade Names and Trademarks	440	—
Total	4,580	—
Accumulated Depreciation	(278)	—
	$ 4,302	$ —

Future amortization expense for intangible assets is as follows:

(Dollars in thousands)	
Year 1	$ 654
Year 2	654
Year 3	654
Year 4	654
Year 5	654
Thereafter	1,032
	$ 4,302

Note 5—Debt

Prior Loan Agreement: On February 18, 2015, the Company entered into a loan and security agreement with Silicon Valley Bank (the Bank) for proceeds of up to $10.0 million at an annual interest rate of 7.0%. Under this agreement, a $6.0 million term loan was funded at closing and an additional term loan in the amount of $2.0 million was funded on June 26, 2015. The proceeds from the term loans were used for general corporate and working capital purposes. Commencing on January 1, 2016, the Company began repaying the advances made in twenty-four consecutive equal monthly installments.

On August 4, 2016, the Company repaid all amounts outstanding under its existing debt facility of $5.5 million, and incurred a $0.5 million loss on early extinguishment of debt, including the accelerated write-off of unamortized warrants and debt issuance costs. Total borrowings outstanding under this agreement totaled $8.0 million as of December 31, 2015. There were no borrowings outstanding under this facility as of December 31, 2016.

Warrants: In connection with funding of the first term loan for $6.0 million, the Company issued 2,300 warrants at an exercise price of $156.6 per share to the Bank and one of its affiliates. The Company valued these warrants at $115.8 per share utilizing the Black Scholes valuation model and the following assumptions: an expected dividend yield of 0%, an expected stock price volatility of 88.07%, a risk-free interest rate of 1.86%, and an expected life of 6.25 years.

In connection with the funding of the second term loan for $2.0 million, the Company issued 1,087 warrants at an exercise price of $110.40 per share to Silicon Valley Bank and one of its affiliates. The Company valued these warrants at $81.30 per share utilizing the Black Scholes valuation model and the following assumptions: an expected dividend yield of 0%, an expected stock price volatility of 87.04%, a risk-free interest rate of 2.20%, and an expected life of 6.25 years.

All warrants have a life of ten years and were fully vested at the date of grant. The value of these warrants were recorded as debt discount in the accompanying balance sheet and were amortized to interest expense over the term of the debt agreement using the effective interest rate method. As of December 31, 2015, $201,000 of unamortized debt discount was netted against long-term debt in the accompanying condensed consolidated balance sheet. In connection with the repayment of the debt on August 4, 2016, the Company wrote off the remaining unamortized value of the warrants totaling $113,000.

New Loan Agreement: On August 5, 2016, the Company entered into a new loan and security agreement with the Bank (the "New Loan Agreement"). Under the New Loan Agreement, the Bank agreed to provide the Company with up to $5.0 million in debt financing, consisting of a term loan in an aggregate original principal amount not to exceed $4.0 million (the "Term Loan") and a revolving line of credit in an aggregate principal amount not to exceed $1.0 million outstanding at any time (the "Revolving Line"; together with the Term Loan, the "Loans"). Proceeds from the Loans were to be used for general corporate and working capital purposes. Advances under the Term Loan were available to the Company until November 30, 2016 and were subject to the Company's compliance with liquidity covenants. The Term Loan expired unused on November 30, 2016. Advances under the Revolving Line are available to the Company until March 31, 2020 and accrue interest at a floating annual rate equal to 1.75% or 1.0% above the prime rate, depending on liquidity factors. Outstanding borrowings, if any, are collateralized by all of the Company's assets, excluding intellectual property which is subject to a negative pledge. There were no borrowings outstanding under this facility as of December 31, 2016.

Note 6—Shareholder's Equity

Series B/B-1 Convertible Preferred Stock: On July 20, 2016, the Company entered into a securities purchase agreement with an institutional investor for an offering of shares of convertible preferred stock and warrants with gross proceeds of approximately $3.5 million in a registered direct offering. The transaction closed on July 26, 2016, and the Company issued 3,468 shares of Series B Convertible Preferred Stock. The Series B Convertible Preferred Stock is non-voting and was convertible into a total of 122,979 shares of common stock at the holder's election at any time at a conversion price of $28.2 per share. Approximately $1.6 million of the proceeds were allocated to the preferred stock, representing the residual proceeds after the warrants (described below) were recorded at fair value.

On October 30, 2016, the Company entered into an exchange agreement with the holders of its Series B Convertible Preferred Stock and agreed to issue such holders 2,227.2 shares of the Company's Series B-1 Convertible Preferred Stock in exchange for the cancellation of all shares of Series B Convertible Preferred Stock held by such holders. The Series B-1 Convertible Preferred Stock has similar terms as the Series B Convertible Preferred Stock, except that the initial conversion price of the Series B-1 Convertible Preferred Stock is $5.10 per share. Prior to the October 30, 2016 exchange, 1,240.8 of the Series B Convertible Preferred Stock had been converted into 44,000 shares of common stock. As of December 31, 2016, 402.8 shares of the Series B-1 Convertible Preferred Stock had been converted into 78,973 shares of common stock, and 1,824.4 shares of Series B-1 remained outstanding.

The Series B and B-1 convertible preferred stock include a net deemed dividend in the amount of $1.9 million, representing the intrinsic value of the shares at the time of issuance, which is reflected as an increase to the loss per share allocable to common shareholders.

Series C and D Convertible Preferred Stock: Also, on October 30, 2016, the Company entered into securities purchase agreements with an institutional investor for shares of convertible preferred stock and warrants with an aggregate purchase price of $3.8 million in a registered direct offering and simultaneous private placement. The first closing of the transaction occurred on November 3, 2016, whereby the Company received $3.6 million in gross proceeds and issued and sold 2,900 shares of Series C Convertible Preferred

Stock, and 700 shares of Series D Convertible Preferred Stock, both at $5.10 per share. At the second closing, which was subject to the Company receiving shareholder approval of the transactions, the Company expected to issue and sell 200 shares of Series D Convertible Preferred Stock convertible into 39,216 shares of common stock at $5.10 per share and warrants to purchase an additional 39,216 shares of common stock at $5.40 per share for a gross purchase price of $0.2 million. The Series C and D convertible preferred stock includes a contingent beneficial conversion amount of $1.3 million and $0.3 million, respectively, representing the intrinsic value of the shares at the time of issuance. This amount will be reflected as an increase to the loss per share allocable to common shareholders in the first quarter of 2017 when the contingency for the conversion was resolved with the shareholder approval allowing for the conversion of the preferred stock into common stock. As of December 31, 2016, no shares of the Series C or D convertible preferred stock had been converted into common stock, and all remained outstanding.

The Series D Convertible Preferred Stock with a carrying value of $0.5 million is classified as temporary equity in the consolidated balance sheet because the Company cannot control that it will settle its redemption in common stock, but it is not remeasured to fair value each period through earnings because the events that could trigger its redemption are not probable of occurrence.

In connection with these transactions, the Company paid the placement agent an aggregate cash placement fee equal to 6% of the aggregate gross proceeds raised in the offering and issued the warrants described below.

Investor Warrants: In connection with the issuance of the Series B Convertible Preferred Stock in July 2016, the Company issued the investor warrants to purchase 122,979 shares of common stock at an exercise price of $ 28.2 per share at no additional cost. The warrants are exercisable for 36 months commencing six months from the closing date and are subject to a reduction of the exercise price if the Company subsequently issues common stock or equivalents at an effective price less than the current exercise price of such warrants.

Concurrently with the closing of the Series C and D Convertible Preferred Stock and warrant financing on November 3, 2016, the exercise price for these warrants was adjusted to $5.10 per share.

In connection with the issuance of the Series C and D Convertible Preferred Stock in November 2016, the Company issued the investor warrants to purchase 705,884 shares of common stock at an exercise price of $5.40 per share at no additional cost. The warrants are exercisable for 60 months commencing on the day that is the later of the receipt of approval of the Company's stockholders of a proposal to approve the issuance of the shares of common stock underlying the warrants or the six-month anniversary of the date of issuance. The warrants are subject to a reduction of the exercise price if the Company subsequently issues common stock or equivalents at an effective price less than the current exercise price of such warrants.

Placement Agent Warrant: In connection with the issuance of the Series B Convertible Preferred Stock, the Company issued 7,379 warrants to the placement agent to purchase shares of common at an exercise price of $40.50 per share. In connection with the issuance of the Series C and D Convertible Preferred Stock, the Company issued 42,353 warrants to the placement agent to purchase shares of common stock at an exercise price of $6.38 per share. These warrants were issued at no additional cost, were exercisable immediately and expire five years from the closing of the offerings. These warrants do not contain repricing provisions.

Both the investor and placement agent warrants are accounted for as liabilities and were recorded at fair value on the date of issuance. These warrants must be measured and recorded at fair value for each subsequent reporting period that the warrants remain outstanding, and any changes in fair value must be recognized in the statement of operations. The change in fair value of these warrants since their issuance was $0.8 million and was reflected as an unrealized gain in the accompanying statement of operations.

Transaction Costs: The Company incurred approximately $0.9 million of cash and non-cash transaction costs which were allocated to the preferred stock and investor warrants on a relative fair value basis. The $0.6 million allocated to the preferred stock was recorded as a reduction of additional paid-in-capital, while the $0.3 million allocated to the investor warrants was expensed as incurred.

