chf solutions

2018 ANNUAL REPORT

CHANGING THE LIVES OF FLUID OVERLOADED PATIENTS WITH A CLINICALLY PROVEN THERAPY

Dear Shareholders,

CHF Solutions' vision is to be the global market leader in fluid management solutions to improve patients' quality of life. We provide healthcare professionals with a sophisticated, yet easy to use, mechanical pump and filtration system to address fluid overload in patients following cardiac surgery and patients suffering from heart failure and related conditions.

We believe that our technology provides a competitive advantage in the fluid management market by providing an effective solution for patients suffering from acute and chronic conditions.

2018 was a year of important accomplishments for CHF Solutions as our expanded commercial team continued to educate health care professionals about the clinical and economic benefits of the Aquadex FlexFlow® System as compared to IV diuretic therapy, the current standard of care. We expanded our field-based team and, by the fourth quarter, have a US direct sales force with 13 territories and five clinical specialists who provide training and clinical support to our customers. We have invested in the development of data to support the economic benefits of our therapy. At the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) in May, data was presented that showed, among other things, a substantial cost savings at 90 days when using ultrafiltration versus diuretic therapy. Outside of the US, we further executed on our commercialization strategy and now have distribution partnerships in Brazil, Germany, Hong Kong, India, Italy, Singapore, Spain, Thailand and the United Kingdom.

Our physician market is pulling us beyond our initial target segment of inpatient treatment of heart failure. In the third quarter, we announced the expansion of our commercial focus into the post-cardiovascular surgery market. The Aquadex FlexFlow System may be used to treat patients suffering from fluid overload following cardiac surgical procedures, such as coronary bypass, valve repairs and replacements, ventricular assist device implants and other procedures. In addition to cardiovascular surgery, we are also investing in the development of new evidence around the use of ultrafiltration in the outpatient setting, including a clinical study on outpatient use that will be initiated by the Department of Veterans Affairs Medical Center in Tampa, Florida. We plan to use such new evidence to seek reimbursement and gain broader adoption of the Aquadex FlexFlow System in the outpatient market. We are also seeking a modification to our product label to include pediatric patients, allowing us to promote the use of Aquadex FlexFlow in this critical patient population. Given our expansion into new market segments, we anticipate continued sales growth as we actively position ourselves in the market as the primary provider of ultrafiltration therapy.

We continue to invest in technology development to provide innovative solutions for physicians. In the second half of 2018, we acquired the AcQtrac™ System and established two partnerships to evaluate diagnostic tools to help assess the best patient candidates for ultrafiltration, target how much fluid to remove, and identify when to discontinue ultrafiltration.

We also filed two patent applications that include improvements to the Aquadex FlexFlow System and a wearable device designed to assist peripheral venous blood flow access during ultrafiltration.

On the manufacturing front, we concluded the transfer of all manufacturing activities in mid 2018 and now manufacture all Aquadex FlexFlow products--consoles, blood circuits and catheters--at our facility in Eden Prairie, Minnesota. We expect in-house manufacturing to have a favorable impact on our gross margins.

In July 2018, we completed an underwritten public offering of common stock for gross proceeds of about $5.4 million and, in March 2019, we completed an underwritten public offering of preferred stock, common stock and warrants for gross proceeds of about $12.4 million. The use of funds will include continuing our important investments to support our expanded commercialization strategy.

Looking ahead, we will continue to fine-tune growth strategies to impact both improved clinical outcomes and healthcare cost reduction by giving healthcare providers a clinically-effective and cost-effective alternative to diuretics. We are proud of our accomplishments in 2018 and are well-positioned for continued growth in 2019. CHF Solutions continues to be at the forefront of fluid management, 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 9, 2019

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, 2018

☐ **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, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit 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 ☒	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, 2018, 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 29, 2018 closing sale price of $25.76 per share) was approximately $8.3 million.

The number of shares of the registrant's common stock, par value $0.0001 per share, outstanding as of February 15, 2019 was 513,445 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement for the 2019 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
Table of Contents

[THIS PAGE INTENTIONALLY LEFT BLANK]

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 a medical device company focused on providing solutions for patients suffering from fluid overload. 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.

Fluid Overload

Fluid overload, also known as hypervolemia, is a condition in which there is too much fluid in the blood and generally refers to the expansion of the extracellular fluid volume. Although the body does need some amount of fluid to remain healthy, too much can cause an imbalance and damage to an individual's health.

The signs and symptoms of fluid overload are not always the same in each patient and may vary. However, possible signs and symptoms of fluid overload include: pitting edema, pulmonary edema/pleural effusion, jugular vein distention, dyspnea, or ascites. Medical conditions or diseases where excess fluid accumulates in the body are: heart failure, kidney failure, nephrotic syndrome, cirrhosis, or burn injuries/trauma. Individuals may also suffer from temporary fluid overload following certain surgical procedures, such as cardiac surgery.
The diagnosis of fluid overload can be made through a variety of tests/exams such as a physical exam (weight and edema), blood chemistry, ECG or EKG, GFR, liver enzymes, and urinalysis, or serum/urine sodium test. Fluid overload has a significant association with the combined events of death, infection, bleeding, arrhythmia, and pulmonary edema[1] and is a leading cause of readmissions with patients suffering from heart failure and patients following cardiac surgery.

The condition of fluid overload is often observed in patients with heart failure and secondary oliguric states.[2] Most of the symptoms of congestive heart failure result from extracellular fluid volume. For this reason, diuretics have been the cornerstone of heart failure treatment for more than 50 years. Over the past 20 years, approaches to treatment have changed dramatically.[3] These dramatic improvements include new medications and new technologies, such as ultrafiltration, to help treat fluid overload.

---

[1] Stein, A et.al. Critical Care, 2012:16:R99

[2] Ronco C, Costanzo MR, Bellomo R, et al. (2010) Fluid Overload Diagnosis and Management. Basel, Switzerland: Karger.

[3] Ellison DH. Diuretic therapy and resistance in congestive heart failure. Cardiology.2001;96:132-143.

Treatments for Fluid Overload

Diuretics

Treatment for fluid overload has traditionally been achieved through use of loop diuretics which may be accompanied by use of other categories of medications, such as ACE inhibitors, beta-blockers, and inotropic drugs. Although diuretics are the mainstay of treatment for congestion or fluid overload, no randomized trials have shown the effects of diuretics on mortality in chronic heart failure patients. Furthermore, appropriate titration of diuretics, specifically in the heart failure population, is unclear. Increasing concern exists that diuretics, particularly at high doses, may be deleterious in the inpatient setting. In addition, patients with heart failure and cardiorenal syndrome have diminished response to loop diuretics, making these agents less effective at relieving congestion.[4] Approximately 40% of heart failure patients have poor diuretic response.[5] This poor response is possibly due to noncompliance or high intake of salt, poor drug absorption, insufficient kidney response to drug, and reduced diuretic secretion.[6] Despite treatment with loop diuretics, patients are frequently hospitalized and treated for recurrent symptoms and signs of fluid overload. Among more than 50,000 patients enrolled in the ADHERE (Acute Decompensated Heart Failure National Registry) study, only 33% lost ≥ 2.27 kg (5 lbs), and 16% gained weight during hospitalization.[7]

Nearly one-half of hospitalized patients with heart failure are discharged with residual fluid excess after receiving conventional diuretic therapies.[8] Regardless of diuretic strategy, 42% of acutely decompensated heart failure subjects in the DOSE (Diuretic Optimization Strategies Evaluation) trial reached the composite endpoint of death, rehospitalization, or emergency department visit at 60 days.[9] There is an association of chronic loop diuretic therapy and greater resource utilization at hospitals.[10] Therefore, an alternative therapy to help stabilize or improve patient care is needed.

Ultrafiltration.

Ultrafiltration, or aquapheresis, is an alternative therapy to diuretics for fluid removal in patients. Ultrafiltration has been a well-documented technique in the treatment of fluid overload in heart failure patients for 25-30 years.[11] Ultrafiltration is a safe and effective alternative therapy to remove extra fluid and salt by gently filtering blood through an ultrafiltration system. With ultrafiltration, medical practitioners can specify and control the amount of fluid to be extracted at a safe, predictable, and effective rate. The use of ultrafiltration therapy in subgroups of patients, such as heart failure and post-cardiac surgery, has demonstrated clinical benefits in treating fluid overload signs and symptoms. In addition to the clinical benefits of ultrafiltration, the therapy provides economic advantages. A recent hospital cost analysis demonstrated a total cost savings of $3,975, or 14.4%, per patient when using ultrafiltration as compared to diuretic therapy over 90 days.[12]

The Aquadex FlexFlow System

The Aquadex FlexFlow system is designed and clinically proven 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. The Aquadex FlexFlow system has been shown to have no

---

4 Kamath SA. The role of ultrafiltration in patients with decompensated heart failure. Int J of Nephrol.2011.

5 Testani JM, Hanberg JS, Cheng S, et al. Rapid and highly accurate prediction of poor loop diuretic natriuretic response in patients with heart failure. Circ Heart Fail. 2016 Jan;9(1):e002370.

