2017 ANNUAL REPORT

chf solutions

OUR OBJECTIVE IS TO IMPROVE THE QUALITY OF LIFE FOR PATIENTS WITH HEART FAILURE AND RELATED CONDITIONS.

Dear Shareholders,

CHF Solutions' vision is to be the global market leader in fluid management solutions to improve patient quality of life. We provide healthcare professionals with a sophisticated, yet easy to use, mechanical pump and filtration system to address fluid overload primarily associated with heart failure and related conditions. We believe that our technology will provide a competitive advantage in the fluid management market by providing an effective solution for decongestion and reducing the cost of care relative to other treatment alternatives.

2017 was a year of important accomplishments for CHF Solutions as we continued to educate health care professionals about improved outcomes against the standard of care for heart failure patients suffering from fluid overload. Our commercialization activity and investment in sales and marketing is key to our strategy but has been gated by our need to raise cash. In the second quarter of 2017, we raised about $9.0 million, which helped us finance operations in 2017. In the second quarter, we added our chief commercial officer, who immediately set out to enhance our commercialization strategy and build a US direct sales force. We identified hospitals with the largest heart failure admission statistics to geographically target new sales territories and began a process to identify needed marketing materials. In the third quarter, we added 6 additional experienced sales representatives and expanded our US direct sales force to 10 territories and recently added three clinical specialists to support training and clinical support to our customers. In 2017, we initiated our international commercialization strategy by signing distribution agreements and partnering with distributors in the United Kingdom, Southeast Asia, and we recently added European distributors in Italy and Spain. Given our expanded US and International commercialization, we anticipate accelerated sales growth and penetration rates as we continue to actively position ourselves in the market as the primary provider of ultrafiltration therapy for cardiologists to remove excess fluid from their fluid overloaded heart failure patients.

On the manufacturing front, our manufacturing implementation has gone very well. During the third quarter, we transitioned the manufacturing equipment from Baxter to our facility in Eden Prairie, Minnesota, successfully commissioned the cleanroom, and completed validation builds. In the fourth quarter, we began manufacturing both consoles and blood filter circuits in our facility and are now building our own finished goods inventory. We expect the in-house manufacturing capability to have a favorable impact on our gross margins as it will alleviate the mark-up over standard cost charged by Baxter for manufacturing product for us.

In late November, we announced the closing of an underwritten public offering of convertible preferred stock, with warrants, for gross proceeds of about $18.0 million. The use of funds will include continuing our important investment in our commercialization strategy with adding additional sales territories, clinical specialists, and marketing personnel. We also have several product enhancements in the pipeline to further increase the utilization of our ultrafiltration therapy.

Looking ahead, we continue to fine-tune growth strategies to impact both improved clinical outcomes and healthcare cost reduction by giving healthcare providers an option to diuretics. We continue to be very optimistic about our future. The key milestones achieved and all the behind-the-scenes work executed during the year are a direct result of the tireless effort and determination of our highly capable and committed team. The achievements of this past year stand us in good stead to continue progressing our strategy in 2018, including the continued expansion of our US sales force, continued growth of our international commercialization, as well as the R&D of new product enhancements for our Aquadex product franchise. CHF Solutions continues to be at the forefront of fluid management in heart failure, spearheading the growing awareness of the issues associated with IV diuretic therapy and the value of ultrafiltration as an opportunity to improve clinical outcomes, reduce rehospitalization rates and alleviate a major expense to the healthcare system.

Sincerely,

John Erb
Chief Executive Officer and Chairman of the Board
April 6, 2018

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, 2017

☐ **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

CHF SOLUTIONS, 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, a smaller reporting company, or emerging growth company. See the definitions of ''large accelerated filer,'' ''accelerated filer,'' ''smaller reporting company,'' and ''emerging growth 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 ☒ Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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, 2017, 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, 2017 closing sale price of $20.60 per share) was approximately $12.7 million.

The number of shares of the registrant's common stock, par value $0.0001 per share, outstanding as of March 16, 2018 was 4,226,251 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement for the 2018 annual meeting of stockholders are incorporated by reference into Part III of this report to the extent described herein.

CHF SOLUTIONS, INC.
ANNUAL REPORT ON FORM 10-K
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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 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 FlexFlow system business (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 system 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 system, medical practitioners can specify and control the amount of fluid to be extracted at a safe, predictable, and effective rate, in a process we refer to as Aquapheresis® therapy. All Aquapheresis treatments must be administered by a healthcare provider, under physician prescription, both of whom have received training in extracorporeal therapies. The Aquadex FlexFlow system has been shown to have no clinically significant impact on electrolyte balance, blood pressure or heart rate[1].

[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.

Benefits of the Aquadex FlexFlow System

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

- Provides complete control over rate and total volume of fluid removed by allowing a medical practitioner to specify the amount of fluid to be removed from each individual patient;
- Aquapheresis therapy can be performed via peripheral or central venous access;
- Removes isotonic fluid (extracts sodium while sparing potassium and magnesium)[2];
- Following ultrafiltration, neurohormonal activation is reset toward a more physiological condition and diuretic efficacy is restored[3];
- Provides highly automated operation with only one setting required to begin;
- Utilizes a single-use, disposable auto-loading blood filter circuit that facilitates easy set-up;
- The console guides medical practitioner through the setup and operational process; and
- Decreased hospital readmissions and duration[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 system can only be used with the Aquadex Blood Set. The Aquadex Catheter is often used in conjunction with the Aquadex FlexFlow system, 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. Based on data from the National Health and Nutrition Examination Survey conducted by the Centers for Disease Control and Prevention/National Center for Health Statistics from 2011 to 2014, the American Heart Association estimates that 6.5 million people in the United States age 20 and over had heart failure[5]. Based on the Atherosclerosis Risk in Communities Study from 2005 to 2013, conducted by the National Heart, Lund and Blood Institute, there are an estimated 960,000 new heart failure cases annually[6]. Annual hospitalizations for heart failure exceed 1 million in both the United States and Europe, and more than 90% are due to symptoms and signs of fluid overload[7]. Congestive heart failure is the highest U.S. chronic health care expense category[8].

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.

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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 Benjamin EJ, al. on behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2017 update: a report from the American Heart Association. Circulation. 2017;135:00-00. (e378)

6 Benjamin EJ, al. on behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2017 update: a report from the American Heart Association. Circulation. 2017;135:00-00. (e378)

7 Costanzo MR, et al. *J Am Coll Cardiol.* 2017; 69: 2428-45.

8 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)

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[9]. 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[10]. 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%, while 78% of patients are admitted directly to the Emergency Department as the first point of care[11] [12].

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

1) **Inpatient Care—**Provided 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 system 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 left ventricle assist device, known as LVAD, programs. Our largest customer, Mount Sinai Hospital, represented 14.4% of our revenues in the year ended December 31, 2017. The loss of this customer would have a material adverse effect on us.

Our Strategy

Our mission is to predict, measure, and control patient fluid balance through science, collaboration, and innovative medical technology. We provide healthcare professionals with a sophisticated, yet easy to use, mechanical pump and filter system to remove excess fluid in fluid overloaded congestive heart failure patients and patients with related conditions. We believe that our technology will provide a competitive advantage in the fluid management market by providing improved clinical benefits and reducing the cost of care relative to other treatment alternatives.

Our strategic focus is to demonstrate a strong business model by driving revenue growth. Growing revenue is the key metric employees, shareholders and potential investors will use to judge our performance. In addition to revenues' contribution to funding operations, revenue growth demonstrates a workable business model and proves a successful business turn-around. Management has identified five critical actions to drive revenue: (i) commercial execution, (ii) enhance product offerings, (iii) demonstrate health economic advantages, (iv) provide important new clinical evidence, and (v) increase partnerships with key opinion leading physicians.

Commercial Execution Strategy – We have allocated, and plan to continue to allocate, resources to aggressively build sales and marketing strength and grow the worldwide market for the Aquadex FlexFlow system. In the third quarter of 2017, we increased our direct sales force by six employees and plan to further expand our direct sales force in 2018. Our trained sales team will focus on sales penetration in large hospital accounts. The Aquadex FlexFlow system can be used in a large hospital in multiple areas, including: the emergency

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

[10] ADHERE Scientific Advisory Committee. ADHERE Final Cumulative National Benchmark Report. Mountain View, CA: Scios Inc.; 2006.

[11] Centers for Medicare & Medicaid Services. Hospital Compare datasets. National Rate (READM_30_HF);3Q2011—2Q2014

[12] 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.

department, the heart failure telemetry floor, the intensive care unit, and the coronary care unit. In addition to expending our direct sales force, we are implementing high quality customer service support systems and technical servicing to increase support to customers. We have also initiated international distribution and support of our products by entering into a distribution and service provider agreement with APC Cardiovascular Ltd., a distributor based in the United Kingdom.

Enhance Product Offering Strategy – We intend to develop products and product enhancements to improve performance and customer satisfaction. We have several projects currently underway to enhance product performance. We plan to introduce a new peripheral access catheter and enhance the functionality of the hematocrit sensor that is part of the Aquadex FlexFlow system console. We also are working to identify or develop a diagnostic tool for physicians to use during an Aquapheresis therapy to more precisely determine the amount of excess fluid to be removed, the rate of ultrafiltration, and when to stop therapy as dry weight is approached.

Health Economics Strategy – We plan to develop new evidence regarding the economic impact of ultrafiltration on heart failure patients with fluid overload. We plan to publish information on the budgetary impacts to hospitals that adopt the Aquadex FlexFlow system into their continuum of care when treating critical heart failure patients with fluid overload in whom diuretic therapy has failed.

New Clinical Evidence Strategy – We plan to expand the body of clinical evidence for Aquapheresis and the Aquadex FlexFlow system to drive adoption and support reimbursement. We plan to initiate an ultrafiltration mechanism of action clinical study to provide scientific evidence that demonstrate that Aquadex effectively decongests patients without causing kidney injury and to provide hypotheses explaining reduced heart failure events following ultrafiltration.

Key Opinion Leaders Strategy – We plan to partner with key opinion leaders to advance medical understanding of the ultrafiltration as a therapy for treating fluid overload. We have recruited a scientific advisory board comprised of six key opinion leading physicians to help us develop and implement both the mechanistic clinical study and the registry. We are partnering with the Cardio Renal Society of America in a leadership role and increasing our involvement with the Heart Failure Society of America. In addition, we are working with several physicians that are implementing hospital observation unit use of the Aquadex FlexFlow system to provide outpatient care for patients that are fluid overloaded but may not require hospitalization.

Sales and Marketing

As of March 1, 2018, we had 19 full-time employees in sales and marketing. During the third quarter of 2017, we hired and trained six sales personnel with extensive medical device sales experience. 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 re-engaging hospital accounts that ordered Aquadex Blood Sets in prior years, re-educating customers on the therapy and assessing each hospital's use of the Aquadex FlexFlow system 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 patient educational 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 system patients 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 the Aquadex FlexFlow system.

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 CARRESS 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 CARRESS 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 CARRESS 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 CARRESS over 60 days and no differences were detected between the groups.

Disparate results between UNLOAD and CARRESS led to initiation of the AVOID-HF trial. AVOID-HF 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-HF 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-HF recapitulated the results of both UNLOAD and CARRESS while providing evidence that had AVOID-HF been followed to completion it would likely have met its primary endpoint of improved outcome in acute decompensated heart failure patients.

We anticipate conducting additional clinical studies to provide further evidence of the safety and effectiveness of the Aquadex FlexFlow system and to support obtaining a specific reimbursement code for Aquapheresis therapy.

Other uses of ultrafiltration with the Aquadex FlexFlow system have not been studied extensively. Case studies and case series demonstrating the use of ultrafiltration in the maintenance of outpatient 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, and testing improvements to the Aquadex FlexFlow system and potential related products. The Aquadex FlexFlow system 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. Research and development costs also include expenses related to clinical research. We may sponsor or conduct additional clinical research related to the Aquadex FlexFlow system to enhance understanding of the product and its use.

Manufacturers and Suppliers

In connection with the acquisition of the Aquadex Business, we entered into a commercial manufacturing and supply agreement with Baxter, which required Baxter to manufacture Aquadex Blood Sets and Aquadex Catheters for a period of 18 months following our acquisition of the Aquadex Business. In May 2017, we notified Baxter that we intended to have it cease the manufacturing Aquadex product effective as of June 30, 2017. We completed the transfer of manufacturing equipment for the Aquadex Business that we purchased from Baxter to our manufacturing facility in July 2017. We began manufacturing Aquadex FlexFlow products in-house in the fourth quarter of 2017. We continued to purchase raw materials and finished goods from an indirect subsidiary of Baxter until February 1, 2018.

Intellectual Property

We have established an intellectual property portfolio through which we seek to protect our system and technology. In connection with 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 system to make, have made, use, sell, offer for sale and import, the Aquadex FlexFlow system 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, have filed against us, or otherwise undertake any bankruptcy, reorganization, insolvency, moratorium, or other similar proceeding. 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.

In addition, as of December 31, 2017, we owned 40 issued patents and five pending patent applications in the United States and in foreign jurisdictions related to our C-Pulse System and had two 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 the Aquadex FlexFlow system, 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. 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 financial return. Even if issued, existing or future patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to obtain commercial benefits from them.