ATM Sales: In March 2014, the Company entered into a sales agreement with Cowen and Company LLC to sell from time to time, in "at the market" offerings, shares of its common stock having an aggregate offering price of up to $40.0 million. There were no issuances of common stock under this facility in the twelve months ended December 31, 2016. During the twelve months ended December 31, 2015, the Company sold 41,879 shares of common stock for net proceeds of $7.1 million after stock issuance costs of $0.2 million. As of December 31, 2016, the Company had a total of $32.6 million available for future sales under the sales agreement.

Note 7— Stock-Based Compensation

Stock Options and Restricted Stock Awards

The Company has various share-based compensation plans, including the Amended and Restated 2002 Stock Plan, the Second Amended and Restated 2011 Equity Incentive Plan, the 2013 Non-Employee Directors' Equity Incentive Plan and the New-Hire Equity Incentive Plan (collectively, the ***"Plans"***). The Plans are designed to assist in attracting, motivating and retaining employees and directors and to recognize the importance of employees to the long-term performance and success of the Company. The Company has also granted stock options to certain non-employees outside of the Plans.

The Company recognized share-based compensation expense related to grants of stock options, RSUs and common stock awards to employees, directors and consultants of $1.0 million, and $2.4 million during the years ended December 31, 2016 and 2015, respectively. The following table summarizes the stock-based compensation expense which was recognized in the consolidated statements of operations for the years ended December 31,

(Dollars in thousands)	2016	2015
Selling, general and administrative	$ 630	$ 1,612
Research and development	385	825
Total	$ 1,015	$ 2,437

The majority of the RSUs and options to purchase common stock vest on the anniversary of the date of grant, which ranges from one to four years. Share-based compensation expense related to these awards is recognized on a straight-line basis over the related vesting term in most cases, which generally is the service period. It is the Company's policy to issue new shares upon the exercise of options.

Stock Options: The following is a summary of the Plans' stock option activity during the years ended December 31:

	2016		2015	
	Options Outstanding	Weighted Average Exercise Price	Options Outstanding	Weighted Average Exercise Price
Beginning Balance	66,382	$ 184.45	72,273	$ 194.36
Granted	45,413	27.17	9,176	117.05
Exercised	—	—	—	—
Forfeited/expired	(23,925)	139.18	(15,067)	192.21
Outstanding at December 31	87,870	$ 115.41	66,382	$ 184.45
Vested at December 31	43,280	$ 189.74	41,505	$ 202.54

For options outstanding and vested at December 31, 2016, the weighted average remaining contractual life was 7.58 years and 7.38 years, respectively. There were no option exercises in 2016 or 2015. The total fair value of options that vested in 2016 and 2015 was $1.1 million, and $1.9 million, respectively, at the fair value of the options as of the date of grant.

Valuation Assumptions: The fair value of each stock option is estimated at the grant date using the Black-Scholes option pricing model. The fair value of stock options under the Black-Scholes model requires management to make assumptions regarding projected employee stock option exercise behaviors, risk-free interest rates, volatility of the Company's stock price, and expected dividends.

The Company has not historically paid cash dividends to its stockholders, and currently does not anticipate paying any cash dividends in the foreseeable future. As a result, the Company has assumed a dividend yield of 0%. The risk free interest rate is based upon the rates of U.S. Treasury bills with a term that approximates the expected life of the option. Since the Company has limited historical exercise data to reasonably estimate the expected life of its option awards, the expected life is calculated using a simplified method. Expected volatility is based on historical volatility of the Company's stock.

The following table provides the assumptions used in the Black-Scholes model for the years ended December 31:

	2016	2015
Expected dividend yield	0%	0%
Risk-free interest rate	1.71%	1.89%
Expected volatility	86%	88%
Expected life (in years)	6.25	6.25

The weighted-average fair value of stock options granted in 2016 and 2015 was $27.17 and $117.05, respectively. As of December 31, 2016, the total compensation cost related to all non-vested stock option awards not yet recognized was $1.2 million and is expected to be recognized over the remaining weighted-average period of 2.5 years.

Restricted Stock Awards: The following table summarizes restricted stock award activity during 2016 and 2015:

	2016		2015	
	RSUs	Weighted Average Grant Price	RSUs	Weighted Average Grant Price
Nonvested, beginning balance	376	$ 128.70	5,210	$ 151.80
Granted	23,366	27.67	906	128.70
Vested	(12,771)	22.73	(5,704)	131.00
Forfeited	(639)	21.30	(36)	96.00
Nonvested at December 31	10,332	$ 27.17	376	$ 128.70

During 2016, and 2015, employees tendered restricted stock units totaling 3,333, and 2,190, respectively, to cover related payroll tax withholdings.

Warrants

Warrants to purchase 885,601, and 9,930 shares of common stock were outstanding at December 31, 2016 and 2015, respectively. As of December 31, 2016, warrants outstanding were exercisable at prices ranging from $5.10 to $210.00 per share, and are exercisable over a period ranging from eight months to 8.5 years.

Note 8 - Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities, warrants, contingent consideration and debt.

Pursuant to the requirements of ASC Topic 820 *"Fair Value Measurement,"* the Company's financial assets and liabilities measured at fair value on a recurring basis are classified and disclosed in one of the following three categories:

- *Level 1* - Financial instruments with unadjusted quoted prices listed on active market exchanges.

- *Level 2* - Financial instruments lacking unadjusted, quoted prices from active market exchanges, including over the counter traded financial instruments. The prices for the financial instruments are determined using prices for recently traded financial instruments with similar underlying terms as well as directly or indirectly observable inputs, such as interest rates and yield curves that are observable at commonly quoted intervals.

- *Level 3* - Financial instruments that are not actively traded on a market exchange. This category includes situations where there is little, if any, market activity for the financial instrument. The prices are determined using significant unobservable inputs or valuation techniques.

The fair value of the Company's common stock warrant liability related to the investor warrants is calculated using a Monte Carlo valuation model and is classified as Level 3 in the fair value hierarchy. The common stock warrants issued July 26, 2016 had a fair value of $1.8 million on the date of issuance and $0.2 million on December 31, 2016. The common stock warrants issued November 3, 2016 had a fair value of $0.8 million on the date of issuance and $1.5 million on December 31, 2016.

The fair value of the Company's common stock warrant liability related to the placement agent warrants is calculated using a Black Scholes valuation model and is classified as Level 3 in the fair value hierarchy.

Fair values were calculated using the following assumptions:

	July 26, 2016	Nov. 3, 2016	Dec. 31, 2016
Risk-free interest rates, adjusted for continuous compounding	0.94%	1.33%	1.47/1.96%
Term (years)	3.5	5.5	3.1/5.3
Expected volatility	78%	41.4%	55.3/49.8%
Dates and probability of future equity raises	various	various	various

A significant change in the inputs used for the Monte Carlo and Black Scholes valuation models such as the expected volatility, bond yield of equivalent securities, or probability of future equity financings, in isolation, would result in significantly higher or lower fair value measurements. In combination, changes in these inputs could result in a significantly higher or lower fair value measurement if the input changes were to be aligned, or could result in a minimally higher or lower fair value measurement if the input changes were of a compensating nature.

During the twelve months ended December 31, 2016, the Company recognized unrealized gains of $0.8 million in the condensed consolidated statements of operations from changes in fair value of the warrant liability.

The fair value of the Company's contingent consideration, as described in Note 2, was initially measured based on the consideration expected to be transferred (probability-weighted), discounted back to present value, and it is considered a Level 3 instrument. The discount rate used was determined at the time of measurement in accordance with accepted valuation methods. The Company measures the liability on a recurring basis using Level 3 inputs including probabilities of payment and projected payment dates. Changes to any of the inputs may result in significantly higher or lower fair value measurements. There were no changes in the fair value of the contingent consideration subsequent to the initial measurement.

All cash equivalents are considered Level 1 measurements for all periods presented. The Company does not have any financial instruments classified as Level 2 or any other classified as Level 3 and there were no movements between these categories during the periods ended December 31, 2016 and 2015. The Company believes that the carrying amounts of all remaining financial instruments approximate their fair value due to their relatively short maturities.

Note 9—Income Taxes

Domestic and foreign loss before income taxes, consists of the following for the years ended December 31:

(Dollars in thousands)	2016	2015
Domestic	$ (15,877)	$ (26,665)
Foreign	31	(42)
Loss before income taxes	$ (15,846)	$ (26,707)

The components of income tax benefit consist of the following for the years ended December 31:

(Dollars in thousands)	2016	2015
Current:		
United States and state	$ —	$ —
Foreign, net	54	124
Deferred:		
United States and state	—	—
Foreign	—	—
Total income tax benefit	$ 54	$ 124

Actual income tax benefit differs from statutory federal income tax benefit as follows for the years ended December 31:

(Dollars in thousands)	2016	2015
Statutory federal income tax benefit	$ 5,388	$ 9,066
State tax benefit, net of federal taxes	2	4
Foreign tax	3	3
R&D tax credit	80	135
Nondeductible/nontaxable items	(86)	(186)
Other	(257)	(164)
Valuation allowance increase	(5,076)	(8,734)
Total income tax benefit	$ 54	$ 124

Deferred taxes consist of the following as of December 31:

(Dollars in thousands)	2016	2015
Deferred tax assets:		
Current:		
Accrued leave	$ 43	$ 71
Other accrued expenses	97	163
Total current deferred tax asset	140	234
Noncurrent:		
Stock based compensation	1,477	1,539
Net operating loss carryforward	49,720	44,462
Deferred rent	17	21
Other	777	52
R&D credit carryforward	531	531
Total noncurrent deferred tax assets	52,522	46,605
Total deferred tax assets	$ 52,662	$ 46,839
Deferred tax liabilities:		
Current:	$ —	$ —
Noncurrent:		
Fixed assets	—	—
Total deferred tax liabilities	$ —	$ —
Net deferred tax asset	52,662	46,839
Less: valuation allowance	(52,662)	(46,839)
Total	$ —	$ —

As of December 31, 2016, the Company had net operating loss ***("NOLs")*** carryforwards of approximately $110.0 million for U.S. federal income tax purposes, which expire between 2024 and 2034, and NOLs in the Commonwealth of Australia of approximately AU$49.0 million which the Company can carry forward indefinitely. U.S. NOLs cannot be used to offset taxable income in foreign jurisdictions. In addition, future utilization of NOL carryforwards in the U.S. may be subject to certain limitations under Section 382 of the Internal Revenue Code.