6 Hoorn EJ and Ellison DH. Diuretic Resistance. Am J Kidney Dis. 2017;69(1):136-142.

7 Costanzo MR, Ronco C, Abrahman WT, et al. Extracorporeal ultrafiltration for fluid overload in heart failure. J Am Coll Cardiol. 2017;69(19):24282445.

8 Gheorghiade M, Filippatos G. Reassessing treatment of acute heart failure syndromes: the ADHERE registry. Eur Heart J Suppl.

9 Felker GM, Lee KL, Bull DA, et al. Diuretic strategies in patients with acute decompensated heart failure. N Engl J Med. 2011;

10 Costanzo MR, Guglin ME, Saltzberg MT, et al. Ultrafiltration versus intravenous diuretics for patients hospitalized for acute decompensated heart failure. J Am Coll Cardiol. 2007; 49(6):675-683.

11 Agostoni PG, Marenzi GC, Pepi M, et al. Isolated ultrafiltration in moderate congestive heart failure. J Am Coll Cardiol. 1993; 21(2):424-431.

12 Costanza MR, et. al. Ultrafiltration vs. Diuretics for the Treatment of Fluid Overload in Patients with Heart Failure: A Hospital Cost Analysis. Value Health. 2018; 21 (Suppl 1):S167.

clinically significant impact on electrolyte balance, blood pressure or heart rate.[13] Unlike other forms of ultrafiltration, which typically require administration specifically by a nephrologist, the Aquadex FlexFlow system may be prescribed by any physician and administered by a healthcare provider, both of whom have received training in extracorporeal therapies.

Benefits of the Aquadex FlexFlow System

The Aquadex FlexFlow 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;
- Can be performed via peripheral or central venous access;
- Removes isotonic fluid (extracts sodium while sparing potassium and magnesium);[14]
- Following ultrafiltration, neurohormonal activation is reset toward a more physiological condition and diuretic efficacy is restored;[15]
- 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 resulting in cost savings at 90 days.[16] [17]

Components of the Aquadex FlexFlow System

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, 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, a small, dual-lumen extended length 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 Flex Flow blood circuit set is proprietary and the Aquadex FlexFlow system can only be used with the Aquadex blood circuit set. The dual lumen extended length catheter (dELC) is designed for use with the Aquadex FlexFlow system, although it is one of many potential catheter options available to the healthcare provider.

Our Market Opportunity

The Aquadex FlexFlow system is indicated for the treatment of patients suffering from fluid overload who have failed diuretics. We are currently focusing our commercial activities in two primary clinical areas where fluid overload is prevalent: heart failure and post-cardiac surgery.

Heart Failure

Heart failure is one of the leading causes of death in the United States and other developed countries. In fact, approximately 50% of patients who develop heart failure die within five years of diagnosis. 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

---

[13] 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.

[14] Ali SS, et al. Congest Heart Fail. 2009; 15(1):1-4.

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

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

[17] Costanzo MR, et. al. Ultrafiltration with Heart Failure: A Hospital Cost Analysis. Poster presented at the ISPOR Meeting, May 23, 2018, Baltimore, MD, USA.

that 6.5 million people in the United States, age 20 and over, had heart failure[18]. Based on the Atherosclerosis Risk in Communities Study from 2005 to 2013, conducted by the National Heart, Lung and Blood Institute, there are an estimated 960,000 new heart failure cases annually[19]. Annual hospitalizations for heart failure exceed one million in both the United States and Europe, and more than 90% are due to symptoms and signs of fluid overload[20]. In addition, approximately 68% of patients are discharged with sub-optimal results.[21] As such, there are over 600,000 heart failure patients in the United States who might benefit from new technologies to treat fluid overload.

Heart failure is a progressive disease caused by impairment of the left side of 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 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 pumps blood throughout the body.

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.[22] 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.[23] [24]

Heart failure often requires inpatient treatment and it carries a huge economic burden in the United States, costing the nation an estimated $60.2 billion each year with hospital costs accounting for 62% of the economic burden.[25] As the population ages, healthcare expenditures are expected to increase substantially.[26] Therefore, therapies aimed at treating congestion and fluid overload is essential from a patient care and health economic perspective.

Patients suffering from heart failure may receive ultrafiltration therapy in two settings: (i) *inpatient care:* provided to a patient admitted to a hospital, extended care facility, nursing home or other longer-term care facility; and (ii) *outpatient care:* provided to a patient who is not admitted to a facility, but receives treatment at a doctor's office, clinic, or hospital outpatient department.

Hospitals in the United States also face potential penalties for heart failure readmissions. As part of the Affordable Care Act of 2012, Medicare instituted the Hospital Readmissions Reduction Program (HRRP), which penalizes hospitals with high 30-day readmission rates for heart failure and other common diseases and procedures. This penalty can be as high as 3% of reimbursement for all Medicare admissions. Technologies that help reduce readmissions, such as the Aquadex FlexFlow system, can help hospitals mitigate these penalties.

Post-Cardiovascular Surgery

Cardiac surgeries are commonly performed throughout the world. According to the National Center for Health Sciences, over 7.3 million cardiovascular operations are performed each year in the United States, including an estimated 340,000 coronary-artery bypass grafting (CABG) procedures[27], 180,000 valve procedures[28], and 3,000

---

[18] 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).

[19] 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).

[20] Costanzo MR, et al. J Am Coll Cardiol. 2017; 69: 2428-45.

[21] Testani JM, et al. Circ Heart Failure. 2016;9(1).

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

[23] Desao AS, Steverson LW. Circulation. 2012 Jul 24, 126(4): 501-506.

[24] 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.

[25] Voigt J, John S, Taylor A, Krucoff M, Reynolds M, Gibson CM. A Reevaluation of the costs of heart failure and its implications for allocation of health resources in the United States. Clin Cardiol. 2014;37(5):312–321.

[26] Heidenreich PA, Albert NM, Allen LA, et al. Forecasting the impact of heart failure in the United States: a policy statement from the American Heart Association. Circ Heart Fail. 2013;6(3):606–619.

[27] https://idataresearch.com/new-study-shows-approximately-340000-cabg-procedures-per-year-in-the-united-states/.

[28] https://idataresearch.com/over-182000-heart-valve-replacements-per-year-in-the-united-states/.

ventricular assist device (VAD) implants[29]. Cardiac surgery is associated with a degree of fluid overload due to cardio pulmonary bypass. Cardio pulmonary bypass often requires a physician to administer a high volume of pre- and post-operative fluids (e.g. cardio pulmonary bypass pumps prime fluid, fluid used for cardioplegia, other fluids administered to address hypotension or post-operative crystalloid). Fluid overload in post-cardiac surgery can readily occur because surgery can affect the pumping actions of the heart, leading to postoperative hemodynamic instability. The condition often remains symptomless for several days until clinical symptoms become apparent, when treatment is almost always too late and ineffective.[30]

The potential complications (e.g. renal failure, stroke, infection, arrhythmias, or prolonged intubation) are reported to be associated with high mortality, particularly when renal replacement therapy is required. Major complications after cardiac operations are associated with an increased risk for operative death, longer hospital length of stay, and higher rates of discharge to a location other than home.[31] Readmissions are a common problem in cardiac surgery and remain high. Approximately 20% of patients who undergo cardiac operations require readmission, an outcome with significant health economic implications. Volume overload was among the top three most prevalent causes for first readmission within 30 days and beyond 30 days.[32] It is estimated that 13.5% of post cardiac surgery patients are readmitted due to fluid overload within 30 days of discharge, which equates to an estimated 70,000 fluid overload-related readmissions for CABG, valve, and VAD procedures per year in the United States.[33]

In addition to reducing readmissions, we believe that managing the patient's fluid shortly after cardiac surgery may lessen the time that a patient is in the intensive care unit, allowing the patient to transfer to a more comfortable and less expensive area of the hospital.

Our Strategy

Our mission is to predict, measure, and control patient fluid balance through science, collaboration, innovative medical technology, and education. We provide healthcare professionals with a sophisticated, yet easy to use, mechanical pump and filter system to remove excess fluid in fluid overloaded patients. 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. Since the acquisition, we have focused our marketing efforts in heart failure patients suffering from fluid overload in the inpatient setting and for the last seven quarters have experienced double-digit year over year revenue growth. During this time, we expanded our field-based employees which includes both sales representatives and clinical specialists and currently have thirteen sales territories in the US, as well as distribution agreements in several countries in Europe and Asia. In 2019, we will continue to focus on heart failure patients in the inpatient setting while expanding to other clinical areas such as heart failure in the outpatient setting and addressing fluid overload in the post-cardiac surgery setting; and, if we receive clearance from the U.S. Food and Drug Administration, or FDA, we intend to expand our commercialization efforts to treatments for pediatric patients.