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 for the Aquadex FlexFlow system in the U.S., other than diuretics. Other systems, such as Baxter's Prismaflex, a filter-based device that is approved for continuous renal replacement therapy for patients weighing 20kg or more with acute renal failure and/or fluid overload, represent indirect competitors, as they can also be used to conduct ultrafiltration.

Our ability to compete effectively depends upon our ability to distinguish Aquadex FlexFlow system 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 products are 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, 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 system, a number of private insurers have approved reimbursement for Aquadex FlexFlow system use for specific indications and points of service. In addition, patients and providers may seek insurance coverage on a case-by-case basis.

We are exploring the ability to increase the range of coverage for uses of Aquadex FlexFlow therapies, such as use in the outpatient setting 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 that may impact payment rates for our system. 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 system was granted FDA 510(k) clearance for commercial use on June 3, 2002. Additional 510(k) clearances have been received for the Aquadex FlexFlow system in subsequent years.

Clinical Trials. To obtain FDA approval to market the C-Pulse System, clinical trials would be required to support a PMA application. We have halted clinical trials related to the C-Pulse System. 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 our 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 our other employees. Any such action by the FDA would have a material adverse effect on our business.

Employees

As of March 1, 2018, we had 46 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

CHF Solutions, 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 CHF Solutions, Inc. Our common stock began trading on the Nasdaq Capital Market (‘‘Nasdaq’’) on February 16, 2012.

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.chf-solutions.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.

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. A 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. We were an

‘‘emerging growth company’’ as defined in the Jumpstart our Business Startups Act of 2012 until the expiration of that status on December 31, 2017. We do not expect the expiration of our emerging growth company status to have a material impact on our business.

On June 1, 2017, we received a notification from Nasdaq informing us that we were no longer in compliance with the minimum bid price requirement, as the bid price of our shares of common stock closed below the minimum $1.00 per share for the 30 consecutive business days prior to the date of the notice. Nasdaq also notified us that we were provided 180 calendar days, or until November 28, 2017, to regain compliance with the minimum bid price requirement. Accordingly, on October 12, 2017, following stockholder approval on October 10, 2017, we implemented a 1-for-20 reverse split of our issued and outstanding shares of common stock. On October 27, 2017, we received formal notice from Nasdaq that we had regained compliance with the minimum $1.00 bid price requirement, as set forth in Nasdaq Listing Rule 5550(a)(2), and the matter is now closed. We cannot assure you that we will be able continue to meet the Nasdaq listing standards. If we do not continue to meet any of the Nasdaq listing standards, our common stock may be subject to delisting from Nasdaq.

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 system 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 system, 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 an effective 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 or marketing. If we are unsuccessful at manufacturing, marketing and selling our Aquadex FlexFlow system, 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, 2017 expresses substantial doubt about our ability to continue as a going concern.

We are an emerging company with a history of incurring net losses. We have incurred net losses since our inception, including net losses of $13.4 million and $15.8 million for the years ended December 31, 2017 and 2016, respectively. As of December 31, 2017, our accumulated deficit was $182.4 million.

The report of our independent registered public accounting firm issued in connection with its audit of our consolidated financial statements for the fiscal year ended December 31, 2017 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 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, 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 system. 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 system and related components. There can be no assurance that we will succeed in these activities, and we may never generate revenues sufficient to achieve profitability. If we do achieve profitability, we may not be able to sustain it.

We believe that we will need to raise additional capital to fund our operations beyond 2018. If additional capital is not available, we will have to delay, reduce or cease operations.

We believe that we will need to raise additional capital to fund our operations beyond 2018. Changing circumstances may cause us to consume capital significantly faster than we currently anticipate and could adversely affect our ability to raise additional capital. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. In addition, the risk that we may not be able to

continue as a going concern may make it more difficult to obtain necessary additional funding on terms favorable to us, or at all. If we raise additional funding through the issuance of equity securities, our stockholders may suffer dilution and our ability to use our net operating losses to offset future income may be limited. If we raise additional funding through debt financing, we may be required to accept terms that restrict our ability to incur additional indebtedness, require us to use our cash to make payments under such indebtedness, force us to maintain specified liquidity or other ratios or restrict our ability to pay dividends or make acquisitions. If we are unable to secure additional funding, our development programs and our commercialization efforts would be delayed, reduced or eliminated, our relationships with our suppliers and manufacturers may be harmed, and we may not be able to continue our operations.

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

Our near-term prospects are highly dependent on revenues from a single product, the Aquadex FlexFlow system, 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 system is limited and our success depends on our ability to increase adoption and utilization of the Aquadex FlexFlow system. 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 system 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 system 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. In addition, market acceptance of the Aquadex FlexFlow system may require that we make enhancements to the system or its components. We cannot be sure that we will be able to successfully develop such enhancements, or that if developed they will be viewed favorable by the market. Our ability to achieve acceptance of our Aquadex FlexFlow system 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 system to both the inpatient and outpatient markets and our potential revenues could be harmed.

We depend on a limited number of customers, the loss of which, or failure of which to order our products in a particular period, could cause our revenues to decline.

Our ten largest customers represented 50.9% of our revenues in the year ended December 31, 2017, with our largest customer representing 14.5% of our revenues during that period. Customer ordering patterns may vary significantly from quarter to quarter, or customers may discontinue providing therapies using our products. If one of our largest customers reduced its purchases in a fiscal period, our revenues for that period may be materially adversely affected. Further, if one of our largest customers discontinued the use of our products, our revenues may be materially adversely affected.

We do not have commercial manufacturing experience and could experience difficulty in producing commercial volumes of the Aquadex FlexFlow system and related components or may need to depend on third parties for manufacturing.

We have no experience in commercial manufacturing. In connection with the acquisition of the Aquadex Business, we entered into 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. In May 2017, we notified Baxter that we intended to have it cease the manufacturing Aquadex product effective as of June 30, 2017. We completed the transfer of manufacturing equipment for the Aquadex Business that we purchased from Baxter to our manufacturing facility in July 2017. We completed the first production units of both the Aquadex FlexFlow console and Aquadex Blood Set in the fourth quarter of 2017. Because we do not have prior commercial manufacturing experience, we may incur manufacturing inefficiencies, delays or interruptions. We may not be able to achieve low-cost manufacturing capabilities and processes that will enable us to manufacture the Aquadex FlexFlow system 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. If we experience difficulties with our 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, 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 system. We depend on our suppliers to provide us with materials in a timely manner that meet our 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 revenues will suffer.

Our strategy requires us to provide a significant amount of customer service, 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 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 system mainly competes against pharmacological therapies, diuretics, as well as a range of other specialized medical device companies with devices at varying stages of development. Many 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.

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 revenues.

Our business strategy depends in part on our ability to expand the use of the Aquadex FlexFlow system in the market as quickly as possible. To achieve expanded market use of the Aquadex FlexFlow system, we may develop enhancement to the system or its components. Depending on their nature, such enhancements may be subject to review by the U.S. Food and Drug Administration (the ''FDA'') under its regulations. Any regulatory delay in our ability to implement enhancements to the Aquadex FlexFlow system or its components could have an adverse effect on our potential revenues.

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 system and our ability to market our Aquadex FlexFlow system. 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 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 products are purchased primarily by customers, such as hospitals or other health care providers. Customers bill various third-party payers for covered Aquadex FlexFlow therapies 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, 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 system, a number of private insurers have approved reimbursement for Aquadex FlexFlow products for specific indications and points of service. In addition, patients and providers may seek insurance coverage on a case-by-case basis. We are exploring the ability to increase the range of coverage for uses of Aquadex FlexFlow therapies, 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.

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 applicable institutional review board (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, resulting in 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 system or any related components could result in significant costs, as well as negative publicity and damage to our reputation that could reduce demand for our products. Personal injuries relating to the use of our products could also result in product liability claims being brought against us. In some circumstances, such adverse events could also cause delays in new product approvals.

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 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 serviced 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 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 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 to comply with these requirements could prevent us from obtaining FDA approval of our products and from marketing such products in the United States. Our manufacturing facilities have not 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. 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 our facilities or the 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. Other countries may impose analogous reporting requirements that could cause us to incur expenses and may also limit our ability to generate revenues from 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. The medical device excise tax has been suspended in 2018 and 2019. If the excise tax is not repealed, we will be subject to this or any future excise tax on our sales of certain medical devices in the U.S. beginning January 1, 2020.

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 system may offer hospitals an economic benefit for using the device on a regular basis for in-patient or out-patient usage to avoid readmissions for heart failure; 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 have been 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 could incur additional impairment charges and 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 a potential acquisition, we may be required to capitalize a significant amount of intangibles, including goodwill. We would be required review our 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 addition, we would be required to evaluate goodwill for impairment annually, or to the extent events or conditions indicate a risk of possible impairment during the interim periods prior to its annual impairment test. In the year ended

December 31, 2017, we recognized impairment charges of $4.0 million related to goodwill and intangibles assets from our acquisition of the Aquadex Business. If we were required to recognize impairment charges related to future acquisitions, those charges 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 system and related components. 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 system to make, have made, use, sell, offer for sale and import, the Aquadex FlexFlow system 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. 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.

In addition, as of December 31, 2017, we owned 40 issued patents and 5 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 the Aquadex FlexFlow system, 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. 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 financial return. Even if issued, existing or future patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to obtain commercial benefits from them. 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. 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 FlexFlow products;

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

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

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

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

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

In the ordinary course of our business, we collect and store sensitive data, including legally protected health information, personally identifiable information, intellectual property and proprietary business information owned or controlled by ourselves or others. At times we may have access to limited amounts of protected health

information as part of other healthcare providers' provision of treatment to patients with our medical devices. We manage and maintain our applications and data utilizing on-site systems. These applications and data encompass a wide variety of business-critical information including research and development information, commercial information, and business and financial information. We face four primary risks relative to protecting this critical information, including: loss of access risk, inappropriate disclosure risk, inappropriate modification risk, and the risk of our being unable to adequately monitor our controls over the first three risks.

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

The number of shares of common stock underlying our outstanding warrants and outstanding preferred stock 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. As of March 16, 2018, we have warrants to purchase 8,522,684 shares of common stock outstanding, with exercise prices ranging from $4.50 to $3,132.00, with a weighted-average exercise price of $5.76. Through March 16, 2018, shares of our Series F Convertible Preferred Stock have been converted into 3,598,328 shares of our common stock. As of March 16, 2018, 1,864 shares of our Series F Convertible Preferred Stock remain outstanding and are currently convertible into 415,672 shares of our common stock. If the effective price per share on a common-stock equivalent basis in a future equity offering is lower than the then-current conversion price of the Series F Convertible Preferred Stock, then the such conversion price shall be reduced to such lower price and additional shares of common stock will be issuable upon the conversion of the of the Series F Convertible Preferred Stock. To the extent the outstanding shares of Series F Convertible Preferred Stock become exercisable for additional shares of common stock, holders of our common stock will experience further dilution.

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

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 June 1, 2017, we received a notification from Nasdaq informing us that we were no longer in compliance with the minimum bid price requirement, as the bid price of our shares of common stock closed below the minimum $1.00 per share for the 30 consecutive business days prior to the date of the notice. Nasdaq also notified us that we were provided 180 calendar days, or until November 28, 2017, to regain compliance with the minimum bid price requirement.

At a special meeting of our stockholders on October 10, 2017, our stockholders approved, among other things, a reverse stock split, and following such special meeting, our Board of Directors approved a 1-for-20 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 October 12, 2017, and the Company's common stock began trading on a split-adjusted basis on Nasdaq on October 13, 2017. On October 27, 2017, we received formal notice from Nasdaq that we had regained compliance with the minimum $1.00 bid price requirement, as set forth in Nasdaq Listing Rule 5550(a)(2), and the matter is now closed.

If, in the future, it appears to the Nasdaq staff that we will not meet the minimum bid price requirement or any other listing standard, our common stock may be subject to delisting from the Nasdaq market. If our common stock is delisted, Baxter, pursuant to the asset purchase agreement for the Aquadex Business, has the right to require us to repurchase, in cash, all or part of the common stock held by Baxter at a price equal to their fair market value, as determined by a third-party appraiser. In addition, our common stock would likely then trade only in the over-the-counter market. If our common stock were to trade on the over-the-counter market, selling our common stock could be more difficult because smaller quantities of shares would likely be bought and sold and transactions could be delayed, and we could face significant material adverse consequences, including:

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

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

In addition to the foregoing, if our common stock is delisted from Nasdaq and it trades on the over-the-counter market, the application of the ''penny stock'' rules could adversely affect the market price of our common stock and increase the transaction costs to sell those shares. The SEC has adopted regulations which generally define a ''penny stock'' as an equity security that has a market price of less than $5.00 per share, subject to specific exemptions. The closing price of our common stock on March 16, 2018 was $4.08. 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 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 1,864 shares of Series F Convertible Preferred Stock outstanding as of March 16, 2018. The rights, preferences and privileges of our Series F Convertible Preferred Stock are described in our Prospectus filed with the SEC on November 22, 2017. As described therein, upon liquidation, dissolution or winding-up of the Company, holders of our Series F Convertible Preferred Stock have the right to receive, out of the assets, whether capital or surplus, of the Company an amount equal to the par value, plus any accrued and unpaid dividends thereon, for each share of such 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. 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-20 reverse split of our issued and outstanding shares of common stock as of 5:00 p.m. Eastern Time on October 12, 2017, and our common stock began trading on a split-adjusted basis on Nasdaq on October 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. March 16, 2018, our certificate of incorporation provides for 100,000,000 shares of authorized common stock and 40,000,000 shares of authorized preferred stock, and we had 4,226,251 shares of common stock outstanding, 11,075,121 shares reserved for issuance upon the conversion, exercise or vesting of outstanding warrants, options and restricted stock units, and 395,345 shares of common stock reserved for future grant 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, which may make it difficult for you to resell sells of common stock at prices you find attractive, or at all.