The Company received $80,000 and $135,000 fully refundable research and development tax credits in 2016 and 2015, respectively, related to qualified research and development expenditures of its Australian subsidiary for its tax years ended June 30, 2015 and 2014, respectively, and recorded the benefit in the year that the refund was received. The Company has not completed its Australian tax return for its Australian subsidiaries tax year ended June 30, 2016. As the Company cannot be reasonably assured of the amount or eligibility of the refundable research and development credit resulting from its 2016 Australian research and development activities, the Company has not reflected the related estimated benefit.

The Company provides for a valuation allowance when it is more likely than not that it will not realize a portion of the deferred tax assets. The Company has established a valuation allowance for U.S. and foreign deferred tax assets due to the uncertainty that enough taxable income will be generated in those taxing jurisdictions to utilize the assets. Therefore, the Company has not reflected any benefit of such deferred tax assets in the accompanying financial statements. For the years ended December 31, 2016 and 2015, the valuation allowance increased by $5.8 million and $7.5 million, respectively.

The accounting guidance related to uncertain tax positions prescribes a recognition threshold and measurement attribute for recognition and measurement of a tax position taken or expected to be taken in a tax return. It also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company had no material uncertain tax positions as of December 31, 2016 or 2015.

The Company recognizes interest and penalties on unrecognized tax benefits as well as interest received from favorable tax settlements within income tax expense. At December 31, 2016 and 2015, the Company recorded no accrued interest or penalties related to uncertain tax positions.

The tax years ended December 31, 2013 through December 31, 2016 remain open to examination by the Internal Revenue Service and for the various states where we are subject to taxation. Additionally, the returns of the Company's Australian and Irish subsidiary are subject to examination by tax authorities of those jurisdictions for the tax years ended and subsequent to June 30, 2012 and December 31, 2014, respectively.

Note 10—Commitments and Contingencies

Leases

The Company leases office space under a non-cancelable operating lease that expires in March 2019. The lease contains provisions for future annual inflationary adjustments. Rent expense is recognized using the straight-line method over the term of the lease.

The Company leases office equipment under non-cancelable operating leases that expire at various times through February 2019.

Rent expense related to operating leases was approximately $286,000, and $261,000 for the years ended December 31, 2016 and 2015, respectively. Future minimum lease payments under non-cancelable operating leases as of December 31, 2016, were approximately $207,000, $203,000, $51,000, $0, and $0 for each of the years ended December 31, 2017, through 2021, respectively.

Employee Retirement Plan

The Company has a 401(k) profit sharing plan that provides retirement benefit to substantially all full-time U.S. employees. Eligible employees may contribute a percentage of their annual compensation, subject to IRS limitations, with the Company matching a portion of the employee's contributions at the discretion of the Company. Matching contributions totaled $122,000 and $147,000 for the years ended December 31, 2016 and 2015, respectively.

Inventory Purchase Commitments

In connection with the acquisition of the Aquadex product line, the Company entered into a manufacturing and supply agreement with Baxter that will expire within a period not to exceed 18 months from the close of the transaction. Upon termination of this agreement, the Company has an obligation to purchase from Baxter the remaining Aquadex inventory. The Company estimates that any remaining inventory will consists mainly of raw materials to be purchased at cost, and that this amount will not exceed $2.5 million.

Contingent Consideration

As described on Note 2, the Company agreed that if it disposes of any of the Aquadex assets for a price that exceeds $4.0 million within three years of the closing, it will pay Baxter 40% of the amount of such excess. In addition, it also agreed that if shares of its common stock cease to be publicly traded on the Nasdaq Capital Market, Baxter has the option to require the Company to repurchase, in cash, all or any part of the common shares held by Baxter at a price equal to their fair market value, as determined by a third-party appraiser.

Note 11—Segment and Geographic Information

The Company has one reportable segment, cardiac and coronary disease products.

At December 31, 2016, long-lived assets were located primarily in the United States.

Note 12—Subsequent Events

Reverse Stock Split
At a special meeting of the Company's stockholders on January 9, 2017, stockholders approved, among other things, a reverse stock split, and following such special meeting, the Company's Board of Directors approved a 1-for-30 reverse split of our issued and outstanding shares of common stock. The Company's common stock began trading on a split-adjusted basis on The Nasdaq Capital Market on January 13, 2017. The reverse stock split did not change the par value of our stock or the authorized number of common or preferred shares. All share and per share amounts in this document have been retroactively adjusted to reflect the reverse stock split for all periods presented.

Second Closing of Series D Convertible Preferred Stock
On January 10, 2017, the Company consummated the second closing contemplated by the securities purchase agreement dated October 30, 2016, which was subject to the Company receiving stockholder approval of the transactions, and issued and sold 200 shares of Series D Convertible Preferred Stock convertible into 39,216 shares of common stock at $5.10 per share and warrants to purchase an additional 39,216 shares of common stock at $5.40 per share for a gross purchase price of $0.2 million. The Company paid the placement agent an aggregate cash placement fee equal to 6% of the aggregate gross proceeds and issued the placement agent

warrants to purchase 2,353 shares of common stock. The investor and placement agent warrants have the same terms as the placement agent warrants issued on November 3, 2016, as described in Note 5 herein.

Warrant Exercise Agreement
On February 15, 2017, the Company entered into a letter agreement with the institutional investors ("the Investors") that hold the majority of its outstanding warrants, to incent the cash exercise of these warrants on or before March 31, 2017 (the "Exercise Period"). These warrants, if exercised in full, would yield gross proceeds of approximately $4.65 million to the Company. In exchange for any such exercise, the Company agreed to provide the Investors a replacement warrant (the "Replacement Warrants") to purchase the same number of shares of common stock as were issued upon exercise of the exercised warrants, with an exercise price equal to the consolidated closing bid price of its common stock on the date of issuance. The agreement also amends the definition of "Beneficial Ownership Limitation" in the existing warrants to mean, solely for purposes of any exercises of warrants that occur during the Exercise Period, "9.99%" and amends the Initial Exercise Date of the existing warrants issued on November 3, 2016 and January 11, 2017 so that such warrants are exercisable on or after the receipt of stockholder approval. Since such stockholder approval was received on January 9, 2017, such warrants were immediately exercisable as of the date of the agreement. The Replacement Warrants will be in the same form as the exercised warrants except the exercise price will not be subject to reduction for subsequent equity and will not allow the Investor to demand that we purchase the Replacement Warrants in the event of a fundamental transaction involving the Company. The fair value of the replacement warrants in excess of the fair value of existing warrants at the time of exercise, if any, will be expensed at the time of issuance in 2017. Concurrent with the signing of the agreement, the Investors exercised 104,419 warrants for cash proceeds of approximately $564,000.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer (together, the ***"Certifying Officers"***), as appropriate, to allow for timely decisions regarding required disclosure.

In designing and evaluating disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired objectives. Also, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. The design of any system of controls is based, in part, upon certain assumptions about the likelihood of future events and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

As of December 31, 2016, the end of the period covered by this report, we conducted an evaluation, under the supervision and with the participation of management, including the Certifying Officers, of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their stated objectives. Based on their evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2016.

Management Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. Internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that our receipts and

expenditures are being made only in accordance with authorizations of our management and Board; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Our management, including our Certifying Officers, recognizes that our internal control over financial reporting cannot prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Management, with the participation of the Certifying Officers, assessed our internal control over financial reporting as of December 31, 2016, the end of our fiscal year. Management based its assessment on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2016.

This report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to rules of the SEC that permit us to provide only management's report in this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter ended December 31, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Directors and Officers

The executive officers and directors of the Company as of March 1, 2017 are as follows:

Name	Age	Title
John L. Erb	68	Chief Executive Officer; President; Chairman of the Board; Director
Claudia Drayton	49	Chief Financial Officer; Secretary
Molly Wade [(1)]	38	Senior Vice President of Strategic Operations
Steve Brandt	61	Director
Matthew E. Likens	64	Director
Jon W. Salveson	52	Director
Gregory D. Waller	67	Director
Warren S. Watson	65	Director

(1) Ms. Wade provided notice on March 2, 2017 that she is leaving the Company effective March 15, 2017.