Heart Failure In-Patients: Heart failure patients suffering from fluid overload may be treated in an inpatient setting, such as a hospital, extended care facility or nursing home. Historically, our commercial efforts have been primarily focused on use of the Aquadex FlexFlow system in the inpatient setting in large hospital accounts. We intend to continue to focus our sales efforts on inpatient facilities, leveraging the clinical benefits and economic advantages of using the Aquadex FlexFlow system over diuretic therapy.

Heart Failure Out-Patients: Further, we intend to expand the use of the Aquadex FlexFlow system with heart failure patients in the outpatient setting, such as a clinic or hospital outpatient department (e.g. observation unit). While currently not reimbursed by Medicare and private payors, outpatient clinics are still using the Aquadex

---

[29] Grand View Research. Market Research Report. 2015; 978-1-68038-603-5.

[30] Xu J, Shen B, Fang Y, et al. Postoperative fluid overload is a useful predictor of the short-term outcome of renal replacement therapy for acute kidney injury after cardiac surgery. Medicine. 2015;94(33):e1360.

[31] Crawford TC, Magruder JT, Grimm JC, et al. Complications after cardiac surgery: All are not created equal. Ann Thorac Surg. 2017;103:32-40.

[32] Iribane A, Chang H, Alexander Jh, et al. Readmissions after cardiac surgery: Experience of the national institutes of health/Canadian institutes of health research cardiothoracic surgical trials network. Ann Thorac Surg. 2014;98:1274-80.

[33] Iribarne A, et al. Ann Thorac Surg. 2014 Oct; 98(4): 1274-80.

FlexFlow system to treat patients suffering from fluid overload because it can be a financial benefit to use the Aquadex FlexFlow system without reimbursement rather than to incur Medicare penalties for readmission into the inpatient setting. We are supporting the development of new evidence regarding the economic impact of ultrafiltration in the outpatient setting, including a clinical study on outpatient use that is expected to be initiated by the Department of Veterans Affairs Medical Center in Tampa, Florida in the second quarter of 2019. We plan to use such new evidence to seek reimbursement and gain broader adoption of the Aquadex FlexFlow system in the outpatient market.

Post Cardio Vascular Surgery: At the end of the third quarter of 2018, we launched a marketing campaign focused on the benefits of the Aquadex FlexFlow system in treating patients suffering from fluid overload following cardiac surgery procedures, such as CABG, valve repairs and replacements procedures, VAD implants and other cardiac surgical procedures. We plan to continue to focus our expanded efforts in this therapeutic area to grow revenue, leveraging the synergies between heart failure cardiologists and cardiovascular surgeons, traditional technology adoption rates of cardiac surgeons, and product purchase cycle of the cardiac surgical centers at large hospitals.

Pediatrics: We intend to seek modification of the product label contained in the 510(k) clearance for our Aquadex FlexFlow system to allow commercial promotion in pediatric patients. Currently, our Aquadex FlexFlow system is not recommended for use in pediatric patients. Therefore, we do not devote commercialization resources toward, nor promote, the use of the Aquadex FlexFlow system in pediatric patients. However, based on their clinical expertise and medical judgement, physicians are permitted to prescribe the Aquadex FlexFlow system for use in pediatric patients. We believe that Aquadex FlexFlow system is currently being prescribed by physicians to treat various conditions in pediatric patients, including heart failure, cardiac surgery[34], extracorporeal membrane oxygenation (ECMO) therapy[35], solid organ transplantation[36], and kidney replacement therapy for neonatal patients. While incidence data is not readily available, it is estimated that there are approximately 10,000 to14,000 pediatric patients with heart failure[37] and approximately 18,000 receiving cardiac surgery, ECMO therapy, and solid organ transplantation. [38, 39, 40] We plan to begin discussions with the FDA in the first half of 2019 regarding a modification to the product label and expect to submit for a modification to our 510(k) clearance by the end of the second quarter of 2019. If we submit for such modification by the end of the second quarter, we believe that we will receive 510(k) clearance from the FDA by the end of 2019. It is possible that the FDA requires additional testing prior to clearance of the modification to our indication for pediatric use or does not clear the modification at all. If we receive FDA clearance for an update to the product label, we intend to expand our commercialization efforts to include promotion to physicians and hospitals who treat this pediatric population.

Outside of the United States, we plan to continue to establish partnerships for the distribution of the Aquadex FlexFlow system. We currently have distribution relationships in Brazil, Germany, Hong Kong, India, Italy, Singapore, Spain, Thailand and the United Kingdom.

Besides driving near term revenue growth through sales of the Aquadex FlexFlow system, we intend to develop product enhancements to improve performance and customer satisfaction. We have projects designed to improve venous access for the Aquadex FlexFlow catheter and enhance the functionality of the hematocrit sensor that is part of the Aquadex FlexFlow console. We also are collaborating with partners to evaluate diagnostic tools 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.

Sales and Marketing

As of February 15, 2019, we had 24 full-time employees in sales and marketing. Our U.S. sales force includes therapy development managers as well as field clinical specialists who provide training, technical and other support services to our customers. Following the acquisition of the Aquadex Business from Baxter International,

---

[34] Hazle M, et al. Pediatr Crit Care Med. 2013 January; 14(1): 44—49. doi:10.1097/PCC.0b013e3182712799.

[35] Selewski DT, et al. Crit Care Med. 2012 September; 40(9): 2694—2699. doi:10.1097/CCM.0b013e318258ff01.

[36] Florescu DF, et al. Pediatr Infect Dis J. 2015 Jan; 34(1):47-51. doi: 10.1097/INF.0000000000000487.

[37] Jayaprasad. Heart Views. 2016 Jul-Sep; 17(3): 92—99.

[38] https://www.cdc.gov/ncbddd/heartdefects/data.html.

[39] Karamlou T, et al. J Thorac Cardiovasc Surg. 2013 Feb;145(2):470-5. doi: 10.1016/j.jtcvs.2012.11.037. Epub 2012 Dec 14.

[40] https://www.organdonor.gov/about/donors/child-infant.html.

Inc. (Baxter) in August 2016, our direct sales force was focused on re-engaging hospital accounts that ordered Aquadex FlexFlow 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. In 2018, we expanded our focus to engage customers who have not previously used the Aquadex FlexFlow system and to market our product for use in post-cardiac surgery. We have grown the sales and marketing organization as necessary to support this growth.

In the United States, our target customers for the Aquadex FlexFlow system include health care systems and academic hospitals specializing in advanced treatment of chronic heart failure and/or cardiac surgery, other hospitals with heart failure related admissions and/or who perform cardiac surgery operations and clinical practices with heart failure or cardiac surgery programs. Our largest customer, Mount Sinai Hospital, represented 10.1% of our 2018 annual revenue. The loss of this customer would have a material adverse effect on our revenue.

Outside of the United States, our Aquadex FlexFlow system is sold by independent specialty distributors who in turn sell to hospitals and clinics in their geographic regions. We currently have distribution relationships in Brazil, Germany, Hong Kong, India, Italy, Singapore, Spain, Thailand and the United Kingdom. We intend to continue to establish distribution partners in additional countries outside of the United States.

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. Currently, we have projects designed to improve venous access for the Aquadex FlexFlow catheter and enhance the functionality of the hematocrit sensor that is part of the Aquadex FlexFlow console. We also are evaluating diagnostic tools 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. These diagnostic tools include the AcQtrac™ System, which we acquired in August 2018, and diagnostic tools marketed by Daxor Corporation (''Daxor'') and NI Medical, Inc. In the second half of 2019, we intend to conduct a clinical evaluation of Daxor's BVA-100 and the Aquadex FlexFlow system, and if successful, we may initiate a co-marketing arrangement with Daxor in the second half of 2019. In the future, 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 FlexFlow business (herein referred to as the ''Aquadex Business''), we entered into a commercial manufacturing and supply agreement with Baxter, which required Baxter to manufacture Aquadex FlexFlow blood circuit sets and Aquadex FlexFlow 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 consoles and blood circuits in-house in the fourth quarter of 2017 and Aquadex FlexFlow catheters in-house in the third quarter of 2018. With the initiation of internal catheter production, we have completed the transfer of all manufacturing activities of the Aquadex FlexFlow system from Baxter.

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 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 December 2018, we filed two patent applications with the United States Patent and Trademark Office. One application is based on our design for a wearable device designed to assist in maintaining peripheral venous blood flow access in the arm during aquapheresis treatment with the Aquadex FlexFlow system. The second application includes multiple potential new features and improvements to the diagnostic capabilities of the Aquadex FlexFlow system, which, if incorporated into the product, would be designed to help patient fluid balance and to improve usability for healthcare providers.