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, 2017, we had U.S. net operating loss (''NOL'') carryforwards of approximately $120.2 million for U.S. income tax purposes, which expire from 2024 through 2037. 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. During 2017, we experienced an ownership change as defined in Section 382 of the Internal Revenue Code which will limit our ability to utilize the our NOLs. We may have experienced additional ownership changes in earlier years further limiting the NOL carry-forwards that may be utilized. We have not yet completed a formal Section 382 analysis. 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, 2017, 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 Nasdaq. 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 a ''smaller reporting company'' as defined by applicable SEC rules. 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. 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 our 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 66⅔% 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 a "smaller reporting company" under federal securities laws and we cannot be certain whether the reduced reporting requirements applicable to such companies will make our common stock less attractive to investors.

We are a ''smaller reporting company'' under federal securities laws. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies, including not being required to comply with the external auditor attestation requirements of Section 404 of SOX and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We will remain a smaller reporting company so long as our public float remains less than $75 million as of the last business day of our most recently-completed second fiscal quarter. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline or be more volatile.

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, including manufacturing. 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, where it now trades under the symbol ''CHFS.'' 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. During 2017, our board of directors and stockholders approved two reverse stock splits. The first reverse stock split was a 1-for-30 reverse split of our outstanding common stock that became effective after trading on January 12, 2017. The second reverse stock split was a 1-for-20 reverse split of our outstanding common stock that became effective after trading on October 12, 2017. All share and per-share amounts have been retroactively adjusted to reflect these reverse stock splits for all periods presented.

	High	Low
2016		
First Quarter	$786.08	$383.98
Second Quarter	$504.05	$252.63
Third Quarter	$810.08	$294.03
Fourth Quarter	$348.03	$ 94.27
2017		
First Quarter	$211.22	$ 34.80
Second Quarter	$ 40.80	$ 11.20
Third Quarter	$ 18.58	$ 11.40
Fourth Quarter	$ 16.50	$ 3.09
2018		
First Quarter (through March 16, 2018)	4.28	3.03

Stockholders of Record. As of March 16, 2018, we had 4,226,251 shares of common stock issued and outstanding, and there were 105 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 a medical device company focused on commercializing the Aquadex FlexFlow System for Aquapheresis therapy. 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 included 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.

On May 23, 2017, we announced that we were changing our name from Sunshine Heart, Inc. to CHF Solutions, Inc. to more appropriately reflect the direction of our business.

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 Nasdaq 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 Nasdaq. On November 21, 2016, Nasdaq informed us that the Panel had granted us continued listing on Nasdaq while we implemented 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 regained compliance with the minimum bid price rule. The Panel had granted us until March 20, 2017 to evidence compliance with the $2.5 million stockholder's equity requirement. On March 28, 2017, we announced that the Panel had granted us an extension through May 10, 2017 to evidence compliance with the minimum shareholder's equity requirement. On May 4, 2017, we were formally notified by Nasdaq that we had regained compliance with the minimum stockholders' equity requirement and we were in compliance with all other applicable requirements for listing on Nasdaq.

On June 1, 2017, we received a subsequent notification from Nasdaq informing us that we were no longer in compliance with the minimum bid price requirement, as the bid price of our shares of common stock (''Common Stock'') closed below the minimum $1.00 per share for the 30 consecutive business days prior to the date of the notice. Nasdaq also notified us that we were provided 180 calendar days, or until November 28, 2017, to regain

compliance with the minimum bid price requirement. We effected a 1-for-20 reverse split of our outstanding common stock that became effective after trading on October 12, 2017. After implementing the reverse stock split described below, we received confirmation from Nasdaq on October 27, 2017, that we had regained compliance with the minimum bid price rule and the listing matter was closed.

Reverse Stock Splits

During 2017, our board of directors and stockholders approved two reverse stock splits. Neither reverse stock split changed the par value of our common stock or the number of common or preferred shares authorized by the Company's Fourth Amended and Restated Certificate of Incorporation. The first reverse stock split was a 1-for-30 reverse split of our outstanding common stock that became effective after trading on January 12, 2017. The second reverse stock split was a 1-for-20 reverse split of our outstanding common stock that became effective after trading on October 12, 2017. All share and per share amounts in this Annual Report on Form 10-K for the years ended December 31, 2017 and 2016, including the consolidated financial statements and notes thereto, have been retroactively adjusted to reflect the reverse stock splits for all periods presented.

Public Offerings

On April 24, 2017, we closed on an underwritten public offering of 140,000 shares of common stock, 6,400 shares of Series E Convertible Preferred Stock and warrants to purchase 460,000 shares of common stock, which included the full exercise of the underwriter's over-allotment option to purchase additional shares and warrants, for gross proceeds of $9.2 million. Net proceeds totaled approximately $8.0 million after deducting the underwriting discounts and commissions and other costs associated with the offering. On November 27, 2017, we closed on an additional underwritten public offering of 18,000 shares of Series F Convertible Preferred Stock and warrants to purchase approximately 8.0 million shares of common stock, for gross proceeds of $18.0 million. Net proceeds totaled approximately $16.2 million after deducting the underwriting discounts and commissions and other costs associated with the offering. See Note 6 to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Warrant Exercise Agreement

On February 15, 2017, we entered into a letter agreement with the institutional investors that held the majority of our outstanding warrants (the ''Original Warrants''), to incent the cash exercise of these warrants on or before March 31, 2017. 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 are in the same form as the exercised warrants except the exercise prices are not subject to reduction for subsequent equity issuances and the Replacement Warrants do not allow the investor to demand that we purchase the Replacement Warrants in the event of a fundamental transaction involving the Company. In connection with this agreement, the investors exercised all Original Warrants for gross cash proceeds to us of $2.0 million, and we issued 43,396 Replacement Warrants with exercise prices ranging from $34.6 per share to $99.8 per share.

We entered into the letter agreement with the investors to incent the exercise of the Original Warrants in order to receive the cash proceeds from the exercise of the Original Warrants and because the exercise of the Original Warrants would allow us to remove the warrant liability from our balance sheet and avoid future fair value adjustments and associated volatility in our consolidated financial statements. As of December 31, 2017, we had no Original Warrants outstanding and we had issued all Replacement Warrants under the letter agreement.

Critical Accounting Policies and Estimates

We have adopted various accounting policies to prepare the consolidated financial statements in accordance with accounting principles generally accepted in the United States (U.S. GAAP). Our most significant accounting policies are disclosed in Note 1 to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K.

The preparation of the consolidated financial statements, in conformity with U.S. GAAP, requires us to make estimates and assumptions that affect the amounts reported in the 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 generally 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, 2017 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, raw materials and subassemblies and are recorded as the lower of cost or market using the first-in, first out method.

Intangible assets

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, and the carrying amount is not considered recoverable, the carrying value is written down to its fair value, generally using a discounted cash flow analysis. An impairment loss is recognized for the amount that the intangible assets exceeds their fair value, generally based on discounted cash flow methods and other fair market value indicators. Our review of our intangible assets during the year ended December 31, 2017, resulted in impairment charges related to our finite-lived intangible assets, which are described in Note 4 to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

The impairment charges were based on fair values determined using market value indicators such as the quoted market prices of our common stock on Nasdaq, as well discounted cash flow models. Discounted cash flow models include assumptions related to our product revenue, gross margins, and operating margins, under varying assumptions about our ability to either achieve profitability or obtain the necessary financings to materialize such projections. As discussed below, we became a revenue generating company after acquiring the Aquadex Business in August 2016 and we expect to incur losses in the near-term as we grow the Aquadex Business. To become and remain profitable, and to generate cash flows from our operations, we must succeed in expanding the adoption and market acceptance of our products. This will require us to succeed in training personnel at hospitals and in effectively and efficiently manufacturing, marketing, and distributing our products. There can be no assurance that we will succeed in these activities, and we may never generate revenues sufficient to achieve profitability or positive cash flows. The discounted cash flow models reflect these uncertainties by assigning future cash flow estimation probability factors and an overall discount rate of 30%.

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. As described in Note 1 to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K, we early adopted Accounting Standards Update No, 2017-04, *Simplifying the Test for Goodwill*

Impairment, and performed a single step in performing our impairment analysis, which is to determine the estimated fair value of our reporting unit and compare it to the carrying value of the reporting unit, including goodwill. To the extent the carrying amount of goodwill exceeds the implied goodwill, the difference is the amount of the goodwill impairment. Our annual impairment test as of November 1, 2018, resulted in $0.2 million of impairment charges related to our goodwill.

The impairment charge was generally based on fair values determined using market value indicators such as the quoted market prices of our common stock on Nasdaq, and discounted cash flow models. Discounted cash flow models include assumptions related to our product revenue, gross margins, and operating margins, under different assumptions about our ability to either achieve profitability or obtain the necessary financings to materialize such projections. As discussed below, we became a revenue generating company after acquiring the Aquadex Business in August 2016 and we expect to incur losses in the near-term as we grow the Aquadex Business. To become and remain profitable, and to generate cash flows from our operations, we must succeed in expanding the adoption and market acceptance of our products. This will require us to succeed in training personnel at hospitals and effectively and efficiently manufacturing, marketing and distributing our products. There can be no assurance that we will succeed in these activities, and we may never generate revenues sufficient to achieve profitability or positive cash flows. We applied a discount rate of 30% to these probability-weighted cash flows to arrive to a fair value indicator of goodwill.

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 (see Note 8 to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K). 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.

Loss per share

We compute basic loss 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 for the year ended December 31, 2017, reflects increases for net deemed dividends to preferred stockholders provided in connection with the close of the public offering of Series E Convertible Preferred Stock in April of

2017, and the close of the public offering of Series F Convertible Preferred Stock in November of 2017, of $1.0 million and $8.7 million, respectively, representing the intrinsic value of the shares at the time of issuance. In addition, the net loss allocable to common stockholders reflects an increase for net deemed dividends of $1.8 million to preferred stockholders provided in connection with the shareholder approval of the Series C and D Convertible Preferred Stock transactions in January of 2017, representing the intrinsic value of the shares at the time of issuance. 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, 2017 and 2016, 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 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.

On April 24, 2017, we closed on an underwritten public equity offering for net proceeds of approximately $8.0 million after deducting the underwriting discounts and commissions and other costs associated with the offering. In addition, on November 27, 2017, we closed on a subsequent underwritten public equity offering for net proceeds of approximately $16.2 million after deducting the underwriting discounts and commissions and other costs associated with the offering. We may be required to seek additional funding to grow our Aquadex Business, which may not be available on terms favorable to us, or at all. We may receive those funds from the proceeds from future warrant exercises, issuances of equity securities, or other financing transactions. Should warrant exercises not materialize or future capital raising be unsuccessful, we may not be able to continue as a going concern. We have made no adjustments 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.

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 ‘‘smaller reporting company’’ under the rules of the SEC. 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 March 2016, the Financial Accounting Standards Board (FASB), issued amended stock compensation guidance to simplify various aspects of employee share-based payments accounting and presentation in the financial statements. The new guidance requires all income tax effects of awards to be recognized in the income statement when the awards vest or are settled, allows an employer to repurchase more of an employee’s shares than previously allowed for tax withholding purposes without triggering liability accounting, allows a company to make a policy election to account for forfeitures as they occur, and eliminates the requirement that excess tax benefits be realized before companies can recognize them. The new guidance also requires excess tax benefits and tax shortfalls to be presented on the cash flow statement as an operating activity rather than as a financing

activity, and clarifies that cash paid to a tax authority when shares are withheld to satisfy its statutory income tax withholding obligation are to be presented as a financing activity. The standard was effective for our interim and annual periods beginning after January 1, 2017. We adopted the guidance in the current year. The adoption of this standard did not have a material impact to our consolidated financial statements.

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. We adopted this standard in the first quarter of 2017 with no impact to our consolidated financial statements as all net deferred tax assets are fully reserved.

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 us to transition to the new model using either a full or modified retrospective approach. We have determined that we will use the modified retrospective approach. This guidance is effective for our interim and annual periods beginning January 1, 2018. As of the end of the fourth quarter of 2017, we have nearly completed our assessment of the amended guidance and we don't expect that the adoption of this standard will not have a material impact on the timing and amount of revenue recognized, but expect to provide expanded disclosures as a result of the adoption. We will continue to evaluate the impact of the amended guidance as it pertains to presentation and disclosure.