John L. Erb currently serves as chief executive officer and president and has served as a director of the Company since September 2012 and as Chairman of the Board since October 2012. He is currently chief executive officer of NuAx, Inc. (formerly Cardia Access, Inc.), a medical device company involved in developing new devices for the treatment of heart disease, a position he has held since February 2007. Previously, Mr. Erb served as executive chairman of the board (during 2007) and as chief executive officer (from 2001 to 2006) of CHF Solutions, Inc., a medical device company involved in the development, manufacturing and distribution of devices to treat congestive heart failure; as president and chief executive officer of IntraTherapeutics, Inc., a medical device company involved in the development, manufacturing and distribution of peripheral vascular stents, from 1997 to 2001; and in various

positions, including vice president of worldwide operations, at Schneider, a division of Pfizer, Inc., from 1991 to 1997. Mr. Erb's prior board experience includes service as a director of SenoRx, Inc., a publicly traded company, from December 2001 to July 2010, service as a director of CryoCath Technologies Inc., a publicly traded Canadian company, from October 2000 to December 2008, and service as director of Vascular Solutions, Inc. (a Nasdaq listed company) from 2002 to February 2017. While on the board of Vascular Solutions, Mr. Erb served as Chairman of the Board of Directors, chairman of the compensation committee, and of the nominating and corporate governance committees. Mr. Erb currently serves as a director of NuAx, as well as Osprey Medical, Inc. (listed on the Australian Securities Exchange; serves as chairman of the compensation committee and a member of the audit committee), Mr. Erb received a B.A. degree in business administration, with a concentration in finance from California State University, Fullerton.

With over 40 years of experience in the medical device industry, including 20 years of experience serving as chief executive officer of medical device companies, Mr. Erb brings to the Board valuable business, management and leadership experience, as well as a deep understanding of the challenges presented in growing a medical device company. In addition, his role on the boards of Vascular Solutions, SenoRx and CryoCath Technologies has provided him with other public company board experience. Having managed significant operations of a multi-national medical device company, Mr. Erb also contributes valuable private company operational experience.

Claudia Drayton has served as our Chief Financial Officer and Secretary since January 2015. Prior to joining the Company, Ms. Drayton spent 15 years at Medtronic, Inc., a $17 billion global leader in the medical device industry. During her tenure at Medtronic, Ms. Drayton held multiple senior managerial finance positions, culminating with an assignment in Europe serving as chief financial officer of the peripheral vascular business (2010-2012) and most recently, as chief financial person and senior finance director of the integrated health solutions business (2012-2014). In these capacities, her responsibilities and experiences included profitability management, strategic planning, mergers and acquisitions, planning and forecasting, and implementation of financial best practices. Before joining Medtronic, Ms. Drayton was an audit and business advisory manager at Arthur Andersen for seven years.

Ms. Drayton holds an MBA from the University of Minnesota's Carlson School of Management, a BS from the University of Mary Hardin-Baylor and is a Certified Public Accountant (inactive).

Molly Wade is our Senior Vice President of Strategic Operations, a position she has held since June 2016 and subsequently held the positions of Vice President of WorldWide Patient Recruitment and Marketing as well as Vice President of Sales and Marketing. Ms. Wade joined the Company in October 2013 as Senior Director of U.S. Patient Recruitment. Prior to joining the Company, Ms. Wade spent six years at CVRx, a small privately held company, conducting clinical research in both hypertension and heart failure. She previously worked for Medtronic, C.R. Bard, and Eli Lilly in various sales capacities.

Ms. Wade holds a B.S. in Health Science/Marketing from the University of Minnesota, Twin Cities (School of Public Health/Carlson School of Management). Ms. Wade provided notice on March 2, 2017 that she is leaving the Company effective March 15, 2017.

Steve Brandt has served as a director of the Company since February 2017. Mr. Brandt is a senior executive with over 35 years of experience in the healthcare industry. Mr. Brandt was employed by Thoratec Corporation from November 2004 to October 2015, serving as Vice President Global Sales and Marketing, Vice President of Global Sales and Vice President International Sales. Prior to Thoratec, Mr. Brandt was Vice President Sales & Marketing for CHF Solutions from October 2002 to November 2004 and Vice President Global Marketing, Cardiovascular Surgery Division for St. Jude Medical from November 2000 to October 2002. Mr. Brandt received his B.S. from Franklin Pierce College.

Mr. Brandt's qualifications to serve on the Board include his extensive experience in the management of medical device companies.

Matthew E. Likens has served as a director of the Company since February 2017. Mr. Likens is a principal at Likens Healthcare and Management Consulting, LLC. He was the President and CEO of Ulthera, Inc. from 2006 to 2016. Prior to Ulthera, Mr. Likens was employed at GMP Companies, Inc. as President of GMP Wireless Medicine from 2001 to 2006 and Executive Vice President, Operations from 2001 to 2004. Mr. Likens previously served in various capacities at Baxter Healthcare Corporation from 1978 to 2001, and was President of Baxter's Renal U.S. business upon his departure in January, 2001. Mr. Likens has a B.B.A. in Marketing from Kent State University.

Mr. Liken's qualifications to serve on the Board include his years of management experience, including his experiences as president and chief executive officer of Ulthera, Inc.

Jon W. Salveson has served as a director of the Company since March 2013. Mr. Salveson is vice chairman, investment banking and chairman of the healthcare investment banking group at Piper Jaffray Companies. He also serves on the board of CryoLife, Inc. (NYSE: CRY), a leading medical device company focused on cardiac and vascular surgery.

Mr. Salveson joined Piper Jaffray in 1993 as an associate, was elected managing director in 1999, and was named group head of Piper Jaffray's international healthcare investment banking group in 2001. Mr. Salveson was appointed global head of investment banking and a member of the executive committee of Piper Jaffray in 2004, and has served in his present position as vice chairman, investment banking since July 2010. Mr. Salveson started his career as a market manager at Bio-Metrics Systems (now part of Surmodics, Inc.),

an innovator in medical device surface modification, where he gained experience working in cardiology and interventional medicine.

Mr. Salveson's qualifications to serve on the Board include his 20-plus years of experience in healthcare investment banking, advising clients on hundreds of merger and acquisition and financing transactions.

Gregory D. Waller has served as a director of the Company since August 2011. Mr. Waller also serves on the board of Endologix Corporation, a publicly traded company (currently, chairman of the audit committee and a member of the nominating and governance committee), and until April 2015 was chief financial officer of Ulthera, Inc., a privately held company that sells an ultrasound device used for non-invasive brow lifts, which was sold to Merz North America in July 2014. From March 2006 to April 2011, Mr. Waller was chief financial officer of Universal Building Products, Inc., a manufacturer of concrete construction accessories. Mr. Waller served as vice president of finance, chief financial officer, and treasurer of Sybron Dental Specialties, Inc., a manufacturer and marketer of consumable dental products, from August 1993 until his retirement in May 2005, and was formerly vice president and treasurer of Kerr, Ormco Corporation, and Metrex. Mr. Waller joined Ormco in December 1980 as vice president and controller and served as vice president of Kerr European Operations from July 1989 to August 1993. Mr. Waller has an M.B.A. with a concentration in accounting from California State University, Fullerton. His prior board service includes service as a director for the following companies: Alsius Corporation, a publicly traded company (chairman of the audit committee and a member of the compensation committee), from June 2007 until its acquisition by Zoll Medical Corporation in September 2009; Biolase Technology, Inc., a publicly traded company (chairman of the audit committee), from October 2009 to August 2010; Cardiogenesis Corporation, a publicly traded company (chairman of the audit committee), from April 2007 until its acquisition by CryoLife, in May 2011; Clarient, Inc., a publicly traded company which was acquired by General Electric Company in December 2010 (chairman of the audit committee and a member of the compensation and corporate governance committees), from December 2006 to December 2010; and SenoRx, a publicly traded company which was acquired by C.R. Bard, Inc. in July 2010 (chairman of the audit committee), from May 2006 to July 2010.

Mr. Waller's qualifications to serve on the Board include his 44 years of financial and management experience, including his experiences as chief financial officer of Universal Building Products, Sybron Dental Specialties and Ulthera, Inc., as well as his familiarity with public company board functions from his service on the boards of other public companies.

As described above, Mr. Waller served as chief financial officer of Universal Building Products from 2006 to 2011. Universal Building Products filed a voluntary petition for bankruptcy on August 4, 2010. Except as described in the preceding sentence, no other event has occurred during the past 10 years requiring disclosure pursuant to Item 401(f) of Regulation S-K.

Warren S. Watson has served as a director of Sunshine Heart since January 2013. Mr. Watson is an executive with over 40 years of experience in the field of medical devices. From 1982 to 2014, Mr. Watson served on the board of directors of Citizens Independent Bank of St. Louis Park, Minnesota, a community bank with four branches and $300 million in assets. From 2010 to 2012, he served as executive chairman of Cameron Health Inc., a medical technology company focused on subcutaneous implantable cardioverter and defibrillator devices. From 2004 to 2009, Mr. Watson served as a director for CardioMems, Inc., a start-up company focused on pulmonary artery pressure monitoring for patients with heart failure. From 2002 to 2009, Mr. Watson served as vice president of Cardiac Rhythm Management Research and Development, an organization leading over 1,800 professionals worldwide; he also served as chair of the Medtronic Corporate Research and Development Council during his tenure with that organization. From 2002 to 2007, Mr. Watson served as vice president and general manager of the San Jose-based CardioRhythm cardiac ablation business.

Mr. Watson's qualifications to serve on the Board include his executive leadership in the field of medical devices, his 40 years of experience in the medical technology field, his successful development of multiple emerging therapies and his general business experience due to his board service for other medical technology companies such as Mardil, Inc. (2013-2016), Cardialen, Inc. (since 2012), NuAx (since 2011) and Closys (2013-2016).

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires the Company's directors and executive officers and persons who beneficially own more than 10% of a registered class of the Company's equity securities (***"insiders"***) to file reports with the SEC regarding their pecuniary interest in our equity securities and any changes thereto, and to furnish copies of these reports to the Company. Based on our review of the insiders' forms furnished to the Company or filed with the SEC and representations made by the directors and applicable executive officers, no insider failed to file on a timely basis a Section 16(a) report during 2016, except that Ms. Drayton filed one late Form 4 (reporting two disposition transactions).