In addition, as of February 15, 2019, we owned 36 issued patents and two pending patent applications in the United States and in foreign jurisdictions related to our C-Pulse System and had one pending application 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 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 demonstrate the advantages of ultrafiltration as compared to diuretics, a pharmacological treatment that is currently the standard of care. In addition, we need to distinguish Aquadex FlexFlow system from the indirect competition of other devices that can also be used to conduct ultrafiltration.

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 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 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 preclinical 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 Federal Food, Drug, and Cosmetic Act (''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 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 to that device that could ''significantly affect its safety or effectiveness,'' such as a significant change in the design, materials, method of manufacture or which results in ''major change'' to the 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 certain devices, clinical trials may be required to support a PMA application. We previously were conducting clinical trials for the C-Pulse System that were halted. We are currently not conducting any clinical trials; however, it is possible that we may need to conduct clinical trials in the future if we develop enhancements to, or expand the approved indication of, the Aquadex FlexFlow system or we acquire additional products that require a clinical trial. Clinical trials generally require submission of an application for an Investigational Device Exemption (IDE) to the FDA prior to commencing the trial. 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.

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. 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.

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

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

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

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

- warning letters or untitled letters;
- fines, injunctions and civil penalties;
- product recall or seizure;

- unanticipated expenditures;
- delays in clearing or approving or refusal to clear or approve products;
- withdrawal or suspension of FDA approval;
- orders for physician notification or device repair, replacement or refund;
- operating restrictions, partial suspension or total shutdown of production or clinical trials; or
- criminal prosecution.

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

European Union

In order to import and sell our products in member countries of the European Union, or EU, medical devices currently must comply with the essential requirements of the European Union Medical Devices Directive (Council Directive 93/42/EEC). Compliance with these requirements is a prerequisite to be able to affix the Conformité Européene, or CE, Mark to our products, without which they cannot be sold or marketed in the EU. To demonstrate compliance with the essential requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the European Union Medical Devices Directive, a conformity assessment procedure requires the intervention of a Notified Body, an organization accredited by a member state of the EU to conduct conformity assessments. Depending on the relevant conformity assessment procedure, the Notified Body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. The Notified Body issues a certificate of conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the essential requirements. This certificate entitles the manufacturer to affix the CE Mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

Recently, the European Union replaced the Medical Devices Directive (93/42/EEC) (MDD) with the new European Medical Devices Regulation, or MDR. The MDR will apply after a transitional period of three years ending on May 26, 2020. Manufacturers have the duration of the transition period to update their technical documentation and processes to meet the new requirements in order to obtain a CE Mark or to issue a EC Declaration of Conformity. After May 26, 2020, medical devices can still be placed on the market under the provision of the MDD or the Active Implantable Medical Devices Directive (''AIMDD'') 90/385/EEC (hereafter referred to together as ''MDD/AIMDD'') until May 27, 2024; provided the CE Mark was issued prior to this date, the manufacturer continues to comply with either one of the directives, and that no significant changes are made in the design and intended purpose of the applicable medical device. By May 27, 2024, all medical devices entering the EU will need to have a new CE Mark under the MDR, even if they have been on the market previously under the MDD/AIMDD.

The CE Mark for Aquadex FlexFlow system has expired and, therefore, we currently cannot import new units of the Aquadex FlexFlow system into the EU. We currently are seeking renewal of the CE Mark, which we expect to receive by the latter half of 2019. It is possible that the conformity assessment conducted by our notified body will be under the MDR. We believe that we will be able to meet the requirements of the MDR; however, it is

possible that we may not be able to meet all of the requirements of this new regulation without additional testing. While we believe that we currently have sufficient product inventory already available for sale in the EU market and the timing of the receipt of the CE Mark will not have a material impact on our revenue, a delay in receipt of the CE Mark could cause a shortage in product availability in the EU.

Employees

As of February 15, 2019, we had 55 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.

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. In August 2016, we acquired the Aquadex Business from a subsidiary of Baxter. In September 2016, we announced a strategic refocus of our strategy that included halting all clinical evaluations of the C-Pulse related technology to fully focus our resources on our recently acquired Aquadex Business. 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.

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 Current Reports on Form 8-K and amendments to reports filed or furnished 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. These reports are also available on the Securities and Exchange Commission's website, www.sec.gov. The information on, or that may be accessed through, any websites noted herein 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 $250 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. As long as our public float remains below $75 million as of the last business day of our most recently completed second fiscal quarter, we are exempt 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 but are required to make our own internal assessment of the effectiveness of our internal controls over financial reporting.

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 and manufacturing our C-Pulse System. On September 29, 2016, we announced a strategic refocus of our strategy that included halting all clinical evaluations of the C-Pulse System to fully focus our resources on commercializing our Aquadex FlexFlow system, taking actions to reduce our cash burn in connection with such strategic refocus and reviewing potential strategic alliances and financing alternatives. In addition, our business strategy depends in part on our ability to grow our business by establishing an effective sales force and selling our products to hospitals and other healthcare facilities while controlling costs. In the third quarter of 2018, we announced our intention to expand our commercialization efforts in post-cardiac surgery, in addition to heart failure. We have limited prior experience with respect to sales or marketing of the Aquadex FlexFlow system in both heart failure and post-cardiac surgery. If we are unsuccessful at 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 consolidated financial statements for the fiscal year ended December 31, 2018 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 $17.0 million and $13.4 million for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, our accumulated deficit was $199.4 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, 2018 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 from a subsidiary of Baxter 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, manufacturing components, and complying with the requirements related to being a U.S. public company listed on Nasdaq. To become and remain profitable, we must succeed in expanding the adoption and market acceptance of the Aquadex FlexFlow 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 2019. 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 2019. 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 sales.

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 sales 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 54.1% and 50.9% of our revenues in the years ended December 31, 2018, and 2017, respectively, with our largest customer representing 10.1% and 14.5%, respectively, of our revenues during such periods. 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 have limited 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 limited experience in commercial manufacturing of the Aquadex FlexFlow system. 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 Flex Flow blood sets and Aquadex FlexFlow catheters for a period of 18 months following the acquisition. 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 consoles and blood circuits in-house in the fourth quarter of 2017 and Aquadex FlexFlow catheters in-house in the third quarter of 2018. With the initiation of internal catheter production, we have completed the transfer of all manufacturing activities of the Aquadex FlexFlow system from Baxter. However, because we have limited 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 have no long-term contracts with third-party suppliers that guarantee volume or the continuation of payment terms. 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. If we do not increase our sales volumes, which drive our demand for our suppliers' products, we may not procure volumes sufficient to receive favorable pricing, which could impact our gross margins if we are unable to pass along price differences to our customers. 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 suppliers, or in the ability of third-party suppliers 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 FlexFlow system effectively and our sales 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 sales 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, pharmaceutical companies and gene- and cell-based therapies is intense and expected to increase. The vast majority of 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 demonstrate the advantages of ultrafiltration as compared to diuretics, a pharmacological treatment that is currently the standard of care. In addition, we need to distinguish Aquadex FlexFlow system from the indirect competition of other devices that can also be used to conduct ultrafiltration.

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

Our ability to operate successfully and manage our potential future growth depends significantly upon our ability to attract, retain and motivate highly skilled and qualified research, technical, clinical, regulatory, sales, marketing, managerial and financial personnel. We face intense competition for such personnel, and we may not be able to attract, retain and motivate these individuals. We compete for talent with numerous companies, as well as universities and nonprofit research organizations. Our future success also depends on the personal efforts and

abilities of the principal members of our senior management and scientific staff to provide strategic direction, manage our operations and maintain a cohesive and stable environment. We do not maintain life insurance on the lives of any of the members of our senior management. The loss of key personnel for any reason or our inability to hire, retain and motivate additional qualified personnel in the future could prevent us from sustaining or growing our business.

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

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 enhancements to the system or its components. Depending on their nature, such enhancements may be subject to review by the FDA and regulatory authorities outside of the United States under the applicable 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 sales. In addition to potential enhancements to the system or its components, we plan to begin discussions with the FDA in the first half of 2019 regarding a modification to the product label contained in the 510(k) clearance for our Aquadex FlexFlow system to allow commercial promotion in pediatric patients and believe that we will submit for a modification to our 510(k) clearance by the end of the second quarter of 2019. Currently, our Aquadex FlexFlow system is not recommended for use in pediatric patients. Therefore, we do not devote commercialization resources toward, nor promote, the use of the Aquadex FlexFlow system in pediatric patients. If we submit for such modification by the end of the second quarter, we believe that we will receive 510(k) clearance from the FDA by the end of 2019. If we receive FDA clearance for an update to the product label, we intend to expand our commercialization efforts to include promotion to physicians and hospitals who treat this pediatric population. It is possible that the FDA requires additional testing prior to clearance of the expanded indication for pediatric use or does not clear the expanded indication at all. A failure to obtain the expanded indication could have a negative impact on our potential sales.

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.

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 $6 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, 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. In addition, regulations in individual countries or regions may restrict our ability to sell our products. Most countries, including the countries in the European Union (EU), require approval or registration to import and/or sell our products in the country.