In January 2017, the FASB issued amended guidance to simplify the accounting for goodwill impairment by removing Step 2 of the goodwill impairment test. A goodwill impairment will now be measured as the amount by which a reporting unit's carrying value exceeds its fair value, limited to the amount of goodwill allocated to that reporting unit. This guidance is to be applied on a prospective basis effective for our interim and annual periods beginning after January 1, 2019, with early adoption permitted for any impairment tests performed after January 1, 2017. We adopted this guidance in the current year, as further described above under Critical Accounting Policies and Estimates.

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 our annual reporting period beginning January 1, 2019, and for interim periods beginning January 1, 2020. We are evaluating the impact that the adoption of this standard will have, if any, on our financial statements and disclosures.

Financial Overview

We are a medical device company focused on commercializing the Aquadex FlexFlow system for ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy. Activities since inception have consisted principally of raising capital, performing research and development and conducting preclinical and clinical studies. During 2016, we acquired the Aquadex Business and announced that we were halting all clinical evaluations of our prior technology, the C-Pulse System. Since then, our activities have consisted mainly of expanding our sales and marketing capabilities and transferring manufacturing capabilities from Baxter to our facilities in Eden Prairie, Minnesota. At December 31, 2017, we had an accumulated deficit of $182.4 million and we expect to incur losses for the foreseeable future. To date, we have been funded by public and private equity financings, and debt. Although we believe that we will be able to successfully fund our operations in the future, 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, 2017	Year Ended December 31, 2016	Increase (Decrease)	% Change
$3,553	$1,289	$2,264	175.64%

Revenue is generated mainly from the sale of disposable blood filters and catheters used in conjunction with our Aquadex consoles. We had no commercial sales prior to the acquisition of the Aquadex Business, which we acquired from Baxter on August 5, 2016. The transaction and pro forma results are further described in Note 2 to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

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 it 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 twelve months ended December 31, 2016, we received reimbursement and recognized $59,000 in revenue for one implant that was performed before the announcement that we were no longer enrolling patients in the study. Since we terminated enrollment in our OPTIONS HF and COUNTER HF clinical trials, we do not expect to generate revenue from those clinical trials in the foreseeable future.

Costs and Expenses

Our costs and expenses were as follows:

(dollars in thousands)	Year Ended December 31, 2017	Year Ended December 31, 2016	Increase (Decrease)	% Change
Cost of goods sold	$ 2,763	$ 713	$ 2,050	287.52%
Selling, general and administrative	$10,170	$8,129	$ 2,041	25.11%
Research and development	$ 1,481	$8,109	$(6,628)	(81.74)%
Goodwill and intangibles impairment	$ 3,951	$ —	$ 3,951	N/A%

Cost of Goods Sold

In connection with the acquisition of the Aquadex product line, 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. The acquisition closed on August 5, 2016. Prior to that date, we did not have commercial sales or related product costs.

In May 2017, we provided notice to Baxter to cease the manufacturing of the Aquadex product line as of June 30, 2017, and we began transitioning activities in house. We began manufacturing our products in house in the fourth quarter of 2017 and will continue to purchase materials and finished goods from Baxter until February 1, 2018.

Cost of sales for the twelve months ended December 31, 2017, include startup costs for the planning and preparation associated with the transfer of these manufacturing activities to our facilities in Eden Prairie, Minnesota. In 2018, we expect our gross margins to improve as we transition to selling internally manufactured inventory, and as volumes increase and we achieve larger efficiencies of scale.

Selling, General and Administrative

The increase 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, during the twelve months ended December 31, 2017, we incurred approximately $3.2 million of incremental expenses related to the commercialization of the Aquadex FlexFlow, compared to the same period a year ago.

Expenditures for the year ended December 31, 2016, reflect approximately $0.9 million in transaction fees (accounting, audit, valuation, and legal fees) incurred in connection with the acquisition of the Aquadex Business in August of 2016.

As we continue to ramp up our sales organization we expect that our selling expenses will continue to increase in future quarters, and that general and administrative expenses will either remain constant or decrease as we continue to streamline activities.

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 included halting clinical evaluations of the neuromodulation technology to fully focus the Company's resources on our recently acquired Aquadex system. We expect to make future investments in development activities related to our Aquadex system, and as a result, we expect that our research and development expenditures will increase in future quarters.

Goodwill and Intangibles Impairment

Impairment charges include $3.8 million related to our identifiable intangible assets, including customer relationships, developed technology, and trademarks and tradenames, as well as $0.2 million related to goodwill. A discussion of our impairment testing methodology and assumptions are included above under Critical Accounting Policies and Estimates.

Other Income (Expense)

The following is a summary of other income (expense)

(dollars in thousands)	Year Ended December 31, 2017	Year Ended December 31, 2016	Increase (Decrease)	% Change
Interest expense	$ —	$(504)	$(504)	(100.0)%
Loss on early retirement of long term debt	$ —	$(500)	$(500)	(100.0)%
Change in fair value of warrant liability	$1,475	$ 818	$ 657	80.32%
Warrant valuation expense	$ (67)	$ —	67	N/A%

Interest Expense

The decrease in interest expense is related to the repayment of borrowings outstanding under our prior term loan with Silicon Valley Bank. Beginning January 1, 2016, we began repaying the principal due on this loan, and 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

The gain recognized for the change in fair value of warrant liability relates to the decrease in value of the warrants issued in connection with financings completed on July 26, 2016, November 3, 2016, and January 10, 2017. These warrants were classified as liabilities on our consolidated balance sheet as of December 31, 2016 and were required to be marked to market at each reporting period, with the changes in fair value recorded on our consolidated statement of operations. All Original Warrants were exercised during the year ended December 31, 2017 pursuant to the warrant exercise agreement described above. Accordingly, we remeasured each of these warrants as of the date of exercise and recorded $1.5 million as an unrealized gain on our statement of operations. Although we issued Replacement Warrants under the warrant exercise agreement, the Replacement Warrants are not accounted for as liabilities based on their terms.

Income tax benefit (expense), net

(dollars in thousands)	Year Ended December 31, 2017	Year Ended December 31, 2016	Increase (Decrease)	% Change
Income tax benefit (expense), net	$(6)	$54	$(60)	(111.11)%

Our income tax benefit for the year ended December 31, 2016 resulted mainly from research and development tax credits in Australia. During 2017, we eliminated research and development expenditures in Australia, and therefore are not eligible for refunds, 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 pursuant to which we agreed to issue 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 in January 2017, 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.

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. In exchange for any such exercise, we agreed to provide the investors a replacement warrant to purchase the same number of shares of common stock as were issued upon exercise of each exercised warrants with an exercise price equal to the consolidated closing bid price of our common stock on the date of issuance. In connection with this agreement, the investors exercised all of the original warrants for gross cash proceeds to us of $2.0 million, and we issued 43,396 replacement warrants with exercise prices ranging from $34.6 per share to $99.8 per share.

On April 24, 2017, we closed on an underwritten public offering for net proceeds of approximately $8.0 million after deducting the underwriting discounts and commissions and other costs associated with the offering, which included the full exercise of the underwriter's over-allotment option to purchase additional shares and warrants. In connection with this offering, we issued a total of 140,000 shares of common stock, 6,400 shares of Series E Convertible Preferred Stock (which were convertible into 320,000 shares of common stock) and warrants to purchase 460,000 shares of common stock. On November 27, 2017, we closed on another underwritten public offering for net proceeds of approximately $16.2 million after deducting the underwriting discounts and commissions and other costs associated with the offering. In connection with this offering we issued 18,000 shares of Series F Convertible Preferred stock (which were convertible into approximately 4.0 million shares of common stock) and warrants to purchase approximately 8.0 million shares of common stock. See Note 6 to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K.

On August 5, 2016, we entered into a 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 and the term loan is no longer available to be drawn. Under the revolving line, we may borrow the lesser of $1 million or 80% of our eligible accounts (subject to customary exclusions), minus the outstanding principal balance of any advances under the revolving line. Advances under the revolving line, if any, will accrue interest at a floating per annum rate equal to 1.75% or 1.0% above the prime rate, depending on liquidity factors. The loan agreement contains customary representations, as well as customary affirmative and negative covenants. Our obligations under the new loan agreement are secured by a security interest in our assets, excluding intellectual property and certain other exceptions. We are subject to a negative pledge covenant with respect to our intellectual property. Advances under the revolving line are subject to various conditions precedent, including our compliance with financial covenants relating to net liquidity relative to monthly cash burn. The revolving line of credit expires on March 31, 2020. We had no borrowings outstanding under the Silicon Valley Bank facility as of December 31, 2017 or 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. There were no issuances of common stock under this facility during years ended December 31, 2017 or 2016. As of December 31, 2017, we had a total of $32.6 million remaining for future sales under the Sales Agreement.

As of December 31, 2017, and 2016, cash and cash equivalents were $15.6 million and $1.3 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 we will need additional funds to finance our operations in the future, which we may receive from the proceeds from future warrant exercises, issuances of equity securities, or other financing transactions.

Cash Flows from Operating Activities

Net cash used in operating activities was $11.9 million and $16.3 million in 2017 and 2016, respectively. The net cash used in each of these periods primarily reflects the net loss for those periods, offset in part by non-cash items such as the impairment of intangible assets and goodwill, stock-based compensation, depreciation and amortization expense, amortization of debt discount and financing fees, and 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 $0.3 million and $4.1 million in 2017 and 2016, respectively. In 2017, we invested primarily in the purchase of laboratory and office equipment. In 2016, we paid $4.0 million for the acquisition of the Aquadex Business.

Cash Flows from Financing Activities

Net cash provided by (used in) financing activities was $26.5 million and $(1.4) million in 2017 and 2016, respectively. Net cash provided by financing activities in 2017 was attributable to proceeds from the public stock offerings completed in April 2017 and November 2017, the net proceeds from the exercise of warrants, and from the second closing of the Series D Convertible Preferred Stock in January 2017. 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.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2017, which represent material expected or contractually committed future obligations:

	Payments Due by Period				
(dollars in thousands)	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**	**Total**
Operating Leases	$212	$67	$—	$—	$279
Total	$212	$67	$—	$—	$279

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, 2017, 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 Nasdaq, 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 was to expire within a period not to exceed 18 months from the close of the transaction. In May 2017, we notified Baxter to cease the manufacturing of the Aquadex product line as of June 30, 2017. In connection with this notification, we agreed to purchase the remaining Aquadex inventory, which consists mainly of raw materials priced at cost, through February 2018, for a total of $2.4 million. As of December 31, 2017, we had purchased and paid $1.2 million of this inventory and $1.2 million remained to be purchased.

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.

Reports of Independent Registered Public Accounting Firms

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the board of directors of CHF Solutions, Inc.:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of CHF Solutions, Inc. and subsidiaries (the ''Company'') as of December 31, 2017, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows, for the year then ended, and the related notes (collectively referred to as the ''financial statements''). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017, and the results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

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, an accumulated deficit, expects to incur losses for the foreseeable future and needs additional working capital. These are the reasons that raise substantial doubt about their 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.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (''PCAOB'') and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting 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.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Baker Tilly Virchow Krause, LLP

We have served as the Company's auditor since 2017.

Minneapolis, Minnesota

March 22, 2018

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders
CHF Solutions, Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of CHF Solutions, Inc. and subsidiaries (the Company) as of December 31, 2016, and the related consolidated statement of operations and comprehensive loss, shareholders' equity, and cash flows for the year 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 CHF Solutions, Inc. and subsidiaries at December 31, 2016, and the consolidated results of their operations and their cash flows for the year 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 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, except for the reverse stock split disclosed in Note 1, as to which the date is March 22, 2018

CHF SOLUTIONS, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	December 31, 2017	December 31, 2016
ASSETS		
Current assets		
Cash and cash equivalents	$ 15,595	$ 1,323
Accounts receivable	545	282
Inventories	1,588	677
Other current assets	136	137
Total current assets	17,864	2,419
Property, plant and equipment, net	570	540
Intangible assets, net	—	4,302
Goodwill	—	189
Other assets	21	21
TOTAL ASSETS	$ 18,455	$ 7,471
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 862	$ 1,987
Accrued compensation	1,021	909
Other current liabilities	208	364
Total current liabilities	2,091	3,260
Common stock warrant liability	—	1,843
Other liabilities	126	126
Total liabilities	2,217	5,229
Commitments and contingencies	—	—
Temporary Stockholders' Equity		
Series D convertible preferred stock as of December 31, 2017 and December 31, 2016, par value $0.0001 per share; authorized 0 and 900 shares, respectively, issued and outstanding 0 and 700, respectively	—	485
Stockholders' equity		
Series A junior participating preferred stock as of December 31, 2017 and December 31, 2016, par value $0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Series B-1 convertible preferred stock as of December 31, 2017 and December 31, 2016, par value $0.0001 per share; authorized 0 and 1,824.4 shares, respectively, issued and outstanding 0 and 1,824.4, respectively	—	—
Series C convertible preferred stock as of December 31, 2017 and December 31, 2016, par value $0.0001 per share; authorized 0 and 2,900 shares, respectively, issued and outstanding 0 and 2,900, respectively	—	—
Series F convertible preferred stock as of December 31, 2017 and December 31, 2016, par value $0.0001 per share; authorized 3,780 and 0 shares, respectively, issued and outstanding 3,780 and 0, respectively	—	—
Preferred stock as of December 31, 2017 and December 31, 2016, par value $0.0001 per share; authorized 39,966,220 and 39,964,375.6 shares, respectively, none outstanding	—	—
Common stock as of December 31, 2017 and December 31, 2016, par value $0.0001 per share; authorized 100,000,000 shares, issued and outstanding 3,798,929 and 38,862, respectively	—	—
Additional paid-in capital	197,367	169,496
Accumulated other comprehensive income:		
Foreign currency translation adjustment	1,227	1,235
Accumulated deficit	(182,356)	(168,974)
Total stockholders' equity	16,238	1,757
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 18,455	$ 7,471