Code of Conduct

The Board has adopted a Code of Business Conduct and Ethics (the ***"Code"***), which sets out basic principles to guide the actions and decisions of our employees, directors and officers, including our principal executive officer, principal financial officer and principal accounting officer. The Code addresses, among other things, ethical principles, insider trading, conflicts of interest, compliance with laws and confidentiality. The Code is posted on our website, *www.sunshineheart.com*, under the "Investors – Corporate Governance"

tab. Any amendments to the Code, or any waivers that are required to be disclosed by the rules of either the SEC or Nasdaq, will be posted on our website under the "Investors – Corporate Governance" tab.

Audit Committee

Gregory D. Waller, Matthew E. Likens and Warren S. Watson are members of the Audit Committee. The Board has affirmatively determined, after considering all of the relevant facts and circumstances that each member of the Audit Committee is independent under the applicable rules of the Nasdaq Global Select Market ("Nasdaq"). The Board has further determined that Audit Committee chairman, Mr. Waller, qualifies as an "audit committee financial expert" in accordance with SEC rules.

Item 11. Executive Compensation.

Summary Compensation Table for 2016

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

Name Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)(1)	Option Awards ($)(2)	Nonequity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
John L. Erb	2016	385,833	—	331,044	363,227	134,000(3)	—	1,214,104
Chief Executive Officer & President; Chairman of the Board	2015(4)	33,519(5)	—	23,333(6)	11,669(7)	—	93,917(8)	162,438
Claudia Drayton	2016	260,000	—	39,936	43,661	60,970(3)	6,238(9)	410,805
Chief Financial Officer; Secretary	2015(10)	240,961	—	—	365,805(11)	48,192	6,675(9)	661,633
Molly Wade (12)	2016	228,751	50,000(13)	30,784	33,655	53,642(3)	6,447(9)	403,279
Senior VP of Strategic Operations	2015	210,000	4,000	—	—	42,000	6,420(9)	262,420

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

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

(3) While the Compensation Committee determined that cash bonuses for 2016 were earned at 67% of target, the Committee made payment of such bonuses contingent upon the closing of one or more equity financings in fiscal 2017 pursuant to which the Company raises a minimum of $4 million in the aggregate and paid in installments following each such closing on a pro rata basis taking into account the amount received in such equity financing divided by the Company's total objective of $8 million for 2017 (so that no bonuses shall be paid if the Company does not receive at least $4 million in proceeds from equity financings in 2017 and, if the Company raises over $4 million but less than $8 million in proceeds from equity financings in 2017, the Company shall pay a fraction of such bonuses with a numerator equal to the amount of funds raised from equity financings in fiscal 2017 and a denominator equal to $8 million). Therefore, such earned bonuses have not yet been paid and the amount that will be paid or whether any amount will be paid is not calculable or determinable through the latest practicable date of this filing.

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

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

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

(7) Reflects stock options granted under the 2013 Directors' Plan on the date of the 2015 annual meeting as Mr. Erb was a non-employee director on such date. The

amounts reported represent the grant date fair value of the stock options. Valuation assumptions used in determining the grant date fair value for are included in Note 5 to the consolidated financial statements included in our annual report on Form 10-K for the year ended December 31, 2015. The grant date fair value per share of the stock options granted on May 21, 2015 was approximately $94.80.

(8) Reflects the amount paid to Mr. Erb in fiscal 2015 as a cash retainer for his service as a non-employee director and our Chairman of the Board pursuant to our non-employee director compensation program prior to his appointment as Chief Executive Officer and President on November 23, 2015.

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

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

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

(12) Ms. Wade provided notice on March 2, 2017 that she is leaving the Company effective March 15, 2017.

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

Narrative Disclosure to Summary Compensation Table for 2016

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

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

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

Equity Compensation. The Compensation Committee engaged Grant Thornton in 2013 to conduct a comprehensive review of the Company's executive compensation program. Grant Thornton assessed our compensation program against a peer group consisting of 21 companies similar to the Company based on industry, market capitalization, revenue and assets. Grant Thornton's comparison of the Company's target total compensation with peer group target pay levels indicated that our salaries were competitive to the median of the peer group; that target total cash compensation was, on average, 14% below the median of the peer group; and that target total compensation was, on average, 2% below the median of the peer group. Grant Thornton's comparison of the Company's current total compensation with peer group pay levels indicated that while current total compensation was, on average, 10% above the median of the peer group, this finding was misleading, given that executive equity holdings were below market. Based on the foregoing, Grant Thornton made several recommendations with respect to the Company's executive compensation program, including that the Company utilize RSU awards; that the Company grant equity awards at or above historic levels to ensure each executive officer moves to a competitive ownership position for a start-up, high-growth firm; and that the Company adopt a new-hire program to facilitate recruitment of executive talent. In light of the foregoing and other factors deemed relevant by the Compensation Committee, in 2013 the Committee recommended, and the Board approved, the New-Hire Plan. The Company also began utilizing RSU awards.

As noted above, the Compensation Committee engaged Compensia in the fourth quarter of 2015 to review the Company's executive compensation program. Compensia's report indicated that stock options and restricted stock grants were the most used equity vehicle among companies in the peer group for long-term compensation. Further Compensia recommended that the Company continue to focus on competitive initial total potential ownership for each executive officer with smaller, periodic refresh grants. The Compensation Committee approved equity compensation awards to the Company's named executive officers, other than Mr. Erb, in the form of incentive stock options and restricted stock unit awards on January 15, 2016. Mr. Erb was granted stock options and a restricted stock unit award in March 2016.

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

(14) In 2015 and 2016, each of the Company's executive officers had a target bonus, set forth as a percentage of annual base salary. In fiscal 2016, the Compensation Committee determined to increase target bonuses to 35% of base salary for each of the named executive officers other than Mr. Erb. The earned bonus was based on the achievement of corporate performance objectives defined and weighted by the Compensation Committee, in consultation with our Chief Executive Officer, and primarily related to the Company's clinical studies, financing activities and integration of the Aquadex Business. The Committee assessed the Company's achievement of those objectives at year end, and calculated a total weighted average performance to objectives of 80% and 67% for 2015 and 2016, respectively. While the Compensation Committee determined that cash bonuses for 2016 were earned at 67% of target, the Committee made payment of such bonuses contingent upon the closing of one or more equity financings in fiscal 2017 pursuant to which the Company raises a minimum of $4 million in the aggregate and paid in installments following each such closing on a pro rata basis taking into account the amount received in such equity financing divided by the Company's total objective of $8 million for 2017 (so that no bonuses shall be paid if the Company does not receive at least $4 million in proceeds from equity financings in 2017 and, if the Company raises over $4 million but less than $8 million in proceeds from equity financings in 2017, the Company shall pay a fraction of such bonuses with a numerator equal to the amount of funds raised from equity financings in fiscal 2017 and a denominator equal to $8 million). Therefore, such earned bonuses have not yet been paid and the amount that will be paid or whether any amount will be paid is not calculable or determinable through the latest practicable date of this filing. The amounts of the earned bonuses for the named executive officers varied in 2016, based on Mr. Erb's evaluation of departmental and individual performance. The Compensation Committee further awarded retention bonuses of $50,000 to each of Ms. Drayton and Ms. Wade in December 2016, payable on July 15, 2017, so long as such officers remain with the Company through June 30, 2017 and the Company receives a minimum of $5 million in equity financing by such date. Ms. Wade provided notice on March 2, 2017 that she is leaving the Company effective March 15, 2017.

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

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

(1) Mr. Erb was a non-employee director in fiscal 2014 and for a portion of fiscal 2015. He was not entitled to non-equity incentive plan compensation as our Interim Chief Executive Officer and President during the remainder of fiscal 2015.

Outstanding Equity Awards at Fiscal Year-End

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

	Option Awards(1)				Stock Awards	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested ($)	Market Value of Shares or Units of Stock That Have Not Vested ($) (4)
John L. Erb	1,800(1)	—	248.10	09/11/2022		
	92(1)	—	167.10	05/28/2024		
	123(1)	—	128.70	05/20/2025		
	—	17,800(2)	27.30	03/16/2026		
					8,080(3)	84,849

Claudia Drayton	1,833(5)	1,833(5)	134.40	01/05/2025		
	480(2)	1,440(2)	31.20	01/15/2026		
					—	—
Molly Wade (2)	923	243	330.00	10/27/2023		
	503	330	148.50	08/01/2024		
	370	1,110	31.20	01/15/2026		
					—	—

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

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

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

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

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

Potential Payments Upon Termination or Change in Control

Equity Compensation Plans

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

Second Amended and Restated 2011 Equity Incentive Plan

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

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

- other than for cause or upon the participant's death or disability, the participant may exercise his or her option (to the extent the option was vested as of the date of termination) within such period of time ending on the earlier of (i) the date three months following the termination or (ii) the expiration of the term of the option. If the option is not exercised within such period, it will terminate.
- upon the participant's disability, the participant may exercise his or her option (to the extent the option was vested as of the date of termination) within such period of time ending on the earlier of (i) the date 12 months following the termination or (ii) the expiration of the term of the option. If the option is not exercised within such period, it will terminate.
- as a result of the participant's death, or if the participant dies within the period during which the option may be exercised after the termination of the participant's continuous service for a reason other than cause, the option may be exercised (to the extent the option was vested as of the date of death) by the participant's estate within the period ending on the earlier of (i) the date 18 months following the date of death or (ii) the expiration of the term of the option. If the option is not exercised within such period, it will terminate.
- for cause, the option will terminate upon the date of termination, and the participant will be prohibited from exercising his or her option from and after such time.