In the EU, we are required to hold a Conformité Européene, or CE, Mark to import our product into the EU. To hold the CE Mark, we must demonstrate compliance with the essential requirements of the European Union Medical Devices Directive (93/42/EEC). Recently, the European Union replaced the Medical Devices Directive with the new European Medical Devices Regulation, or MDR. The MDR will apply after a transitional period of three years ending on May 26, 2020. Manufacturers have the duration of the transition period to update their technical documentation and processes to meet the new requirements in order to obtain a CE Mark or to issue a EC Declaration of Conformity. After May 26, 2020, medical devices can still be placed on the market under the provision of the MDD or the Active Implantable Medical Devices Directive (''AIMDD'') 90/385/EEC (hereafter referred to together as ''MDD/AIMDD'') until May 27, 2024; provided the CE Mark was issued prior to this date, the manufacturer continues to comply with either one of the directives, and that no significant changes are made in the design and intended purpose of the applicable medical device. By May 27, 2024, all medical devices entering the EU will need to have a new CE Mark under the MDR, even if they have been on the market previously under the MDD/AIMDD

The CE Mark for the Aquadex FlexFlow system has expired and, therefore, we currently cannot import new units of the Aquadex FlexFlow system into the EU. We currently are seeking renewal of the CE Mark, which we expect to receive by the latter half of 2019. It is possible that the conformity assessment conducted by our Notified Body in connection with this renewal will be under the MDR. We believe that we will be able to meet the requirements of the MDR; however, it is possible that we may not be able to meet all of the requirements of this new regulation without additional testing. While we believe that we currently have sufficient product inventory already available for sale in the EU market and the timing of the receipt of the CE Mark will not have a material impact on our revenue, a delay in receipt of the CE Mark could cause a shortage in product availability in the EU.

Any one or more of these factors associated with international operations could increase our costs, reduce our revenues, or disrupt our operations, which could have a material adverse effect on our business, financial condition and results of operations.

If we are not able to maintain sufficient quality controls, then the approval or clearance of our products by the European Union, the FDA or other relevant authorities could be withdrawn, delayed or denied and our sales 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 from sales. Other countries may impose analogous reporting requirements that could cause us to incur expenses and may also limit our ability to generate revenues from sales of our products.

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

The Patient Protection and Affordable Care Act, as amended, (the ''Affordable Care Act'') as well as other healthcare reform may have a significant impact on our business. The Affordable Care Act is extremely complex, and, as a result, additional legislation is likely to be considered and enacted over time. 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 uncertainties regarding the implementation of the Affordable Care Act, including possible repeal of the Affordable Care Act, ongoing legal challenges, and further judicial interpretations, create unpredictability for the health care industry, which itself constitutes a risk.

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 as part of the Affordable Care Act, requires applicable medical device companies to track and publicly report, with limited exceptions, all payments and other 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. Effective in 2019, payments to certain nurses, who prescribe treatments,

has been added to the list of recipients that companies need to track. 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 making referrals for the furnishing of any ''designated health services,'' for which payment may be made under the Medicare or Medicaid programs, to any entity with which the physician (or an 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.

Our operating results may fluctuate from quarter to quarter and year to year.

Our sales and operating results may vary significantly from quarter to quarter and from year to year in the future. Our operating results are affected by a number of factors, many of which are beyond our control. Factors contributing to these fluctuations include the following:

- changes in the prices at which we sell our consoles and disposable blood sets and catheters;
- our bulk ordering practices by our customers;

- general economic uncertainties and political concerns;
- introduction of new products, product enhancements and new applications by our competitors;
- the timing of the introduction and market acceptance of new products, product enhancements and new applications;
- changes in demand for our Aquadex FlexFlow system;
- our ability to maintain sales volumes at a level sufficient to cover fixed manufacturing and operating costs;
- the effect of regulatory approvals and changes in domestic and foreign regulatory requirements;
- our highly variable sales cycle;
- changes in customers' or potential customers' budgets as a result of, among other things, reimbursement policies of government programs and private insurers for treatments that use the Aquadex FlexFlow system;
- variances in shipment volumes as a result of product, supply chain and training issues; and
- increased product costs.

Our sales volumes from quarter to quarter may fluctuate significantly as a result of such ordering practices. Furthermore, from time to time, we offer our disposable blood sets and disposable catheters at a discount to the list price, and our agreements with certain customers may contain volume or other discounts from our normal selling prices and other special pricing considerations.

Discounted pricing can impact our operating results through increasing sales volumes, causing our average selling prices and operating margins to decline and, if we are unable to offset discounts by increasing our sales volume, our net sales could decline. As a result of discounted prices and/or bulk sales orders by our customers, our sales volume may significantly fluctuate quarter to quarter and our sales volume for one quarter may not be indicative of our sales volume for future periods.

Our expense levels are based, in part, on expected future sales. If sales levels in a particular quarter do not meet expectations, we may be unable to adjust operating expenses quickly enough to compensate for the shortfall of sales, and our results of operations may be adversely affected. In addition, we have historically made a significant portion of each quarter's product shipments near the end of the quarter. If that pattern continues, any delays in shipment could have a material adverse effect on results of operations for such quarter.

Due to these and other factors, we believe that quarter to quarter and year to year comparisons of our past operating results may not be meaningful. You should not rely on our results for any quarter or year as an indication of our future performance. Our operating results in future quarters and years may be below expectations, which would likely cause the price of our common stock to fall.

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'' as defined in the license. 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 December 2018, we filed two patent applications with the United States Patent and Trademark Office. One application is based on our design for a wearable device designed to assist in maintaining peripheral venous blood flow access in the arm during aquapheresis treatment with the Aquadex FlexFlow system. The second application includes multiple potential new features and improvements to the diagnostic capabilities of the Aquadex FlexFlow system, which, if incorporated into the product, would be designed to help patient fluid balance and to improve usability for healthcare providers.

In addition, as of February 15, 2019, we owned 36 issued patents and two pending patent applications in the United States and in foreign jurisdictions related to our C-Pulse System and had one pending application 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 reverse split of our common stock effected on January 2, 2019 could decrease our total market capitalization and increase the volatility of our stock price.

At a special meeting of our stockholders on December 28, 2018, our stockholders approved a reverse split of our outstanding common stock at a ratio in the range of 1-for-2 to 1-for-14. Following such special meeting, our board of directors approved a 1-for-14 reverse split of our issued and outstanding shares of common stock. We filed with the Secretary of State of the State of Delaware a Certificate of Amendment to our Fourth Amended and Restated Certificate of Incorporation to effect the reverse stock split. The reverse stock split was effective as of 5:00 pm Eastern Time on January 2, 2019, and our common stock began trading on a split-adjusted basis on The Nasdaq Capital Market on January 3, 2019.

There can be no assurance that the total market capitalization of our common stock after the reverse stock split will be equal to or greater than the total market capitalization before the reverse stock split or that the per share

market price of our common stock following the reverse stock split will increase in proportion to the reduction in the number of shares of common stock outstanding before the reverse stock split. Furthermore, a decline in the market price of our common stock after the reverse stock split may result in a greater percentage decline than would occur in the absence of a reverse stock split, and the liquidity of our common stock could be adversely affected following such a reverse stock split.

We previously effected a 1-for-20 reverse split of our issued and outstanding shares of common stock as of October 12, 2017 and a 1-for-30 reverse split of our issued and outstanding shares of common stock as of January 12, 2017. Our total market capitalization following such reverse split was substantially lower than our total market capitalization prior to such split, and the per share market price of our common stock following such reverse stock split, after initially increasing, eventually decreased such that the market price following the split did not increase in proportion to the reduction in the number of shares of common stock outstanding before the reverse stock split.

Our business could be negatively affected as a result of actions of activist stockholders, and such activism could impact the trading value of our securities.

Stockholders may, from time to time, engage in proxy solicitations or advance stockholder proposals, or otherwise attempt to effect changes and assert influence on our board of directors and management. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs and require significant time and attention by our board of directors and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our board of directors or senior management team arising from a proxy contest could lead to the perception of a change in the direction of our business or instability which may result in the loss of potential business opportunities, make it more difficult to pursue our strategic initiatives, or limit our ability to attract and retain qualified personnel and business partners, any of which could adversely affect our business and operating results. If individuals are ultimately elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively implement our business strategy and create additional value for our stockholders. We may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would serve as a further distraction to our board of directors and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant fluctuations in our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

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

On September 21, 2016, we received notice from the Listing Qualifications Staff (the ‘‘Staff’’) of Nasdaq indicating that the Staff had determined to delist our securities from Nasdaq due to our then 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. We received confirmation from Nasdaq on February 9, 2017, after implementing a 1-for-30 reverse stock split on January 12, 2017, that we had regained compliance with the minimum bid price rule. 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 at such time.