See notes to the consolidated financial statements

CHF SOLUTIONS, INC. AND SUBSIDIARIES

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

	Year Ended December 31,	
	2017	**2016**
Net sales	**$** 3,553	$ 1,289
Costs and Expenses:		
Cost of goods sold	2,763	713
Selling, general and administrative	10,170	8,129
Research and development	1,481	8,109
Goodwill and intangibles impairment	3,951	—
Total costs and expenses	18,365	16,951
Loss from operations	(14,812)	(15,662)
Other income (expense):		
Interest expense	—	(504)
Loss on early retirement of long-term debt	—	(500)
Other income, net	28	2
Warrant valuation expense	(67)	—
Change in fair value of warrant liability	1,475	818
Total other income (expense)	1,436	(184)
Loss before income taxes	(13,376)	(15,846)
Income tax (expense) benefit, net	(6)	54
Net loss	$(13,382)	$(15,792)
Basic and diluted loss per share	$ (37.51)	$(536.12)
Weighted average shares outstanding – basic and diluted	665	33
Other comprehensive income:		
Foreign currency translation adjustment	$ (8)	$ (11)
Total comprehensive loss	$(13,390)	$(15,803)

See notes to the consolidated financial statements

CHF SOLUTIONS, INC. AND SUBSIDIARIES

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

In thousands	Outstanding Shares of Common Stock	Common Stock	Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Equity
Balance December 31, 2015	**30,574**	**$—**	**$164,107**	**$1,246**	**$(153,182)**	**$ 12,171**
Net loss	—	—	—	—	(15,792)	(15,792)
Foreign currency translation adjustment	—	—	—	(11)	—	(11)
Stock based compensation, net	472	—	949	—	—	949
Issuance of preferred stock, net	—	—	4,440	—	—	4,440
Issuance of common stock for acquisition	1,667	—	—	—	—	—
Conversion of preferred stock into common stock	6,149	—	—	—	—	—
Balance December 31, 2016	**38,862**	**$—**	**$169,496**	**$1,235**	**$(168,974)**	**$ 1,757**
Net loss	—	—	—	—	(13,382)	(13,382)
Foreign currency translation adjustment	—	—	—	(8)	—	(8)
Stock based compensation, net	375	—	499	—	—	499
Issuance of common stock, net	194,794	—	5,399	—	—	5,399
Issuance of preferred stock, net	—	—	21,973	—	—	21,973
Conversion of preferred stock into common stock	3,564,898	—	—	—	—	—
Balance December 31, 2017	**3,798,929**	**$—**	**$197,367**	**$1,227**	**$(182,356)**	**$ 16,238**

See notes to the consolidated financial statements

CHF SOLUTIONS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows
(In thousands)

In thousands	For the years ended December 31, 2017	2016
Operating Activities		
Net loss	$(13,382)	$(15,792)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	769	697
Stock based compensation expense, net	499	949
Amortization of debt discount and financing fees	—	187
Goodwill and intangibles impairment	3,951	—
Loss on retirement of long-term debt	—	500
Change in fair value of warrant liability	(1,475)	(818)
Warrant valuation expense	67	—
Changes in assets and liabilities:		
Accounts receivable	(263)	(282)
Inventory	(911)	(677)
Other current assets	1	342
Other assets and liabilities	—	(464)
Accounts payable and accrued expenses	(1,176)	(934)
Net cash used in operations	(11,920)	(16,292)
Investing activities:		
Purchase of property and equipment	(259)	(117)
Purchase of Aquadex product line	—	(4,000)
Net cash used in investing activities	(259)	(4,117)
Financing activities:		
Net proceeds from public stock offerings	24,281	—
Net proceeds from exercise of warrants	1,989	—
Net proceeds from the sale of preferred stock, common stock and warrants	184	6,636
Repayments of long-term debt	—	(8,000)
Net cash provided by (used in) financing activities	26,454	(1,364)
Effect of exchange rate changes on cash	(3)	(17)
Net increase (decrease) in cash and cash equivalents	14,272	(21,790)
Cash and cash equivalents—beginning of period	1,323	23,113
Cash and cash equivalents—end of period	$ 15,595	$ 1,323
Supplemental schedule of non-cash activities		
Warrants issued as inducement to warrant exercise	$ 509	$ —
Conversion of temporary equity to permanent equity	$ 485	$ —
Common stock issued for business acquisition	$ —	$ 950
Supplemental cash flow information		
Interest paid on debt borrowings	$ —	$ 840
Cash paid for income taxes	$ 6	$ 47

See notes to the consolidated financial statements

Note 1—Nature of Business and Significant Accounting Policies

Nature of Business

CHF Solutions, Inc. (the ''Company'') is a medical device company focused on commercializing the Aquadex FlexFlow® System for Aquapheresis® therapy. 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. CHF Solutions, Inc. is a Delaware corporation headquartered in Minneapolis with wholly owned subsidiaries in Australia, Ireland and Delaware. The Company has been listed on Nasdaq 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 (herein referred to as the ''Aquadex Business.'') 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, and reviewing potential strategic alliances and financing alternatives. On May 23, 2017, the Company announced it was changing its name from Sunshine Heart, Inc. to CHF Solutions, Inc. to more appropriately reflect the direction of its business.

During 2017, the Company's board of directors and stockholders approved two reverse stock splits (together, the Reverse Stock Splits). Neither reverse stock split changed the par value of the Company's common stock or the number of common or preferred shares authorized by the Company's Fourth Amended and Restated Certificate of Incorporation. The first reverse stock split was a 1-for-30 reverse split of the Company's outstanding common stock that became effective after trading on January 12, 2017. The second reverse stock split was a 1-for-20 reverse split of the Company's outstanding common stock that became effective after trading on October 12, 2017. All share and per-share amounts have been retroactively adjusted to reflect the Reverse Stock Splits 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, 2017 and 2016, 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, 2017, the Company had an accumulated deficit of $182.4 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. These factors raise substantial doubt about the Company's ability to continue as a going concern through at least twelve months from the report date.

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.

On April 24, 2017, the Company closed on an underwritten public equity offering for net proceeds of approximately $8.0 million after deducting the underwriting discounts and commissions and other costs associated with the offering. In addition, on November 27, 2017, the Company closed on a subsequent underwritten public equity offering for net proceeds of approximately $16.2 million after deducting the underwriting discounts and commissions and other costs associated with the offering (see Note 6 - Equity). The Company may require additional funding to grow its Aquadex Business, which may not be available on terms favorable to the Company, or at all. The Company may receive those funds from the proceeds from future warrant exercises, issuances of equity securities, or other financing transactions. Should warrant exercises not materialize or future capital raising be unsuccessful, the Company may not be able 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 CHF Solutions, Inc. and its wholly owned subsidiaries, CHF Solutions, LLC, Sunshine Heart Company Pty Limited, and Sunshine Heart Ireland Limited. All intercompany 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, 2017 or 2016.

Inventories

Inventories are recorded as the lower of cost or market using the first-in, first out method. Inventories consisted of the following as of December 31 (in thousands):

	2017	2016
Finished Goods	$ 902	$644
Work in Process	217	—
Raw Materials	469	33
Total	$1,588	$677

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 was $229,000 and $419,000 for the years ended December 31, 2017, and 2016, 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. The Company reviewed its property and equipment in conjunction with its intangible asset impairment analysis and determined that the fair value of property and equipment equaled or exceeded its carrying value. As a result, there have been no impairment losses recognized for the years ended December 31, 2017 or 2016.

Intangible assets

The Company's intangible assets consisted of customer relationships, developed technology, and trademarks and tradenames. All intangible assets recognized by the Company resulted from the acquisition of the Aquadex Business. All intangible assets were estimated to have a useful life of 7 years. The Company reviews its definite lived intangible assets for impairment when impairment indicators exist. When impairment indicators exist, the Company determines 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, and the carrying amount is not considered recoverable, the carrying value is written down to its fair value, generally using a discounted cash flow analysis. An impairment loss is recognized for the amount that the intangible assets exceeds their fair value, generally based on discounted cash flow methods and other fair market value indicators. The Company's review of its intangible assets during the year ended December 31, 2017, resulted in $3.8 million of impairment charges related to its finite-lived intangible assets.

The Company has a single reporting unit. The impairment charges were based on fair values determined using market value indicators such as the quoted market prices of the Company's common stock on Nasdaq, as well discounted cash flow models. Discounted cash flow models include assumptions related to the Company's product revenue, gross margins, and operating margins, under varying assumptions about the Company's ability to either achieve profitability or obtain the necessary financings to realize such projections. As discussed above, the Company became a revenue generating company after acquiring the Aquadex Business in August 2016 and expects to incur losses in the near-term as it grows the Aquadex Business. To become and remain profitable, and to generate cash flows from operations, the Company must succeed in expanding the adoption and market acceptance of its products. This will require that the Company succeed in training personnel at hospitals and in effectively and efficiently manufacturing, marketing, and distributing its products. There can be no assurance that the Company will succeed in these activities, and it may never generate revenues sufficient to achieve

profitability or positive cash flows. The discounted cash flow models reflect these uncertainties by assigning future cash flow estimations probability factors and an overall discount rate of 30%.

Amortization expense was $540,000 and $278,000 for the years ended December 31, 2017 and 2016, 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. As described below, the Company early adopted Accounting Standards Update No, 2017-04, *Simplifying the Test for Goodwill Impairment*, and performed a single step in performing its impairment analysis, which is to determine the estimated fair value of its reporting unit and compare it to the carrying value of the reporting unit, including goodwill. 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. The Company's annual impairment test on November 1, 2018, resulted in $0.2 million of impairment charges related to goodwill.

The Company has a single reporting unit. The impairment charge was based on fair values determined using market value indicators such as the quoted market prices of the Company's common stock on Nasdaq, as well discounted cash flow models. Discounted cash flow models include assumptions related to the Company's product revenue, gross margins, and operating margins, under varying assumptions about the Company's ability to either achieve profitability or obtain the necessary financings to realize such projections. As discussed above, the Company became a revenue generating company after acquiring the Aquadex Business in August 2016 and expects to incur losses in the near-term as it grows the Aquadex Business. To become and remain profitable, and to generate cash flows from operations, the Company must succeed in expanding the adoption and market acceptance of its products. This will require that the Company succeed in training personnel at hospitals and in effectively and efficiently manufacturing, marketing, and distributing its products. There can be no assurance that the Company will succeed in these activities, and it may never generate revenues sufficient to achieve profitability or positive cash flows. The discounted cash flow models reflect these uncertainties by assigning future cash flow estimations probability factors and an overall discount rate of 30%.

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 recorded 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 generally 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 7- Stock Based Compensation, 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 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. On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (Tax Reform Act) was signed into law making significant changes to the Internal Revenue Code. Changes include a reduction in the corporate tax rates, changes to operating loss carry-forwards and carrybacks, and a repeal of the corporate alternative minimum tax. The legislation reduces the U.S. corporate income tax rates from 34% to 21%. As a result of the enacted law, the Company is required to revalue its deferred tax assets and liabilities at the new enacted rate. The Company re-measured the U.S. deferred income tax assets and liabilities balances using the new enacted tax rate (see Note 9). There was no income tax impact from the remeasurement due to the 100% valuation allowance on the Company's deferred tax assets.

Loss per share

Basic loss per share is computed based on the net loss for each period divided by the weighted average number of common shares outstanding. The net loss for the year ended December 31, 2017, reflects increases for net deemed dividends to preferred stockholders provided in connection with the close of the public offering of Series E Convertible Preferred Stock in April of 2017, and the close of the public offering of Series F Convertible Preferred Stock in November of 2017, of $1.0 million and $8.7 million, respectively, representing the intrinsic value of the shares at the time of issuance. In addition, the net loss allocable to common stockholders reflects an increase for net deemed dividends of $1.8 million to preferred stockholders provided in connection with the shareholder approval of the Series C and D Convertible Preferred Stock transactions in January of 2017, representing the intrinsic value of the shares at the time of issuance. The net loss allocable to common shareholders 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,	
	2017	2016
Stock options	36,362	4,354
Restricted stock units	245	499
Warrants to purchase common stock	8,522,684	44,268
Series B, C and D convertible preferred stock	—	53,179
Series F convertible preferred stock	842,940	—
Total	9,402,231	102,300

The following table reconciles reported net loss with reported net loss per share for the years ended December 31:

(in thousands, except per share amounts)	2017	2016
Net loss	$(13,382)	$(15,792)
Deemed dividend to preferred shareholders (see Note 6)	(11,590)	(1,900)
Net loss after deemed dividend	(24,972)	(17,692)
Weighted average shares outstanding	665	33
Basic and diluted loss per share	$ (37.51)	$(536.12)

Research and Development

Research and development costs include activities related to research, development, design, and testing improvements of the Aquadex FlexFlow system and potential related products. Research and development costs also include expenses related to clinical research that the Company may sponsor or conduct to enhance understanding of the product and its use. Research and development expenses are expensed as incurred.