In addition, if the participant is a member of senior management, and if a change in control occurs and as of, or within six months after, the effective time of the change in control, the participant's continuous service terminates due to (i) an involuntary termination,

which is not for cause or due to death or disability, or (ii) a resignation for good reason, 25% of the unvested portion of the option as of the date of termination will vest and become exercisable immediately upon such termination.

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

New-Hire Equity Incentive Plan

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

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

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

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

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

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

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

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

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

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

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

- an annual base salary of at least $400,000, reviewed at least annually;
- initial equity grants of an option to purchase 17,800 shares of common stock and 11,866 restricted stock units, in each case, granted in accordance with the terms and conditions of the Company's Second Amended and Restated 2011 Equity Incentive Plan;
- an opportunity to receive additional annual equity awards as determined by the Compensation Committee based on Mr. Erb's performance and commensurate with grants made to chief executive officers in the Company's compensation peer group;
- an opportunity for Mr. Erb to receive an annual performance bonus in an amount of up to 50% of Mr. Erb's annual base salary for such fiscal year based upon achievement of certain performance goals to be established by the Board;
- participation in welfare benefit plans, practices, policies and programs provided by the Company and its affiliated companies (including, without limitation, medical, prescription, dental, disability, employee life, group life, accidental death and travel accident insurance plans and programs) to the extent available generally or to other senior executive officers of the Company;
- prompt reimbursement for all reasonable expenses incurred by Mr. Erb in accordance with the plans, practices, policies and programs of the Company; and
- 22 days paid time off, to accrue and to be used in accordance with the Company's policies and practices in effect from time to time, as well as all recognized Company holidays.

In connection with the equity grant contemplated by the agreement, Mr. Erb received an option to purchase 17,800 shares of the Company's common stock at an exercise price of $27.3 per share and an award of 11,866 restricted stock units, both of which were issued on March 16, 2016.

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

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

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

The ***"Conditional Benefits"*** include the following: (i) a lump sum amount equal to one times Mr. Erb's annual base salary as of the termination date; (ii) continued medical coverage for 12 months following the termination date; (iii) continued vesting of equity awards for 12 months following the termination date; and (iv) a pro-rata annual bonus for the year in which the termination date occurs, determined on the basis of an assumed full-year target bonus and the number of days in the applicable fiscal year occurring on or before the termination date. ***Base Salaries.*** The initial annual base salaries of the Company's executive officers are negotiated in connection with their hiring. The Compensation Committee reviews the base salaries of the executive officers on an annual basis and generally grants salary increases following such reviews. Base salary increases are typically between 3-5% and represent a combination of a cost of living and inflation adjustment and a merit raise.

Non-Employee Director Compensation Table for 2016

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

Name	Fees Earned or Paid in Cash ($)(1)	Stock Awards ($)(2)	Option Awards ($)(3)	Total ($)
Paul R. Buckman (4)	46,597	23,333	11,669	81,599
Jon W. Salveson	55,000	23,333	11,669	90,002
Gregory D. Waller	55,000	23,333	11,669	90,002
Warren S. Watson	55,000	23,333	11,669	90,002
Total	**211,597**	**93,332**	**46,676**	351,605

(1) Reflects cash retainers.

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

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

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

As a named executive officer of the Company, compensation paid to Mr. Erb for the 2015 and 2016 fiscal years is fully reflected under "Named Executive Officer Compensation Tables—Summary Compensation Table for 2016". Messrs. Brandt and Likens were appointed to the Board in February 2017 and, therefore, received no compensation from the Company in fiscal 2017.

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

2016 Director Compensation Program. Our non-employee directors receive a mix of cash and share-based compensation. The compensation mix is intended to encourage non-employee directors to continue Board service, further align the interests of the Board and stockholders, and attract new non-employee directors with outstanding qualifications. Directors who are employees or officers of the Company do not receive any additional compensation for Board service.

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

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

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

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

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

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

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

The Company does not provide any perquisites to directors.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Equity Compensation Plan Information

The following table sets forth certain information as of December 31, 2016 concerning our equity compensation plans:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	965,227(1)	$15.19(2)	57,738(3)
Equity compensation plans not approved by security holders	18,596(4)	$100.51	11,391(5)
Total	**983,823**	**$16.82**	**69,129**

(1) Consists of shares of our common stock that may be issued pursuant to outstanding stock options, stock warrants and RSUs under the 2002 Stock Plan, the 2011 Equity Incentive Plan and the 2013 Directors' Plan.

(2) Excludes RSUs because they convert into shares of our common stock on a one-for-one basis upon vesting at no additional cost.

(3) Consists of 43,048 shares of our common stock remaining available for future issuance under the 2011 Equity Incentive Plan and 14,690 shares of our common stock remaining available for future issuance under the 2013 Directors' Plan. No additional awards may be issued under the 2002 Stock Plan.

Each of the 2011 Equity Incentive Plan and the 2013 Directors' Plan contains an "evergreen" provision, pursuant to which the number of shares available for issuance under the plan automatically adjusts by a percentage of the number of fully diluted shares outstanding. Specifically, pursuant to the 2011 Equity Incentive Plan, for a period of five years commencing on January 1, 2013 and ending on (and including) January 1, 2017, the aggregate number of shares of common stock that may be issued pursuant to stock awards will automatically adjust on each January 1 so that it will equal (i) 13% of the fully diluted shares as of the immediately preceding December 31, reduced by (ii) the number of shares of common stock issuable upon exercise of outstanding options under the 2002 Stock Plan. Pursuant to the 2013 Directors' Plan, the share reserve under the plan will automatically increase on January 1st of each year, for a period of not more than ten years, commencing on January 1, 2014 and ending on (and including) January 1, 2023, to an amount equal to 2% of the fully diluted shares outstanding on December 31st of the preceding calendar year; provided that the Board may act prior to January 1st of a given year to provide that there will be no January 1st increase in the share reserve for such year or that the increase in the share reserve for such year will be a lesser number of shares than would otherwise occur.

(4) Consists of shares of our common stock that may be issued pursuant to outstanding stock options under the New-Hire Plan. The Board approved the New-Hire Plan in July 2013. The New-Hire Plan provides for the grant of the following awards: options not intended to qualify as incentive stock options under Section 422 of the Internal Revenue Code, restricted stock awards, RSU awards, stock appreciation rights and other stock awards. Eligible award recipients are individuals entering into employment with the Company who were not previously employees or directors of the Company or following a *bona fide* period of non-employment. All awards must constitute inducements material to such individuals' entering into employment with the Company within the meaning of the Nasdaq listing rules, and all awards must be granted either by the Compensation Committee or a majority of the Company's independent directors. Promptly following the grant of an award under the New-Hire Plan, the Company must (i) issue a press release disclosing the material terms of the award and (ii) notify Nasdaq that it granted such award in reliance on the "inducement grant exemption" from Nasdaq's stockholder approval requirements for equity compensation plans.

(5) Consists of 11,391 shares remaining available for future issuance under the New-Hire Plan.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information regarding the beneficial ownership (as defined in Rule 13d-3 of the Securities Exchange Act of 1934, as amended (the ***"Exchange Act"***)) of our common stock as of March 1, 2017 by (i) each of the directors and named executive officers, (ii) all of the directors and executive officers as a group, and (iii) to our knowledge, beneficial owners of more than 5% of our common stock. As of March 1, 2017, there were 1,741,745 shares of our common stock outstanding. Unless otherwise indicated and subject to applicable community property laws, each owner has sole voting and investment powers with respect to the securities listed below.

Name of Beneficial Owner	Number of Shares	Right to Acquire (1)	Total	Aggregate Percent of Class (2)
John L. Erb.....	7,698	7,456	15,154	1%
Steven F. Brandt	--	392	392	*

Matthew E. Likens	--	392	392	*
Jon W. Salveson	1,141	1,939	3,080	*
Gregory D. Waller	1,260	1,559	2,819	*
Warren S. Watson	1,141	1,939	3,080	*
Claudia Drayton	739	2,662	3,401	*
Eric Lovett	--	1,083	1,083	*
Molly Wade	907	2,056	2,963	*
All directors and executive officers as a group (7 persons)	12,886	18,395	31,281	1.9%
Sabby Management, LLC 10 Mountainview Road, Suite 205 Upper Saddle River, NJ 07458	52,135(4)	1,136,370(5)	1,188,505	4.99(6)%

* Less than one percent.

(1) Except as otherwise described below, amounts reflect the number of shares that such holder could acquire through (i) the exercise of outstanding stock options, (ii) the vesting/settlement of outstanding RSUs and (iii) the exercise of outstanding warrants to purchase common stock, in each case within 60 days of March 1, 2017.

(2) Based on 1,741,745 shares outstanding as of March 1, 2017.

(3) Ms. Wade provided notice on March 2, 2017 that she is leaving the Company effective March 15, 2017.

(4) Based on information provided by Sabby Management, LLC as of February 10, 2017.