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. After implementing a 1-for-20 reverse stock split on October 12, 2017, we received confirmation from Nasdaq on October 27, 2017 that we had regained compliance with the minimum bid price rule.

At a special meeting of our stockholders on December 28, 2018, our stockholders approved a reverse split of our outstanding common stock at a ratio in the range of 1-for-2 to 1-for-14, which was submitted to stockholder approval to reduce the risk that our common stock could be delisted from the Nasdaq Capital Market for non-compliance with the minimum bid price rule. Following such special meeting, our board of directors approved a 1-for-14 reverse split of our issued and outstanding shares of common stock. We filed with the Secretary of State of the State of Delaware a Certificate of Amendment to our Fourth Amended and Restated Certificate of Incorporation to effect the reverse stock split. The reverse stock split was effective as of 5:00 pm Eastern Time on January 2, 2019, and our common stock began trading on a split-adjusted basis on The Nasdaq Capital Market on January 3, 2019.

There can be no assurance that the total market capitalization of our common stock after the reverse stock split will be equal to or greater than the total market capitalization before the reverse stock split or that the per share market price of our common stock following the reverse stock split will increase in proportion to the reduction in the number of shares of common stock outstanding before the reverse stock split.

On February 15, 2019, the closing price of our common stock was $10.05 per share. If the bid price of our common stock closes below the minimum $1.00 per share for 30 consecutive business days in the future, we will likely receive notice that we no longer comply with the minimum bid price rule and, if it appears to the Nasdaq staff that we will not be able to comply with Nasdaq Listing Rule 5550(a)(2) or any other listing standard, our common stock may be subject to delisting. If our common stock is delisted, Baxter, pursuant to the asset purchase agreement for the business relating to the Aquadex FlexFlow system, 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, 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. 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 number of shares of common stock underlying our outstanding warrants and outstanding preferred stock is significant in relation to our currently outstanding common stock. Conversion or exercise of such outstanding convertible securities will cause dilution to holders of our common stock, and could cause downward pressure on the market price for our common stock.

The number of shares of common stock issuable upon conversion of our 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 February 15, 2019,we have warrants to purchase 599,293 shares of common stock outstanding, with exercise prices ranging from $29.68 to $43,848 with a weighted-average exercise price of $50.23.

Through February 15, 2019, shares of our Series F Preferred Stock have been converted into 279,526 shares of our common stock. As of February 15, 2019, there were 535 shares of Series F Preferred Stock outstanding, convertible into an aggregate of 18,190 shares of common stock. The certificate of designation for our Series F Preferred Stock contains an anti-dilution provision, which provision requires the lowering of the applicable conversion price, as then in effect, to the purchase price per share of common stock or common stock equivalents issued in the future. 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 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 could depress the trading market for our common stock over an extended period of time.

In addition, the fact that our stockholders, option holders and warrant holders can sell substantial amounts of our common stock in the public market, whether or not sales have occurred or are occurring, could make it more difficult for us to raise additional financing through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate, or at all.

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 and 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 previously approved, pursuant to this authority, the issuance of preferred stock, and we have 535 shares of Series F Preferred Stock outstanding as of February 15, 2019. As described therein, upon liquidation, dissolution or winding-up of the Company, holders of our Series F 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.

At a special meeting of our stockholders on December 28, 2018, our stockholders approved a reverse split of our outstanding common stock at a ratio in the range of 1-for-2 to 1-for-14. Following such special meeting, our board of directors approved a 1-for-14 reverse split of our issued and outstanding shares of common stock.

We filed with the Secretary of State of the State of Delaware a Certificate of Amendment to our Fourth Amended and Restated Certificate of Incorporation to effect the reverse stock split. The reverse stock split was effective as of 5:00 pm Eastern Time on January 2, 2019, and our common stock began trading on a split-adjusted basis on The Nasdaq Capital Market on January 3, 2019. Because the number of authorized shares of our common stock will not be reduced proportionately, the reverse stock split will increase our board of directors' ability to issue authorized and unissued shares without further stockholder action. As of February 15, 2019, 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 have 513,445 shares of common stock outstanding, 754,990 shares reserved for issuance upon the conversion, exercise or vesting of outstanding preferred stock, warrants, options and restricted stock units, and 43,651 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, and this may make it difficult for you to resell the common stock you want or at prices you find attractive.

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

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

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

Our loan agreement subjects us to operating restrictions and financial covenants and may restrict our business and financing activities.

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 revolving line of credit expires on March 31, 2020. Advances under the revolving line, if any, are subject to various conditions precedent, including our compliance with financial covenants relating to net liquidity relative to monthly cash burn. We have not made borrowings under the Silicon Valley Bank facility since its inception.

Our obligations under the 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. The loan agreement contains customary representations, as well as customary affirmative and negative covenants. Among other restrictions, the negative covenants, subject to exceptions, prohibit or limit our ability to: declare dividends or redeem or purchase equity interests; incur additional liens; make loans and investments; incur additional indebtedness; engage in mergers, acquisitions, and asset sales; transact with affiliates; undergo a change in control; add or change business locations; and engage in businesses that are not related to its existing business. These covenants may restrict our ability to finance our operations and to pursue our business activities and strategies. Our ability to comply with these covenants may be affected by events beyond our control.

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

As of December 31, 2018, we had U.S. net operating loss (“NOL”) carryforwards of approximately $135.2 million for U.S. income tax purposes. Approximately $120.1 million of NOL carryforwards will expire from 2024 through 2037. Pursuant to the Tax Cuts and Jobs Act of 2017, the NOL that was generated in the current year of approximately $15.1 million does not expire. 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 and 2018, we believe 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 carryforwards that may be utilized. We have not yet completed a formal Section 382 analysis. As a result, prior or future changes in ownership, 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, 2018, 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 Sarbanes-Oxley Act of 2002 and the listing requirements of The Nasdaq Capital Market. We expect these rules and regulations will continue to increase our legal and financial compliance costs and make some activities more time-consuming and costly, and these activities may increase general and administrative expenses and divert management's time and attention away from revenue-generating activities. Furthermore, now that we are a revenue-generating company following the acquisition of the Aquadex Business in August 2016, our costs to comply with regulations applicable to U.S. reporting companies may further increase. We also expect these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers.

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

As long as our public float remains below $75 million as of the last business day of our most recently completed second fiscal quarter, we are exempt 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 but are required to make our own internal assessment of the effectiveness of our internal controls over financial reporting.

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 66 2/3% majority stockholder approval in order for stockholders to amend certain provisions of our certificate of incorporation or bylaws or adopt new bylaws; providing that, subject to the rights of preferred shares, the directors will be divided into three classes and the number of directors is to be fixed exclusively by our board of directors; and providing that none of our directors may be removed without cause. Section 203 of the DGCL, from which we did not elect to opt out, provides that if a holder acquires 15% or more of our stock without prior approval of our board of directors, that holder will be subject to certain restrictions on its ability to acquire us within three years. These provisions may delay or deter a change in control of us, and could limit the price that investors might be willing to pay in the future for shares of our common stock.

We are 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 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 $250 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.

Stockholder litigation could divert the attention of management from the day-to-day operation of our business or result in us incurring substantial costs and liabilities.

We cannot be sure that our stockholders will not initiate securities litigation against us in the future. If securities or stockholder derivative litigation were to be commenced against us, our defense of such litigation could divert the attention of management from the day-to-day operation of our business or result in us incurring substantial costs and liabilities, irrespective of the merits of the litigation.

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, 2022. 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 $25,000. 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.

Stockholders of Record. As of February 15, 2019, we had 513,445 shares of common stock issued and outstanding, and there were 20 holders of record of our common stock. A substantially greater number of stockholders may be ''street name'' or beneficial holders, whose shares are held of record by banks, brokers and other financial institutions.

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. In addition, pursuant to our loan agreement with Silicon Valley Bank, we are prohibited from paying cash dividends without the prior consent of Silicon Valley Bank. 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.

The following table sets forth certain information as of December 31, 2018 concerning our equity compensation plans:

Plan category	Number of securities to be issued upon exercise of outstanding options and rights (a)	Weighted-average exercise price of outstanding options and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	33,552[(1)]	$64.14[(2)]	35,460[(3)]
Equity compensation plans not approved by security holders	106,994[(4)]	$52.02	4,911[(5)]
Total	**140,546**	**$61.25**	**40,609**

(1) Consists of shares of our common stock that may be issued pursuant to outstanding stock options and RSUs under the 2011 Equity Incentive Plan, the 2017 Equity Incentive Plan and the 2013 Directors' Plan.

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

(3) Consists of 35,460 shares of our common stock remaining available for future issuance under the 2017 Equity Incentive Plan (the ''2017 Plan'') and 238 shares of our common stock remaining available for future issuance under the 2013 Directors' Plan. No additional awards may be issued under the 2002 Stock Plan or the 2011 Equity Incentive Plan.