Reclassification

For comparability, certain December 31, 2016 amounts have been reclassified to conform to classifications adopted in December 31, 2017. The reclassifications had no impact on previously reported net loss or equity.

Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board (FASB), issued amended stock compensation guidance to simplify various aspects of employee share-based payments accounting and presentation in the financial statements. The new guidance requires all income tax effects of awards to be recognized in the income statement when the awards vest or are settled, allows an employer to repurchase more of an employee's shares than previously allowed for tax withholding purposes without triggering liability accounting, allows a company to make a policy election to account for forfeitures as they occur, and eliminates the requirement that excess tax benefits be realized before companies can recognize them. The new guidance also requires excess tax benefits and tax shortfalls to be presented on the cash flow statement as an operating activity rather than as a financing activity, and clarifies that cash paid to a tax authority when shares are withheld to satisfy its statutory income tax withholding obligation are to be presented as a financing activity. The standard was effective for our interim and annual periods beginning after January 1, 2017. The Company adopted the guidance in the current year. The adoption of this standard did not have a material impact to the Company's consolidated financial statements.

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. The Company has determined that it will use the modified retrospective approach. This guidance will be effective for the Company's interim and annual periods beginning January 1, 2018. As of the end of the fourth quarter of 2017, the Company had nearly completed its assessment of this amended guidance and it does not expect that the adoption of this standard will not have a material impact on the timing and amount of revenue recognized, but it expects to provide expanded disclosures as a result of the adoption. The Company will continue to evaluate the impact of the amended guidance as it pertains to presentation and disclosure.

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 did not have an impact on the Company's consolidated financial statements as all deferred tax assets are fully reserved.

In January 2017, the FASB issued amended guidance to simplify the accounting for goodwill impairment by removing Step 2 of the goodwill impairment test. A goodwill impairment will now be measured as the amount by which a reporting unit's carrying value exceeds its fair value, limited to the amount of goodwill allocated to that reporting unit. This guidance is to be applied on a prospective basis effective for the Company's interim and annual periods beginning after January 1, 2019, with early adoption permitted for any impairment tests performed after January 1, 2017. The Company adopted this amended guidance in the current year, as further described above under Significant Accounting Policies.

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 consolidated financial statements are filed for events requiring adjustment to or disclosure in the consolidated 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 agreed to 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 years ended December 31, 2017 and 2016, the Company recorded $3.6 and $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 was 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 1,666 shares of the Company's common stock, worth $0.95 million based on the closing market value of $570 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 consolidated 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, 2016. 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, 2016 or that may be obtained in the future, and do not reflect future synergies, integration costs, or other such costs or savings.

Twelve months ended December 31, 2016 *(in thousands, except share amounts)*	
Pro forma net sales	$ 3,160
Pro forma net loss from operations	(15,340)
Pro forma basic and diluted net loss per share	$(464.84)

Note 3—Property, Plant and Equipment

Property, plant and equipment were as follows:

(in thousands)	December 31, 2017	December 31, 2016
Office Furniture & Fixtures	$ 287	$ 280
Leasehold Improvements	224	145
Software	129	124
Production Equipment	926	968
Computer Equipment	277	245
Capital Lease Asset	307	307
Total	2,150	2,069
Accumulated Depreciation	(1,580)	(1,529)
	$ 570	$ 540

Note 4—Intangible Assets

Intangible assets were as follows:

(in thousands)	December 31, 2017	December 31, 2016
Customer Relationships	$ 3,090	$3,090
Developed Technology	1,050	1,050
Trade Names and Trademarks	440	440
Total	4,580	4,580
Accumulated Amortization	(818)	(278)
Impairment Charge	(3,762)	—
	$ —	$4,302

The Company's review of its intangible assets during the year ended December 31, 2017, resulted in $3.8 million of impairment charges related to its finite-lived intangible assets. The impairment charges were based on fair values determined using market value indicators such as the quoted market prices of the Company's common stock on Nasdaq, as well discounted cash flow models. Discounted cash flow models include assumptions related to the Company's product revenue, gross margins, and operating margins, under varying assumptions about the Company's ability to either achieve profitability or obtain the necessary financings to realize such projections. As discussed in Note 1, the Company became a revenue generating company after acquiring the Aquadex Business in August 2016 and expects to incur losses in the near-term as it grows the Aquadex Business. To become and remain profitable, and to generate cash flows from operations, the Company must succeed in expanding the adoption and market acceptance of its products. This will require that the Company succeed in training personnel at hospitals and in effectively and efficiently manufacturing, marketing, and distributing its products. There can be no assurance that the Company will succeed in these activities, and it may never generate revenues sufficient to achieve profitability or positive cash flows. The discounted cash flow models reflect these uncertainties by assigning future cash flow estimations probability factors and an overall discount rate of 30%.

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. There were no borrowings outstanding under this facility as of December 31, 2017 or 2016.

Warrants: In connection with the funding of these term loans, the Company issued 115 warrants at an exercise price of $3,132 per share and 55 warrants at an exercise price of $2,208 per share to the Bank and one of its affiliates. The Company valued these warrants at $2,316 per share and $1,626 per share, respectively, utilizing the Black Scholes option pricing model and the following assumptions: an expected dividend yield of 0%, an expected stock price volatility of 88.07% and 87.04%, a risk-free interest rate of 1.86% and 2.20%, and an expected life of 6.25 years. The warrants have a life of ten years and were fully vested at the date of grant.

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, 2017 or 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 6,149 shares of common stock at the holder's election at any time at a conversion price of $564.0 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 had similar terms as the Series B Convertible Preferred Stock, except that the initial conversion price of the Series B-1 Convertible Preferred Stock was $102 per share. As of December 31, 2016, 402.8 shares of the Series B-1 Convertible Preferred Stock had been converted into 3,948 shares of common stock, and 1,824.4 shares of Series B-1 Convertible Preferred Stock remained outstanding. As of December 31, 2017, all remaining Series B-1 Convertible Preferred Stock had been converted into an additional 17,866 shares of common stock and none 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 a securities purchase agreement 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 with conversion prices of $102 per share. At the second closing, on January 10, 2017, the Company issued and sold 200 shares of Series D Convertible Preferred Stock with a conversion price of $102 per share for gross proceeds of $0.2 million. The Series C and D Convertible Preferred Stock included a contingent beneficial conversion amount of $1.3 million and $0.5 million, respectively,

representing the intrinsic value of the shares at the time of issuance. This amount is reflected as an increase to the loss per share allocable to common stockholders 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, 2,900 shares of Series C Convertible Preferred Stock and 700 shares of Series D Convertible Preferred Stock were outstanding, and none had been converted. As of December 31, 2017, all shares of the Series C and D Convertible Preferred Stock had been converted into an aggregate of 55,712 shares of common stock and none remained outstanding.

The Series D Convertible Preferred Stock with a carrying value of $0.5 million was classified as temporary equity in the consolidated balance sheet as of December 31, 2016 because the Company could not control the settlement of its redemption in common stock. The temporary equity was not remeasured to fair value each period through earnings because the events that could trigger its redemption were not probable of occurrence. There were no shares of the Series D Convertible Preferred Stock outstanding as of December 31, 2017.

Series E Convertible Preferred Stock: On April 24, 2017, the Company closed on an underwritten public offering of common stock, Series E Convertible Preferred Stock and warrants to purchase shares of common stock for gross proceeds of $9.2 million, which included the full exercise of the underwriter's over-allotment option to purchase additional shares and warrants. Net proceeds totaled approximately $8.0 million after deducting the underwriting discounts and commissions and other costs associated with the offering.

The offering comprised of Class A Units, priced at a public offering price of $20.00 per unit, with each unit consisting of one share of common stock and one five-year warrant to purchase one share of common stock with an exercise price of $22 per share, and Class B Units, priced at a public offering price of $1,000 per unit, with each unit comprised of one share of preferred stock, which was convertible into 50 shares of common stock, and warrants to purchase 50 shares of common stock, also with an exercise price of $22 per share. The conversion price of the Series E Convertible Preferred Stock as well as the exercise price of the warrants are fixed and do not contain any variable pricing features nor any price based anti-dilutive features apart from customary adjustments for splits and reverse splits of common stock. A total of 140,000 shares of common stock, 6,400 shares of Series E Convertible Preferred Stock convertible into 320,000 shares of common stock and warrants to purchase 640,000 shares of common stock were issued in the offering including the full exercise of the underwriter's over-allotment option to purchase additional shares and warrants. The Series E Convertible Preferred Stock included a beneficial conversion amount of $1.0 million, representing the intrinsic value of the shares at the time of issuance. This amount is reflected as an increase to the loss per share allocable to common stockholders in the year ended December 31, 2017. As of December 31, 2017, all shares of the Series E Convertible Preferred Stock had been converted into an aggregate of 320,000 shares of common stock and none remained outstanding.

Series F Convertible Preferred Stock: On November 27, 2017, the Company closed on an underwritten public offering Series F Convertible Preferred Stock and warrants to purchase shares of common stock for gross proceeds of $18.0 million. Net proceeds totaled approximately $16.2 million after deducting the underwriting discounts and commissions and other costs associated with the offering.

The offering was comprised of Series F preferred stock, convertible into shares of the Company's common stock at a conversion price of $4.50 per share. Each share of Series F preferred stock was accompanied by a Series 1 warrant, which expires on the first anniversary of its issuance, to purchase 223 shares of the Company's common stock at an exercise price of $4.50 per share, and a Series 2 warrant, which expires on the seventh anniversary of its issuance, to purchase 223 shares of the Company's common stock at an exercise price of $4.50 per share. The Series F preferred stock and the warrants were immediately separable and were issued separately. The conversion price of the Series F Convertible Preferred Stock as well as the exercise price of the warrants are fixed and do not contain any variable pricing features, nor any price based anti-dilutive features apart from customary adjustments for splits and reverse splits of common stock. A total of 18,000 shares of Series F Convertible Preferred Stock convertible into approximately 4.0 million shares of common stock and warrants to purchase approximately 8.0 million shares of common stock were issued in the offering. The Series F Convertible Preferred Stock included a beneficial conversion amount of $8.7 million, representing the intrinsic value of the shares at the time of issuance. This amount is reflected as an increase to the loss per share allocable to common stockholders in the year ended December 31, 2017. As of December 31, 2017, 14,220 shares of the Series F Convertible Preferred Stock had been converted into an aggregate of 3,171,060 shares of common stock and 3,780 remained outstanding.

In connection with the issuance of the Series B, C and D Convertible Preferred Shares, 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 warrants as described below. In connection with the issuance of the Series E and F Convertible Preferred Shares, the Company paid the placement agent an aggregate cash placement fee equal to 9% and 8%, respectively, of the aggregate gross proceeds raised in the offering and issued no warrants to the placement agent.

Investor Warrants: In connection with the issuance of the Series B Convertible Preferred Stock in July 2016, the Company issued the investor at no additional cost warrants to purchase 6,149 shares of common stock at an exercise price of $564 per share. The warrants were exercisable for 36 months commencing six months from the closing date and were subject to a reduction of the exercise price if the Company subsequently issued 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 $102 per share.

In connection with the issuance of the Series C and D Convertible Preferred Stock in November 2016, the Company issued the investor at no additional cost warrants to purchase 35,295 shares of common stock at an exercise price of $108 per share. In connection with the issuance of the Series D Convertible Preferred Stock at the second closing in January 2017, the Company issued the investor at no additional cost warrants to purchase 1,961 shares of common stock at an exercise price of $108 per share. The warrants were exercisable for 60 months commencing on the earlier of the day 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. These warrants were subject to a reduction of the exercise price if the Company subsequently issued common stock or equivalents at an effective price less than the current exercise price of such warrants.

Warrant Exercise Agreement: On February 15, 2017, the Company entered into a letter agreement with the institutional investors that held the majority of its outstanding warrants (the ''Original Warrants''), to incent the cash exercise of these warrants on or before March 31, 2017. 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 Original Warrants, with an exercise price equal to the consolidated closing bid price of its common stock on the date of issuance. The Replacement Warrants were issued in the same form as the Original Warrants except the exercise prices are not subject to reduction for subsequent equity issuances and the Replacement Warrants do not allow the investor to demand that the Company purchase the Replacement Warrants in the event of a fundamental transaction involving the Company. In connection with this agreement, between February and March 2017, the investors exercised all of the Original Warrants for gross cash proceeds to the Company of $2.0 million, and the Company issued 43,396 Replacement Warrants with exercise prices ranging from $34.6 per share to $99.8 per share.

The Company entered into the letter agreement with the investors to incent the exercise of the Original Warrants in order to receive the cash proceeds from the exercise of the Original Warrants and because the exercise of the Original Warrants would allow the Company to remove the warrant liability from its balance sheet and avoid future fair value adjustments and associated volatility in its consolidated financial statements, as the Replacement Warrants are not accounted for as liabilities based on their terms. As of December 31, 2017, there were no Original Warrants outstanding and all Replacement Warrants under the letter agreement had been issued.