(5) Includes (1) 286,092 shares of common stock issuable upon exercise of warrants to purchase shares of common stock held by Sabby Volatility Warrant Master Fund, Ltd., (2) 581,987 shares of common stock issuable upon exercise of warrants to purchase shares of common stock held by Sabby Healthcare Master Fund, Ltd., (3) 5,058 shares of Common Stock issuable upon conversion of outstanding shares of Series C Convertible Preferred Stock held by Sabby Volatility Warrant Master Fund, Ltd., (4) 62,568 shares of Common Stock issuable upon conversion of outstanding shares of Series C Convertible Preferred Stock held by Sabby Healthcare Master Fund, Ltd., (5) 51,305 shares of Common Stock issuable upon conversion of outstanding shares of Series D Convertible Preferred Stock held by Sabby Volatility Warrant Master Fund, Ltd. and (6) 104,841 shares of Common Stock issuable upon conversion of outstanding shares of Series D Convertible Preferred Stock held by Sabby Healthcare Master Fund, Ltd., that are, in each case, convertible or exercisable within 60 days of February 10, 2017. The conversion prices of our Series C Convertible Preferred Stock and Series D Convertible Preferred Stock are subject to adjustment.

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

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Related Party Transactions

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

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

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

Director Independence

The Board believes that there should be at least a majority of independent directors on the Board. The Board recently undertook its annual review of director independence in accordance with the applicable rules of the Nasdaq Capital Market (***"Nasdaq"***). The independence rules include a series of objective tests, including that the director is not employed by us and has not engaged in various types of business dealings with us. In addition, the Board is required to make a subjective determination as to each independent director that no relationships exist which, in the opinion of the Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, the Board reviewed and discussed information provided by the directors and us with regard to each director's business and personal activities as they may relate to us and our management. In particular, the Board considered (i) that Mr. Watson, in his capacity as Chairman of the Nominating and Corporate Governance Committee, received $25,000 from the Company in fiscal 2015 as compensation for duties as such committee chairman in connection with the amendment and restatement, implementation and administration of the Company's Code of Business Conduct and Ethics and (ii) that Mr. Salveson is an executive officer of Piper Jaffray Companies, the parent company of Piper Jaffray & Co., which served as joint book-running manager for the Company's confidentially marketed public offering that closed on September 24, 2013. The Board determined that Mr. Watson continued to satisfy the objective independence tests and that his independence was not otherwise impaired under the subjective criteria, because, among other things, such payment was made to him in his capacity as Chairman of the Nominating and Corporate Governance Committee for services related to such role and the dollar amounts at issue were immaterial. In prior years, the Board determined that Mr. Salveson was not an independent director, but in the first quarter of fiscal 2016, the Board reassessed Mr. Salveson's independence and determined that he satisfies the objective independence tests and that his independence was not otherwise impaired under the subjective criteria because, among other reasons, the fees paid to Piper Jaffray in connection with the confidentially marketed public offering were well below the threshold dollar amount for payments made to affiliated entities set forth in the objective independence tests and due to the amount of time that has passed since such fees were paid.

The Board has affirmatively determined, after considering all of the relevant facts and circumstances, that all of our directors are independent directors under the applicable rules of Nasdaq, except for Mr. Erb, our current Chief Executive Officer and President. Following the resignation of our Lead Independent Director, Paul R. Buckman, the Board designated Warren S. Watson to serve as our lead independent director.

Each member of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee is independent under Nasdaq rules. In addition, the Board has affirmatively determined that the members of the Audit Committee and Compensation Committee qualify as independent in accordance with the additional independence rules established by the SEC and Nasdaq.

Following the determination of Mr. Salveson's independence, on May 26, 2016, Mr. Salveson replaced Mr. Buckman on the Nominating and Corporate Governance Committee, and Mr. Salveson was added as a third member of the Compensation Committee. In connection with the resignation of Mr. Buckman from our Board, on November 16, 2016, Mr. Salveson replaced Mr. Buckman on the Audit Committee, and Mr. Salveson became chairman of the Compensation Committee.

Following the appointment of Messrs. Brandt and Likens, on March 6, 2017, Mr. Likens replaced Mr. Salveson on the Audit and Nominating and Corporate Governance Committees and Mr. Brandt was added as a third member of the Compensation Committee and a fourth member of the Nominating and Corporate Governance Committee.

Item 14. Principal Accounting Fees and Services.

The Audit Committee has adopted an auditor services pre-approval policy applicable to services performed for the Company by its independent registered public accounting firm. In accordance with this policy, the Committee's practice is to assess the permissibility of and pre-approve all audit, audit-related and non-audit services to be provided by the independent registered public accounting firm during the year. The Committee may form and delegate authority to subcommittees consisting of one or more members when appropriate, including the authority to grant pre-approvals of audit and permissible audit-related and non-audit services. Any pre-approvals granted pursuant to delegated authority must be reported to the Committee at its next regular meeting.

The Audit Committee has determined that the provision of the non-audit services described in the table below was compatible with maintaining the independence of our independent registered public accounting firm. The Committee reviews each non-audit service to be provided and assesses the impact of the service on the auditor's independence.

Ernst & Young served as our independent registered public accounting firm for the years ended December 31, 2016 and December 31, 2015. The following table sets forth the fees we incurred for audit and other services provided by Ernst & Young in 2016 and 2015.

All of such services described below were pre-approved in conformity with the Audit Committee's pre-approval policies and procedures described above.

	2016 ($)	2015 ($)
Audit Fees(1)	426,600	208,330
Audit-Related Fees (2)	34,500	45,000
Tax Fees(3)	52,852	51,708
All Other Fees	–	–
Total	**513,952**	**305,038**

(1) Audit fees in 2016 and 2015 consisted of fees relating to the audit of the Company's annual consolidated financial statements included in our annual report on Form 10-K, the review of interim condensed consolidated financial statements included in the Company's quarterly reports on Form 10-Q. In 2016, audit fees included one-time fees associated with the Aquadex acquisition and the convertible preferred financings in July and November of 2016.

(2) Audit-related fees include fees associated with the review of the Company's registration statements and the completion of comfort letter procedures associated with the Company's securities offerings.

(3) Tax fees in 2016 and 2015 consisted of fees for tax compliance, tax advice and tax planning services. Such fees primarily related to federal and state tax compliance and planning.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

The following documents are filed as a part of this Annual Report on Form 10-K:

(a) Financial Statements: The financial statements filed as part of this report are listed in Part II, Item 8.

(b) Financial Statement Schedules: The schedules are either not applicable or the required information is presented in the consolidated financial statements or notes thereto.

(c) Exhibits: The exhibits incorporated by reference or filed as part of this Annual Report on Form 10-K are listed in the attached Index to Exhibits.

POWER OF ATTORNEY

Each individual person whose signature appears below hereby appoints John Erb and Claudia Drayton as attorneys-in-fact with full power of substitution, severally, to execute in the name and on behalf of each such person, individually and in each capacity stated below, one or more amendments to this annual report which amendments may make such changes in the report as the attorney-in-fact acting in the premises deems appropriate, to file any such amendment to the report with the SEC, and to take all other actions either of them deem necessary or advisable to enable the Company to comply with the rules, regulations and requirements of the SEC.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 8, 2017

SUNSHINE HEART, INC.

By: /S/ JOHN L. ERB
John L. Erb
Chief Executive Officer and Chairman of the Board

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/S/ JOHN L. ERB John L. Erb	Chief Executive Officer and Director (principal executive officer)	March 8, 2017
/S/ CLAUDIA DRAYTON Claudia Drayton	Chief Financial Officer (principal financial and accounting officer)	March 8, 2017
/S/ STEVEN BRANDT Steven Brandt	Director	March 8, 2017
/S/ MATTHEW LIKENS Matthew Likens	Director	March 8, 2017
/S/ JON W. SALVESON Jon W. Salveson	Director	March 8, 2017
/S/ GREGORY D. WALLER Gregory D. Waller	Director	March 8 2017
/S/ WARREN S. WATSON Warren S. Watson	Director	March 8, 2017

EXHIBIT INDEX

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

	Warrant issued to Northland Securities, Inc.				
4.5	Registration Rights Agreement between the Company and Gambro UF Solutions, Inc. dated August 5, 2016	8-K	001-35312	August 8, 2016	4.1
4.6	Form of common stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated October 30, 2016, among the Company and the purchasers signatory thereto	8-K	001-35312	October 31, 2016	4.1
4.7	Form of common stock Purchase Warrant issued pursuant to the Letter Agreement between the Company and the purchasers signatory thereto, dated February 15, 2017	8-K	001-35312	February 16, 2017	4.1
10.1	Letter Agreement dated February 15, 2017 among the Company, Sabby Volatility Warrant Master Fund, Ltd. and Sabby Healthcare Master Fund, Ltd.	8-K	001-35312	February 16, 2017	10.1
10.2	Securities Purchase Agreement, dated July 20, 2016 among the Company and the purchasers signatory thereto	8-K	001-35312	July 22, 2016	10.1
10.3	Patent License Agreement between the Company and Gambro UF Solutions, Inc. dated August 5, 2016	8-K	001-35312	August 8, 2016	10.1
10.4	Loan and Security Agreement between the Company and Silicon Valley Bank dated August 5, 2016	8-K	001-35312	August 8, 2016	10.2
10.5	Amended and Restated 2002 Stock Plan†	10	001-35312	December 16, 2011	10.2
10.6	Form of Notice of Stock Option Grant and Option Agreement for Amended and Restated 2002 Stock Plan†	10	001-35312	September 30, 2011	10.3
10.7	Second Amended and Restated 2011 Equity Incentive Plan, as amended†	14A	001-35312	July 27, 2012	App. A
10.8	Form of Stock Option Grant Notice and Option Agreement for 2011 Equity Incentive Plan †	10	001-35312	September 30, 2011	10.5