Each of the 2017 Equity Incentive Plan and the 2013 Directors' Plan contains an ''evergreen'' provision, pursuant to which the number of shares available for issuance under the plan automatically adjusts by a percentage of the number of fully diluted shares outstanding. Specifically, pursuant to the 2017 Equity Incentive Plan, the share reserve under the plan will automatically increase on January 1st of each year, for a period of not more than ten years, commencing on January 1, 2018 and ending on (and including) January 1, 2027, to an amount equal to 13% of the fully diluted shares outstanding on December 31st of the preceding calendar year; provided that the board of directors may act prior to January 1st of a given year to provide that there will be no January 1st increase in the share reserve for such year or that the increase in the share reserve for such year will be a lesser number of shares than would otherwise occur. Pursuant to the 2013 Directors' Plan, the share reserve under the plan will automatically increase on January 1st of each year, for a period of not more than ten years, commencing on January 1, 2014 and ending on (and including) January 1, 2023, by an amount equal to 2% of the fully diluted shares outstanding on December 31st of the preceding calendar year; provided that the board of directors may act prior to January 1st of a given year to provide that there will be no January 1st increase in the share reserve for such year or that the increase in the share reserve for such year will be a lesser number of shares than would otherwise occur.

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

(5) Consists of 4,911 shares remaining available for future issuance under the New Hire Plan.

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 consolidated 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. In the United States, we hold 501(k) clearance from the FDA to market and sell the Aquadex FlexFlow system. In the European Union, we are required to hold a CE Mark to import our product into the EU. The CE Mark for the Aquadex FlexFlow system has expired; however, we expect to receive renewal by the latter half of 2019, which would allow us to import additional inventory into the EU. We believe that we currently have sufficient inventory already available for sale in the EU market and the timing of the receipt of the CE Mark will not have a material impact on our revenue.

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. 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. In September 2016, we announced a strategic refocus of our strategy that included halting all clinical evaluations of the C-Pulse related technology to fully focus our resources on our recently acquired Aquadex Business.

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

Reverse Stock Splits

In December 2018, our stockholders approved a reverse stock split of our outstanding common stock at a ratio in the range of 1-for-2 to 1-for-14 and, in January 2019, our board of directors approved a 1-for-14 reverse split of our outstanding common stock that became effective after trading on January 2, 2019. In addition, 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. These reverse stock splits did not change 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. All share and per share amounts in this Annual Report on Form 10-K for the years ended December 31, 2018 and 2017, including the consolidated financial statements and notes thereto, have been retroactively adjusted to reflect the reverse stock splits for all periods presented.

Cardiac Surgery Market

In late third quarter of 2018, we announced the expansion of our commercialization efforts to the use of the Aquadex FlexFlow system to reduce fluid overload following cardiac surgery. Cardiac surgeries are commonly performed throughout the world. According to the National Center for Health Sciences, over 7.3 million cardiovascular operations are performed each year in the United States, including over 340,000 coronary artery bypass graft procedures and 180,000 valve procedures[6] and 3,000 ventricular assist device (VAD) implants[7]. The Aquadex FlexFlow system may be used to remove excess fluid from patients following these operations.

Public Offerings

We filed an S-1 on December 31, 2018, which was amended January 22, 2019, to raise additional capital. 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.

On July 3, 2018, we closed on an underwritten public offering of 181,941 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 $5.4 million, including the full exercise of the underwriters' over-allotment option to purchase additional shares of the Company's common stock, prior to deducting underwriting discounts and commissions and offering expenses (the "July 2018 Offering"). Net proceeds totaled approximately $4.6 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.

In connection with the July 2018 Offering, and to induce certain institutional investors who hold warrants issued by the Company in November 2017 ("November 2017 Warrants") to participate in the July 2018 Offering, we entered into letter agreements with such institutional investors. Pursuant to the terms of these agreements, we agreed, effective July 3, 2018, to reduce the per share exercise price of the November 2017 Warrants held by such institutional investors to $29.68 and to extend the expiration date of the warrants that were to expire on November 27, 2018 to November 27, 2019. The number of common shares underlying the warrants that were repriced did not change. The repriced warrants are exercisable for 554,322 shares of common stock in the aggregate, of which, following such amendment, half expire on November 27, 2019 and half expire on November 27, 2024.

Additionally, our outstanding Series F Preferred Stock is subject to full-ratchet anti-dilution protection in the event that we sell any common stock at a price lower than the then-conversion price of the Series F Preferred Stock. As a result of the July 2018 Offering, effective July 3, 2018, the conversion price of the Series F Preferred Stock was reduced from $63.00 to $29.68, the per share price to public in the July 2018 Offering.

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 of America (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 instruments, inventory and accounts receivable reserves, 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 in accordance with Accounting Standards Codification (ASC), Topic 606, *Revenue from Contracts with Customers*, which we adopted effective January 1, 2018. Accordingly, we recognize revenue when our customers obtain control of their products or services, in an amount that reflects the consideration that we expect to receive in exchange for those goods and services. See Note 2 to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

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, 2018 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 net realizable value using the first-in, first out method.

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.

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 consolidated statement of operations and comprehensive loss 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 or warrants to purchase shares of our common stock. These RSUs or warrants 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. There were no deemed dividends during 2018. 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 shares underlying outstanding convertible preferred stock, 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, 2018 and 2017, we 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, 2018, we had an accumulated deficit of $199.4 million and we expect to incur losses for the foreseeable future. To date, we have been funded by debt and equity financings, and although we believe that we will be able to successfully fund our operations, there can be no assurance that we will be able to do so or that we will ever operate profitably. These factors raise substantial doubt about our ability to continue as a going concern through at least twelve months from the report date

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 system. This will require us to succeed in 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.

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. 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. In addition, on July 3, 2018, we closed on an underwritten public equity offering for net proceeds of approximately $4.6 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 our public float remains below $75 million as of the last business day of our most recently completed second fiscal quarter. 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 May 2014, August 2015, March 2016, April 2016 and May 2016, the Financial Accounting Standards Board (“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. We adopted this new standard on January 1, 2018, utilizing the modified retrospective approach. There was no impact to the amount or timing of revenue that we had recognized in prior periods. See Note 2 to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for additional accounting policy and transition disclosures.

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 was 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 during 2017, and recognized $0.2 million of impairment losses related to our goodwill.

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. The original guidance required application on a modified retrospective basis with the earliest period presented. In August 2018, the FASB issued new guidance which includes an option to not restate comparative periods in transition. This guidance is effective for our annual and quarterly periods beginning January 1, 2019. We have nearly completed the assessment of the impact that the adoption of this standard will have on our consolidated financial statements and expect that the adoption of this guidance will result in an increase in both the assets and liabilities recorded on our consolidated balance sheets in an amount ranging from $575,000 to $625,000. We do not expect that the adoption of this standard will have a material impact on the consolidated statement of operations and comprehensive loss or in the statement of cash flows. We do expect to include additional qualitative and quantitative disclosures as required. We expect to use the effective date of this standard as the date of initial application, with no retrospective adjustments to prior comparative periods.

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, 2018, we had an accumulated deficit of $199.4 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, 2018	Year Ended December 31, 2017	Increase (Decrease)	% Change
$ 4,998	$ 3,553	$ 1,445	40.7%

Revenue is generated mainly from the sale of disposable blood filters and catheters used in conjunction with our Aquadex FlexFlow consoles. We had no commercial sales prior to the acquisition of the Aquadex Business, which we acquired from Baxter on August 5, 2016.

We sell primarily in the United States to hospitals and clinics through our direct salesforce. We sell outside the United States to independent specialty distributors who in turn sell to hospitals and clinics in their geographic regions. The increase in sales is driven by execution of our commercialization strategy which includes continued expansion of our commercial footprint by the hiring of new sales representatives, clinical education specialists, and marketing personnel.

Costs and Expenses

Our costs and expenses were as follows:

(dollars in thousands)	Year Ended December 31, 2018	Year Ended December 31, 2017	Increase (Decrease)	% Change
Cost of goods sold	$ 3,670	$ 2,763	$ 907	32.8%
Selling, general and administrative	$ 15,311	$ 10,170	$ 5,141	50.6%
Research and development	$ 3,053	$ 1,481	$ 1,572	106.1%
Goodwill and intangibles impairment	$ —	$ 3,951	$ (3,951)	(100.0)%

Cost of Goods Sold

In connection with the acquisition of the Aquadex Business, we entered into a manufacturing and supply agreement with Baxter. Cost of sales reflects the agreed-upon price paid to Baxter for the manufacturing of the disposables and consoles, as well as startup costs associated with the transfer of manufacturing activities to our facilities in Eden Prairie, Minnesota.

We provided notice to Baxter to cease the manufacturing of the Aquadex FlexFlow system as of June 30, 2017, and we began transitioning activities in house. As part of the manufacturing transition, we agreed to continue to purchase inventory from Baxter through February 1, 2018. We began manufacturing our products in house in the fourth quarter of 2017, and in August 2018, we announced that the transfer of all manufacturing activities was complete.