Warrant Valuation: Both the Original Warrants and placement agent warrants were 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 consolidated statement of operations. In connection with the warrant exchange agreement described above, the Company remeasured each Original Warrant as of the date of exercise and recorded $1.5 million for the change in fair value of these warrants as an unrealized gain in the accompanying consolidated statement of operations for year ended December 31, 2017. The warrant liability totaled $1.8 million as of December 31, 2016 and $0 as of December 31, 2017.

The Replacement Warrants were valued at $0.5 million using the Black Scholes option pricing model with the following assumptions: an expected dividend yield of 0%, expected stock price volatility of 49.65%-50.38%, risk-free interest rates of 1.95%-1.97% and an expected life of 5 years. The warrants have a five-year life and

were fully vested at the date of grant. The terms of the Replacement Warrants do not require them to be accounted for as liabilities and are therefore recorded in equity. As in incentive to early exercise the Original Warrants, the fair value provided to investors through the Replacement Warrants exceeded the fair value of the Original Warrants that was relinquished by the warrant holders by approximately $0.1 million, which has been reflected as an expense in the consolidated statement of operations for the year ended December 31, 2017.

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 Third Amended and Restated 2017 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 $0.5 million, and $1.0 million during the years ended December 31, 2017 and 2016, 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)	2017	2016
Selling, general and administrative	$452	$ 630
Research and development	50	385
Total	$502	$1,015

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:

	2017		2016	
	Options Outstanding	Weighted Average Exercise Price	Options Outstanding	Weighted Average Exercise Price
Beginning Balance	4,354	$2,295.37	3,260	$3,664.61
Granted	34,651	$ 11.57	2,257	$ 543.63
Exercised	—	—	—	—
Forfeited/expired	(2,643)	$2,666.48	(1,163)	$2,729.60
Outstanding at December 31	36,362	$ 91.48	4,354	$2,295.37
Vested at December 31	2,344	$ 964.27	2,134	$3,780.79

For options outstanding and vested at December 31, 2017, the weighted average remaining contractual life was 9.33 years and 8.29 years, respectively. There were no option exercises in 2017 or 2016. The total fair value of options that vested in 2017 and 2016 was $0.7 million, and $1.1 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 option pricing 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 weighed average assumptions used in the Black-Scholes option pricing model for the years ended December 31:

	2017	2016
Expected dividend yield	0%	0%
Risk-free interest rate	1.97%	1.71%
Expected volatility	103%	86%
Expected life (in years)	6.25	6.25

The weighted-average fair value of stock options granted in 2017 and 2016 was $11.97 and $543.63, respectively. As of December 31, 2017, the total compensation cost related to all non-vested stock option awards not yet recognized was approximately $744,000 and is expected to be recognized over the remaining weighted-average period of 3.1 years.

Restricted Stock Awards: The following table summarizes restricted stock award activity during 2017 and 2016:

	2017		2016	
	RSUs	Weighted Average Grant Price	RSUs	Weighted Average Grant Price
Nonvested, beginning balance	499	$583.29	15	$2,574.00
Granted	138	$108.20	1,131	$ 553.88
Vested	(392)	$132.70	(619)	$ 443.40
Forfeited	—	—	(28)	$ 426.00
Nonvested at December 31	245	$521.23	499	$ 583.29

During 2017, and 2016, employees tendered restricted stock units totaling 15, and 165, respectively, to cover related payroll tax withholdings.

Warrants

Warrants to purchase 8,522,684, and 44,268 shares of common stock were outstanding at December 31, 2017 and 2016, respectively. As of December 31, 2017, warrants outstanding were exercisable at prices ranging from $4.50 to $383.57 per share, and are exercisable over a period ranging from eleven months to 7.5 years.

Note 8 - Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, warrants, and contingent consideration.

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

The following is a rollfoward of the fair value of Level 3 warrants:

(in thousands)	
July 26, 2016 warrant issuance	$ 1,883
November 3, 2016 warrant issuance	778
Change in fair value	(818)
Ending balance December 31, 2016	1,843
Change in fair value	(1,475)
Exercise of warrants	(368)
Ending balance as of December 31, 2017	$ —

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 option pricing 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.

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, 2017 and 2016. 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:

(in thousands)	2017	2016
Domestic	$(13,367)	$(15,877)
Foreign	(9)	31
Loss before income taxes	$(13,376)	$(15,846)

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

(in thousands)	2017	2016
Current:		
United States and state	$—	$—
Foreign, net	(6)	54
Deferred:		
United States and state	—	—
Foreign	—	—
Total income tax benefit (expense)	$ (6)	$54

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

(in thousands)	2017	2016
Statutory federal income tax benefit	$ 4,548	$ 5,388
State tax benefit, net of federal taxes	48	2
Foreign tax	—	3
R&D tax credit	—	80
Foreign deferred exchange rate adjustments	899	—
Nondeductible/nontaxable items	(114)	(86)
New federal rate adjustment	(16,081)	—
Other	(1,085)	(257)
Valuation allowance decrease (increase)	11,779	(5,076)
Total income tax benefit (expense)	$ (6)	$ 54

Deferred taxes consist of the following as of December 31:

(in thousands)	2017	2016
Deferred tax assets:		
Noncurrent:		
Accrued leave	$ 32	$ 43
Other accrued expenses	28	97
Stock based compensation	336	1,477
Net operating loss carryforward	38,947	49,720
Deferred rent	7	17
Other	108	777
Intangibles	895	
R&D credit carryforward	531	531
Total deferred tax assets	$ 40,884	$ 52,662
Less: valuation allowance	(40,884)	(52,662)
Total	$ —	$ —

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (Tax Reform Act) was signed into law making significant changes to the Internal Revenue Code. Changes include a reduction in the corporate tax rates, changes to operating loss carry-forwards and carrybacks, and a repeal of the corporate alternative minimum tax. The legislation reduces the U.S. corporate income tax rates from 34% to 21%. As a result of the enacted law, the Company is required to revalue its deferred tax assets and liabilities at the new enacted rate. The Company re-measured the U.S. deferred income tax assets and liabilities balances using the new enacted tax rate. There was no income tax impact from the re-measurement due to the 100% valuation allowance on the Company's deferred tax assets.

As of December 31, 2017, the Company had net operating loss ***("NOLs")*** carryforwards of approximately $120.2 million for U.S. federal income tax purposes, which expire between 2024 and 2037, 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 fully refundable research and development tax credits in 2016, related to qualified research and development expenditures of its Australian subsidiary for its tax years ended June 30, 2015, and recorded the benefit in the year that the refund was received. The Company received no refunds in 2017 as it has ceased its research and development activities in Australia.

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 year ended December 31, 2017, the valuation allowance decreased by $11.8 million primarily as result of the impact of the tax reform re-measurement of deferred tax assets. For the year ended December 31, 2016 the valuation allowance increased by $5.8 million primarily due to current year operating losses. During 2017, the Company experienced an ownership change as defined in Section 382 of the Internal Revenue Code which will limit the ability to utilize the Company's net operating losses (NOLs). The Company may have experienced additional ownership changes in earlier years further limiting the NOL carry-forwards that may be utilized. The Company has not yet completed a formal Section 382 analysis. The general limitation rules allow the Company to utilize its NOLs subject to an annual limitation that is determined by multiplying the federal long-term tax-exempt rate by the Company's value immediately before the ownership change.

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, 2017 or 2016.

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, 2017 and 2016, the Company recorded no accrued interest or penalties related to uncertain tax positions.

The tax years ended December 31, 2014 through December 31, 2017 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, 2013 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 $290,000, and $286,000 for the years ended December 31, 2017 and 2016, respectively. Future minimum lease payments under non-cancelable operating leases as of December 31, 2017, were approximately $212,000, $60,000, $7,000, $0, and $0 for each of the years ended December 31, 2018, through 2022, 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 Internal Revenue Service limitations, with the Company matching a portion of the employee's contributions at the discretion of the Company. Matching contributions totaled $138,000 and $122,000 for the years ended December 31, 2017 and 2016, respectively.

Inventory Purchase Commitments

In connection with the acquisition of the Aquadex Business, the Company entered into a manufacturing and supply agreement with Baxter that was to expire within a period not to exceed 18 months from the close of the transaction. In May 2017, the Company notified Baxter to cease the manufacturing of the Aquadex product line as of June 30, 2017. In connection with this notification, the Company agreed to purchase the remaining Aquadex inventory, which consists mainly of raw materials priced at cost, through February 2018, for a total of $2.4 million. As of December 31, 2017, the Company had purchased and paid $1.2 million of this inventory and $1.2 million remained to be purchased.

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 Nasdaq, 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, 2017, long-lived assets were located primarily in the United States.

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, 2017, 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, 2017.

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, 2017, 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, 2017.

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, 2017 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.

The information required by this item is set forth under the following captions in our proxy statement to be filed with respect to the 2018 annual meeting of stockholders (the ***"Proxy Statement"***), all of which is incorporated herein by reference: ''Proposal 1 — Election of Directors,'' ''Board Matters — Committees of the Board,'' ''Board Matters — Corporate Governance,'' ''Executive Officers'' and ''Additional Matters — Section 16(a) Beneficial Ownership Reporting Compliance.''

Item 11. Executive Compensation.

The information required by this item is set forth under the following captions in the Proxy Statement, all of which is incorporated herein by reference: ''Board Matters — Director Compensation,'' ''Named Executive Officer Compensation Tables'' and ''Certain Relationships and Related Transactions — Compensation Committee Interlocks and Insider Participation.''

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

The information required by this item is set forth under the following captions in the Proxy Statement, all of which is incorporated herein by reference: ''Security Ownership of Certain Beneficial Owners and Management'' and ''Additional Matters — Equity Compensation Plan Information.''

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

The information required by this item is set forth under the following captions in the Proxy Statement, all of which is incorporated herein by reference: ''Proposal 1 — Election of Directors — Director Independence'' and ''Certain Relationships and Related Transactions — Related Party Transactions.''

Item 14. Principal Accounting Fees and Services.

The information required by this item is set forth under the following captions in the Proxy Statement, all of which is incorporated herein by reference: ''Audit Committee Matters.''

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 following exhibits are incorporated by reference or filed as part of this Annual Report on Form 10-K:

EXHIBIT INDEX .

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
2.1	Asset Purchase Agreement between Sunshine Heart, Inc. and Gambro UF Solutions, Inc. dated August 5, 2016	8-K	001-35312	August 8, 2016	2.1	
3.1	Fourth Amended and Restated Certificate of Incorporation	10	001-35312	February 1, 2012	3.1	
3.2	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	January 13, 2017	3.1	
3.3	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	May 23, 2017	3.1	
3.4	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	October 12, 2017	3.1	
3.5	Second Amended and Restated Bylaws	8-K	001-35312	May 23, 2017	3.2	
3.6	Form of Certificate of Designation of Series A Junior Participating Preferred Stock	8-K	001-35312	June 14, 2013	3.1	
3.7	Form of Certificate of Designation of Preferences, Rights and Limitations of Series F Convertible Preferred Stock	S-1/A	333-221010	November 17, 2017	3.7	
4.1	Warrant to Purchase Stock, dated February 18, 2015, issued to Silicon Valley Bank	8-K	001-35312	February 19, 2015	4.1	

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
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 Warrant issued to Northland Securities, Inc.	8-K	001-35312	July 22, 2016	4.3	
4.5	Registration Rights Agreement between Sunshine Heart, Inc. and Gambro UF Solutions, Inc. dated August 5, 2016	8-K	001-35312	August 8, 2016	4.1	
4.6	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	
4.8	Form of common stock Purchase Warrant issued pursuant to the Underwriting Agreement between the Company and Ladenburg Thalmann & Co. Inc., dated April 19, 2017	S-1/A	333-216841	April 4, 2017	4.8	
4.9	Form of Warrant to purchase shares of common stock	S-1/A	333-221010	November 17, 2017	4.9	
10.1	Securities Purchase Agreement, dated July 20, 2016 among the Company and the purchasers signatory thereto	8-K	001-35312	July 22, 2016	10.1	
10.2	Patent License Agreement between Sunshine Heart, Inc. and Gambro UF Solutions, Inc. dated August 5, 2016	8-K	001-35312	August 8, 2016	10.1	

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
10.3	Loan and Security Agreement between Sunshine Heart, Inc. and Silicon Valley Bank dated August 5, 2016	8-K	001-35312	August 8, 2016	10.2	
10.4	Amended and Restated 2002 Stock Plan†	10	001-35312	December 16, 2011	10.2	
10.5	Form of Notice of Stock Option Grant and Option Agreement for Amended and Restated 2002 Stock Plan†	10	001-35312	September 30, 2011	10.3	
10.6	Second Amended and Restated 2011 Equity Incentive Plan, as amended†	14A	001-35312	July 27, 2012	App. A	
10.7	Form of Stock Option Grant Notice and Option Agreement for 2011 Equity Incentive Plan†	10	001-35312	September 30, 2011	10.5	
10.8	Form of Stock Option Grant Notice and Option Agreement (Senior Management) for 2011 Equity Incentive Plan†	10	001-35312	September 30, 2011	10.6	
10.9	Form of Stock Option Grant Notice and Option Agreement (Director) for 2011 Equity Incentive Plan†	8-K	001-35312	September 18, 2012	10.1	
10.10	Form of Stock Grant Notice and Award Agreement for 2011 Equity Incentive Plan†	8-K	001-35312	September 10, 2013	10.1	
10.11	Form of Restricted Stock Unit Grant Notice and Agreement for 2011 Equity Incentive Plan†	8-K	001-35312	September 10, 2013	10.2	
10.12	2013 Non-Employee Directors' Equity Incentive Plan†	14A	001-35312	April 5, 2013	App. A	
10.13	Form of Stock Option Grant Notice and Option Agreement for 2013 Non-Employee Directors' Equity Incentive Plan†	10-K	001-35312	May 29, 2013	10.2	
10.14	Form of Restricted Stock Unit Award Grant Notice and Agreement for 2013 Non-Employee Directors' Equity Incentive Plan†	10-K	001-35312	March 20, 2015	10.11	