10.9	Form of Stock Option Grant Notice and Option Agreement (Senior Management) for 2011 Equity Incentive Plan†	10	001-35312	September 30, 2011	10.6	
10.10	Form of Stock Option Grant Notice and Option Agreement (Director) for 2011 Equity Incentive Plan†	8-K	001-35312	September 18, 2012	10.1	
10.11	Form of Stock Grant Notice and Award Agreement for 2011 Equity Incentive Plan†	8-K	001-35312	September 10, 2013	10.1	
10.12	Form of Restricted Stock Unit Grant Notice and Agreement for 2011 Equity Incentive Plan†	8-K	001-35312	September 10, 2013	10.2	
10.13	2013 Non-Employee Directors' Equity Incentive Plan†	14A	001-35312	April 5, 2013	App. A	
10.14	Form of Stock Option Grant Notice and Option Agreement for 2013 Non-Employee Directors' Equity Incentive Plan†	10-K	001-35312	March 20, 2014	10.10	
10.15	Form of Restricted Stock Unit Award Grant Notice and Agreement for 2013 Non-Employee Directors' Equity Incentive Plan†	10-K	001-35312	March 20, 2014	10.11	
10.16	New-Hire Equity Incentive Plan†	10-Q	001-35312	August 8, 2013	10.1	
10.17	First Amendment to New-Hire Equity Incentive Plan†	10-Q	001-35312	November 12, 2013	10.1	
10.18	Second Amendment to New-Hire Equity Incentive Plan†	10-Q	333-202904	March 20, 2015	10.1	
10.19	Form of Stock Option Grant Notice and Option Agreement for New-Hire Equity Incentive Plan†	10-K	001-35312	March 20, 2014	10.14	
10.20	Form of Indemnity Agreement for the Company's executive officers and directors†	10	001-35312	September 30, 2011	10.1	
10.21	Form of Change in Control Agreement for the Company's executive officers†	10-K	001-35312	March 20, 2015	10.16	
10.22	Non-Employee Director Compensation Policy†	10-Q	001-35312	August 8, 2013	10.2	
10.23	Lease Agreement dated October 21, 2011 by and between the Company and Silver Prairie	10	001-35312	December 16, 2011	10.18	

	Crossroads, LLC					
10.24	Sales Agreement dated March 21, 2014 by and between the Company and Cowen and Company, LLC	S-3	333-194731	March 21, 2014	1.2	
10.25	Loan and Security Agreement between the Company and Silicon Valley Bank dated February 18, 2015	8-K	001-35312	February 19, 2015	10.1	
10.26	First Amendment to Loan and Security Agreement between the Company and Silicon Valley Bank dated December 8, 2015	8-K	001-35312	December 9, 2015	99.1	
10.27	Second Amendment to Lease, dated as of April 20, 2015, by and between the Company and Capital Partners Industrial Fund I, LLLP dba Prairie Crossroads Business Center	8-K	001-35312	April 23, 2015	10.1	
10.28	Executive Employment Agreement between the Company and John L. Erb, dated March 1, 2016†	8-K	001-35312	March 2, 2016	10.1	
10.29	Separation and Release Agreement by and between the Company and Brian J. Brown, dated February 3, 2016†	10-Q	001-35312	May 5, 2016	10.2	
10.30	Separation and Release Agreement by and between the Company and Debra Kridner, dated January 24, 2016†	10-Q	001-35312	May 5, 2016	10.3	
10.31	Third Amendment to the Sunshine Heart, Inc. New-Hire Equity Incentive Plan†	S-8	333-210215	March 15, 2016	99.1	
10.32	Claudia Drayton Retention Bonus Letter, dated as of December 12, 2016†	8-K	001-35312	December 16, 2016	10.1	
10.33	Molly Wade Retention Bonus Letter, dated as of December 12, 2016†					*
21	List of subsidiaries of the Company					X
23	Consent of Ernst & Young LLP					X
31.1	Section 302 Certification—CEO					X

31.2	Section 302 Certification—CFO	X
32.1	Section 906 Certification—CEO	X
32.2	Section 906 Certification — CFO	X
101.INS	XBRL Instance Document.	X
101.SCH	XBRL Taxonomy Extension Schema Document.	X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	X

† Indicates management compensatory plan, contract or arrangement.

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

EXHIBIT 21

SUBSIDIARIES

Entity	Jurisdiction of Formation
Sunshine Heart Company Pty Limited	Australia
Sunshine Heart Ireland Limited	Ireland
CHF Solutions, LLC	Delaware

Exhibit 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

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

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

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

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

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

(6) Registration Statement (Form S-8 No. 333-202904) pertaining to the Sunshine Heart, Inc. Second Amended and Restated 2011 Equity Incentive Plan, the Sunshine Heart, Inc. 2013 Non-Employee Directors' Equity Incentive Plan, and the Sunshine Heart, Inc. New-Hire Equity Incentive Plan, as amended.

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

(8) Registration Statement (Form S-1 No. 333-215112) of Sunshine Heart, Inc. and in the related prospectus; and

(9) Registration Statement (Form S-1 No. 333-216053) of Sunshine Heart, Inc. and in the related prospectus.

of our report dated March 8, 2017, with respect to the consolidated financial statements of Sunshine Heart, Inc. and Subsidiaries included in this Annual Report (Form 10-K) of Sunshine Heart, Inc. for the year ended December 31, 2016.

/s/ Ernst & Young LLP
Minneapolis, Minnesota
March 8, 2017

EXHIBIT 31.1

SUNSHINE HEART, INC.
CEO SECTION 302 CERTIFICATION

I, John L. Erb, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 8, 2017

/S/ JOHN L. ERB
John L. Erb
Chief Executive Officer

EXHIBIT 31.2

SUNSHINE HEART, INC.
CFO SECTION 302 CERTIFICATION

I, Claudia Drayton, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 8, 2017

/S/ CLAUDIA DRAYTON
Claudia Drayton
Chief Financial Officer

EXHIBIT 32.1

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

In connection with the Annual Report of Sunshine Heart, Inc. (the ***"Company"***) on Form 10-K for the 12 months ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the ***"Report"***), I, John L. Erb, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 8, 2017

/S/ JOHN L. ERB
John L. Erb
Chief Executive Officer

EXHIBIT 32.2

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

In connection with the Annual Report of Sunshine Heart, Inc. (the ***"Company"***) on Form 10-K for the 12 months ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the ***"Report"***), I, Claudia Drayton, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 8, 2017

/S/ CLAUDIA DRAYTON
Claudia Drayton
Chief Financial Officer

Sunshine Heart Business Overview

Aquadex FlexFlow System

AN EFFECTIVE TREATMENT FOR FLUID OVERLOAD

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

Advantages of Aquadex

- Removes isotonic fluid via ultrafiltration - extracts more than diuretic therapy while sparing potassium and magnesium[2]
- Simple to use, highly automated, and provides complete control over rate and total volume of fluid removed
- Effectively and safely decreases length of stay and hospital readmissions[3]

Clinical Evidence

A HISTORY OF CLINICAL EVIDENCE

Ultrafiltration (UF) is the leading method for removing excess salt and water to relieve congestion in patients with heart failure and other related conditions. Several trials including SAFE, the preliminary safety and efficacy study, demonstrated fluid removal goals were achievable in 92% of patients. Both RAPID-HF and UNLOAD demonstrated clinical benefit of UF as compared to usual care (diuretics). The UNLOAD trial showed that patients had 38% greater weight loss, 50% reduction in total number of re-hospitalizations, 52% reduction in Emergency Department or clinic visits, and 63% total reduction in days re-hospitalized.

The CARRESS trial showed a rise in creatinine among renal patients on a fixed UF treatment strategy as compared to diuretics, although levels normalized at 7 days post treatment with no difference in body weight, re-hospitalization rates or mortality between the two approaches.

In summary, UF is an acceptable method for addressing HF and fluid overloaded patients.

Aquadex Growth Drivers

PREPARING FOR THE FUTURE

1. **Grow the HF Outpatient Market:** Continue supporting outpatient usage and expansion to include collaborations and programs aimed at decreasing readmission rates and hospital stay.
2. **Enhance the HF Inpatient Market:** Over one million hospitalizations annually in US for acute HF with 90% presenting fluid overload.[4]
3. **Expansion into other applicable therapies**
4. **Reimbursement Opportunity:** Working to build acceptance through clinical evidence to gain reimbursement for Aquapheresis therapy.

Board of Directors

John L. Erb (Chairman)

Jon W. Salveson

Gregory D. Waller

Warren S. Watson

Matthew Likens

Steve Brandt

Corporate Officers

John L. Erb
Chief Executive Officer

Claudia Napal Drayton
Chief Financial Officer

Company Secretary

Claudia Napal Drayton

Transfer Agent and Registrar

American Stock Transfer &
Trust Company, LLC
6201 15th Avenue
Brooklyn, NY 11219
Website: www.amstock.com
Phone: 1 800 937 5449

Company Headquarters

12988 Valley View Road
Eden Prairie, MN 55344
Website: www.sunshineheart.com
Phone: +1 952 345 4200

Independent Registered Public Accounting Firm

Ernst & Young LLP
Minneapolis, MN

ANNUAL MEETING

May 25, 2017

SUNSHINE HEART

12988 Valley View Road
Eden Prairie, MN 55344
Phone +1 952 345 4200
www.sunshineheart.com

Rx Only

Indication: The Aquadex FlexFlow® System 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 having received training in extracorporeal therapies.

References from inside back cover:

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. Costanzo MR, et al. J Am Coll Cardiol. 2005 Dec 6; 46(11): 2047-2051.
4. Costanzo MR, et al. J Am Coll Cardiol. 2007 Feb 13; 49(6): 675-683.