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
10.15	New-Hire Equity Incentive Plan†	10-Q	001-35312	August 8, 2013	10.1	
10.16	First Amendment to New-Hire Equity Incentive Plan†	10-Q	001-35312	November 12, 2013	10.1	
10.17	Second Amendment to New-Hire Equity Incentive Plan†	S-8	333-202904	March 20, 2015	99.12	
10.18	Third Amendment to New-Hire Equity Incentive Plan†	S-8	333-210215	March 15, 2016	99.13	
10.19	Fourth Amendment to New-Hire Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.4	
10.20	Fifth Amendment to New-Hire Equity Incentive Plan†	8-K	001-35312	January 18, 2018	10.1	
10.21	Form of Stock Option Grant Notice and Option Agreement for New-Hire Equity Incentive Plan†	10-Q	001-35312	November 12, 2013	10.2	
10.22	2017 Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.1	
10.23	Form of Stock Option Grant Notice and Option Agreement for 2017 Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.2	
10.24	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement for 2017 Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.3	
10.25	Form of Indemnity Agreement for the Company's executive officers and directors†	10	001-35312	September 30, 2011	10.1	
10.26	Form of Change in Control Agreement for the Company's executive officers†	10-K	001-35312	March 20, 2015	10.16	
10.27	Non-Employee Director Compensation Policy†	10-Q	001-35312	August 8, 2013	10.2	
10.28	Lease Agreement dated October 21, 2011 by and between the Company and Silver Prairie Crossroads, LLC	10	001-35312	December 16, 2011	10.18	

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
10.29	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	
10.30	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	
10.31	Separation and Release Agreement between the Company and David A. Rosa, dated November 30, 2015†	8-K	001-35312	November 30, 2015	99.1	
10.32	Executive Employment Agreement between Sunshine Heart, Inc. and John L. Erb, dated March 1, 2016†	8-K	001-35312	March 2, 2016	10.1	
10.33	Separation and Release Agreement by and between Sunshine Heart, Inc. and Brian J. Brown, dated February 3, 2016†	10-Q	001-35312	May 5, 2015	10.2	
10.34	Separation and Release Agreement by and between Sunshine Heart, Inc. and Debra Kridner, dated January 24, 2016†	10-Q	001-35312	May 5, 2016	10.3	
10.35	Claudia Drayton Retention Bonus Letter, dated as of December 12, 2016†	8-K	001-35312	December 16, 2016	10.1	
10.36	Molly Wade Retention Bonus Letter, dated as of December 12, 2016†	S-1	333-221010	October 18, 2017	10.35	
10.37	Letter Agreement dated February 15, 2017 among the Company, Sabby Volatility Warrant Master Fund, Ltd. and Sabby Healthcare Master Fund, Ltd.	8-K	003-35312	February 16, 2017	10.1	
10.38	Offer Letter by and between the Company and Jim Breidenstein dated April 12, 2017†	10-Q	001-35312	May 12, 2017	10.4	
10.39	Warrant Agency Agreement between the Company and American Stock Transfer & Trust Company, LLC dated April 24, 2017	8-K	001-35312	April 25, 2017	10.1	

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
10.40	Warrant Agency Agreement, by and between CHF Solutions, Inc. and American Stock Transfer & Trust Company, LLC dated November 27, 2017	8-K	001-35312	November 28, 2017	10.1	
21	List of Subsidiaries					X
23.1	Consent of Baker Tilly Virchow Krause, LLP					X
23.2	Consent of Ernst & Young LLP					X
24	Power of Attorney (included on signature page)					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.

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 22, 2018

CHF SOLUTIONS, 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.

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.

Signature	Title	Date
/S/ JOHN L. ERB John L. Erb	Chief Executive Officer and Director (principal executive officer)	March 22, 2018
/S/ CLAUDIA DRAYTON Claudia Drayton	Chief Financial Officer (principal financial and accounting officer)	March 22, 2018
/S/ STEVEN BRANDT Steven Brandt	Director	March 22, 2018
/S/ MATTHEW LIKENS Matthew Likens	Director	March 22, 2018
/S/ JON W. SALVESON Jon W. Salveson	Director	March 22, 2018
/S/ GREGORY D. WALLER Gregory D. Waller	Director	March 22, 2018
/S/ WARREN S. WATSON Warren S. Watson	Director	March 22, 2018

EXHIBIT 21

SUBSIDIARIES

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

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Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-1 (File No.333-215112, 333-216053, 333-216841, 333-221010, and 333-221716) and Form S-8 (File No. 333-218464, 333-210215, 333-202904, 333-194642, 333-190499, 333-188935, 333-183925, 333-183924) of CHF Solutions, Inc. of our report dated March 22, 2018, relating to the consolidated financial statements, which includes an explanatory paragraph relating to the Company's ability to continue as a going concern and appears on page 40 of this annual report on Form 10-K for the year ended December 31, 2017.

/s/ Baker Tilly Virchow Krause, LLP
Minneapolis, Minnesota
March 22, 2018

Exhibit 23.2

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-8 No. 333-210215) 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;

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

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

(10) Registration Statement (Form S-1 No. 333-216841) of Sunshine Heart, Inc. and in the related base prospectus;

(11) Registration Statement (Form S-8 No. 333-218464) pertaining to the CHF Solutions, Inc. 2017 Equity Incentive Plan, the CHF Solutions, Inc. 2013 Non-Employee Directors' Equity Incentive Plan, and the CHF Solutions, Inc. New-Hire Equity Incentive Plan;

(12) Registration Statement (Form S-1 No. 333-221010) of CHF Solutions, Inc. and in the related base prospectus; and

(13) Registration Statement (Form S-1 No. 333-221716) of CHF Solutions, Inc. and in the related base prospectus.

of our report dated March 8, 2017 (except for the reverse stock split disclosed in Note 1, as to which the date is March 22, 2018) with respect to the consolidated financial statements of CHF Solutions, Inc. and subsidiaries included in this Annual Report (Form 10-K) of CHF Solutions, Inc. and subsidiaries for the year ended December 31, 2017.

/s/ Ernst & Young, LLP
Minneapolis, Minnesota
March 22, 2018

EXHIBIT 31.1

CHF SOLUTIONS, INC.
CEO SECTION 302 CERTIFICATION

I, John L. Erb, certify that:

1. I have reviewed this Annual Report on Form 10-K of CHF Solutions, 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 22, 2018

/S/ JOHN L. ERB

John L. Erb
Chief Executive Officer

EXHIBIT 31.2

CHF SOLUTIONS, INC.
CFO SECTION 302 CERTIFICATION

I, Claudia Drayton, certify that:

1. I have reviewed this Annual Report on Form 10-K of CHF Solutions, 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 22, 2018

/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 CHF Solutions, Inc. (the ***"Company"***) on Form 10-K for the 12 months ended December 31, 2017 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 22, 2018

/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 CHF Solutions, Inc. (the ***"Company"***) on Form 10-K for the 12 months ended December 31, 2017 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 22, 2018

/S/ CLAUDIA DRAYTON

Claudia Drayton
Chief Financial Officer

CHF SOLUTIONS BUSINESS OVERVIEW

AQUADEX FLEXFLOW® SYSTEM

CONTROL CONGESTION, RESTORE BALANCE

The Aquadex FlexFlow System has been shown to safely and precisely remove isotonic fluid from patients with volume overload who have failed diuretic therapy. While diuretics are the standard of care for clinicians to manage patients with fluid overload, 40% of patients do not respond to treatment.[1]

The Aquadex FlexFlow System provide an alternative for clinicians to predictably control fluid removal by setting the rate and amount of fluid to be removed. Aquadex FlexFlow System has been shown to stabilize or improve cardiac hemodynamics[2,3,4,5,6] and have no significant change on electrolytes.[2,7,8,9,10]

AQUADEX FEATURES

- Aquadex FlexFlow offers a safe and effective approach to treating fluid overload
- Allows the medical practitioner precise control over the amount of fluid removed from each individual patient
- Aquadex provides a highly automated operation with only one setting required to begin therapy
- The Aquadex console is simple to use and guides the user through the setup and operational process

CLINICAL EVIDENCE

Aquadex has a strong clinical history. Several clinical trials have been conducted to evaluate the safety and effectiveness of Aquadex therapy. They include SAFE, the preliminary safety and efficacy study that demonstrated fluid removal goals were achieved in 92% of treatments.[11] RAPID-CHF and UNLOAD demonstrated clinical benefit of ultrafiltration compared to standard care (diuretics).[4,12] The UNLOAD trial concluded that ultrafiltration safely produces greater weight and fluid loss than diuretics, reduces 90-day resource utilization for heart failure patients, and a reported 53% reduction in the risk of rehospitalization for heart failure.[12] Additionally, the AVOID-HF[13] trial showed ultrafiltration compared to diuretics trended toward a longer time to first heart failure event within 90 days, and fewer heart failure and cardiovascular events.

The CARRESS-HF trial[14] showed a rise in serum creatinine among patients pre-existing worsened renal function on a fixed UF rate compared to diuretics. A per-protocol analysis was conducted[15] on the same CARRESS-HF patient population that showed ultrafiltration is associated with greater decongestion in acute decompensated heart failure patients compared to diuretics, despite a transient rise in serum creatinine and neurohormonal activity.

AQUADEX GROWTH DRIVERS

1. **Established Customer Base–** Capitalized on the opportunity to expand utilization in the current base of active customers
2. **Underpenetrated Inpatient Market–** 1 million annual heart failure admissions, 40% whom are resistant to diuretics provide a tremendous inpatient opportunity[1]
3. **Untapped Outpatient Market–** Aquadex technology is designed to be used in multiple clinical settings. This flexibility allows for easy utilization in an Outpatient environment
4. **Global Expansion Opportunity–** We have contracted with European and Asia distributors to expand our footprint outside the US and tap into the large worldwide market
5. **Expanded Clinical Applications–** Aquadex removes excess fluid in diuretic resistant patients with a variety of volume overloaded conditions

chf solutions

12988 Valley View Road
Eden Prairie, MN 55344

+1 952 345 4200
CHF-Solutions.com

ANNUAL MEETING
May 16, 2018

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

Jim Breidenstein
Chief Commercial Officer

COMPANY SECRETARY

Claudia Napal Drayton

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Baker Tilly Virchow Krause, LLP
Minneapolis, MN

TRANSFER AGENT AND REGISTRAR

American Stock Transfer &
Trust Company, LLC
6201 15th Avenue
Brooklyn, NY 11219
+1 800 937 5449
Amstock.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.

Sources from inside back cover:
[1]Testani JM, Hanberg JS, Cheng S, et al. Circ Heart Failure. 2016; 9(1). [2]Teo LY, Lim CP, Neo CL, et al. Singapore Med J. 2016; 57(7):378-83.
[3]Hanna MA, Tang WH, Teo BW, et al. Congest Heart Fail. 2012; 18(1):54-63. [4]Bart BA, Boyle A, Bank AJ, et al. J Am Coll Cardiol. 2005; 46(11): 2043-6.
[5]Marenzi G, Lauri G, Grazi M, et al. J Am Coll Cardiol. 2001; 38 (4): 963-8. [6]Ronco C, Bellomo R, Ricci Z. Cardiology. 2001; 96(3-4): 196-201.
[7]Sav T, Cecen F, Albayrak E. Minerva Urologica e Nefrologica. 2017; 69(4):400-7. [8]Radzishevsky E, Salman N, Paz H, et al. Isr Med Assoc J. 2015; 17(1):24-6.
[9]De Vecchis R, Esposito C, Ariano C. Minerva Cardioangiol. 2014; 62(2):131-46. [10]Costanzo MR, Saltzberg MT, Jessup M, et al. J Card Fail. 2010; 16(4):227-84.
[11]Jaski BE, Ha J, Bart GD, et al. J Cardiac Failure. 2003; 9(3)227-231. [12]Costanzo MR, Guglin ME, Saltzberg MT, et al. J Am Coll Cardiol. 2007; 49(6):675-683.
[13]Costanzo MR, Negoianu D, Jaski BE, et al. JACC Heart Failure. 2016; 4(2):95-105. [14]Bart BA, Goldsmith SR, Lee KL, et al. N Engl J Med. 2012; 367:2296-304.
[15]Grodin JL, Carter SC, Bart BA, et al. Eur J Heart Failure. 2018. [16]Hines AJ, Barrett M, Jiang, HJ; et al. HCUP Statistical Brief #172, April 2014