Cost of sales for the years ended December 31, 2018 and 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 2019, 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 investments made in our commercial organization to expand our outreach in the field with incremental sales specialists, clinical specialists and marketing support. Our general and administrative costs have remained consistent to the prior year. The increase also reflects incremental non-cash stock option expense totaling $1.5 million.

We expect investments in our commercial organization to increase modestly in 2019 as new investments level off and we seek productivity gains from the investments made in 2018. We expect 2019 general and administrative expenses to remain consistent with 2018 levels.

Research and Development

The increase in research and development expenses relate to investments we are making to improve the functionality of our Aquadex FlexFlow system, including console software updates and catheter improvements. We expect that our research and development expenditures will increase modestly in future quarters as we continue to make improvements to our offerings.

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. As of December 31, 2017, all intangibles and goodwill were fully impaired.

Other Income (Expense)

The following is a summary of other income (expense)

(dollars in thousands)	Year Ended December 31, 2018	Year Ended December 31, 2017	Increase (Decrease)	% Change
Change in fair value of warrant liability	$ —	$ 1,475	$ (1,475)	(100.0)%
Warrant valuation expense	$ —	$ (67)	$ (67)	(100.0)%

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 of the warrants issued as part of those financings were exercised during the year ended December 31, 2017 pursuant to the warrant exercise agreement described in Note 6 to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K. 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, those warrants are not accounted for as liabilities based on their terms.

Income tax expense

(dollars in thousands)	Year Ended December 31, 2018	Year Ended December 31, 2017	Increase (Decrease)	% Change
Income tax expense	$ (6)	$ (6)	$ —	—%

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 3,105 replacement warrants with exercise prices ranging from $484.4 per share to $1,397.2 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 10,000 shares of common stock, 6,400 shares of Series E Convertible Preferred Stock (which were convertible into 22,858 shares of common stock) and warrants to purchase 32,165 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 286,715 shares of common stock) and warrants to purchase approximately 573,310 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 July 3, 2018, we closed on an underwritten public offering of 181,941 shares of common stock, for gross proceeds of $5.4 million. Net proceeds totaled approximately $4.6 million after deducting the underwriting discounts and commissions and other costs associated with the offering. See Note 6 to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K for information regarding the Warrant Reprice Agreements and adjustment of the conversion price of the Series F Preferred Stock in connection with the July 2018 offering.

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, if any, 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, 2018 or 2017.

As of December 31, 2018, and 2017, cash and cash equivalents were $5.5 million and $15.6 million, respectively. Prior to our acquisition of the Aquadex Business 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 strategy that included halting all clinical evaluations of our C-Pulse related technology to fully focus our resources on our recently acquired Aquadex Business. 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. We can provide no assurances that any source of financing will be available to us on favorable terms or at all. If we are unable to raise financing in a timely manner, we would likely need to scale back our operations.

The Company filed an S-1 on December 31, 2018, which was amended January 22, 2019, to raise additional capital. 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.

Cash Flows from Operating Activities

Net cash used in operating activities was $14.6 million and $11.9 million in 2018 and 2017, 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, and the effects of changes in operating assets and liabilities.

Cash Flows from Investing Activities

Net cash used in investing activities was $0.2 million and $0.3 million in 2018 and 2017, respectively primarily in the purchase of manufacturing, laboratory, and office equipment.

Cash Flows from Financing Activities

Net cash provided by financing activities was $4.6 million and $26.5 million in 2018 and 2017, respectively. Net cash provided by financing activities in 2018 was attributable to proceeds from the public offering of common stock completed in July 2018. 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.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2018, which represent material expected or contractually committed future obligations:

(Dollars in thousands)	Payments Due by Period				
	Less than 1 year	1-3 years	3-5 years	More than 5 years	Total
Operating Leases	$ 217	$ 494	$ —	$ —	$ 711
Total	$ 217	$ 494	$ —	$ —	$ 711

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, 2022. 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 $25,000. 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 September 2020.

Capital Resource Requirements

As of December 31, 2018, we did not have any material commitments for capital expenditures.

Off-Balance Sheet Arrangements

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.

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

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

Not Applicable

Item 8. Financial Statements and Supplementary Data.

Report of Independent Registered Public Accounting Firm

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of CHF Solutions, Inc. and subsidiaries (the ''Company'') as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows, for the years then ended, and the related notes (collectively referred to as the ''consolidated financial statements''). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of their operations and their cash flows for the years 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 audits. 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 audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits 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 audits 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 audits 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 audits 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 audits provide a reasonable basis for our opinion.

/s/ Baker Tilly Virchow Krause, LLP

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

Minneapolis, Minnesota
February 21, 2019

CHF SOLUTIONS, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	December 31, 2018	December 31, 2017
ASSETS		
Current assets		
Cash and cash equivalents	$ 5,480	$ 15,595
Accounts receivable	786	545
Inventories	1,658	1,588
Other current assets	203	136
Total current assets	8,127	17,864
Property, plant and equipment, net	536	570
Other assets	113	21
TOTAL ASSETS	$ 8,776	$ 18,455
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,133	$ 862
Accrued compensation	1,498	1,021
Other current liabilities	209	208
Total current liabilities	2,840	2,091
Other liabilities	—	126
Total liabilities	2,840	2,217
Commitments and contingencies		
Stockholders' equity		
Series A junior participating preferred stock as of December 31, 2018 and December 31, 2017, par value $0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Series F convertible preferred stock as of December 31, 2018 and December 31, 2017, par value $0.0001 per share; authorized 535 and 3,780 shares, respectively, issued and outstanding 535 and 3,780, respectively		
Preferred stock as of December 31, 2018 and December 31, 2017, par value $0.0001 per share; authorized 39,969,465 and 39,966,220 shares, respectively, none outstanding	—	—
Common stock as of December 31, 2018 and December 31, 2017, par value $0.0001 per share; authorized 100,000,000 shares, issued and outstanding 513,445 and 271,357, respectively	—	—
Additional paid-in capital	204,101	197,367
Accumulated other comprehensive income:		
Foreign currency translation adjustment	1,223	1,227
Accumulated deficit	(199,388)	(182,356)
Total stockholders' equity	5,936	16,238
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 8,776	$ 18,455

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,	
	2018	2017
Net sales	$ 4,998	$ 3,553
Costs and Expenses:		
Cost of goods sold	3,670	2,763
Selling, general and administrative	15,311	10,170
Research and development	3,053	1,481
Goodwill and intangibles impairment	—	3,951
Total costs and expenses	22,034	18,365
Loss from operations	(17,036)	(14,812)
Other income (expense):		
Other income, net	10	28
Warrant valuation expense	—	(67)
Change in fair value of warrant liability	—	1,475
Total other income, net	10	1,436
Loss before income taxes	(17,026)	(13,376)
Income tax expense	(6)	(6)
Net loss	$(17,032)	$(13,382)
Basic and diluted loss per share	$ (42.14)	$(525.01)
Weighted average shares outstanding – basic and diluted	404	48
Other comprehensive loss:		
Foreign currency translation adjustment	$ (4)	$ (8)
Total comprehensive loss	$(17,036)	$(13,390)

See notes to the consolidated financial statements

CHF SOLUTIONS, INC. AND SUBSIDIARIES

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

	Outstanding Shares of Common Stock	Common Stock	Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Equity
Balance December 31, 2016	**2,801**	**$—**	**$169,496**	**$1,235**	**$(168,974)**	**$ 1,757**
Net loss	—	—	—	—	(13,382)	(13,382)
Foreign currency translation adjustment	—	—	—	(8)	—	(8)
Stock-based compensation, net	17	—	499	—	—	499
Issuance of common stock, net	42,017	—	5,399	—	—	5,399
Issuance of preferred stock, net	—	—	21,973	—	—	21,973
Conversion of preferred stock into common stock	226,522	—	—	—	—	—
Balance December 31, 2017	**271,357**	**$—**	**$197,367**	**$1,227**	**$(182,356)**	**$ 16,238**
Net loss	—	—	—	—	(17,032)	(17,032)
Foreign currency translation adjustment	—	—		(4)		(4)
Stock-based compensation, net	12	—	2,087	—	—	2,087
Issuance of unregistered shares	7,116	—	—	—	—	—
Issuance of common stock, net	181,941	—	4,647	—	—	4,647
Conversion of preferred stock into common stock	53,019	—	—	—	—	—
Balance December 31, 2018	**513,445**	**$—**	**$204,101**	**$1,223**	**$(199,388)**	**$ 5,936**

See notes to the consolidated financial statements

CHF SOLUTIONS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows
(In thousands)

	For the years ended December 31,	
	2018	**2017**
Operating Activities		
Net loss	$(17,032)	$(13,382)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	232	769
Stock-based compensation expense	2,087	499
Goodwill and intangibles impairment	—	3,951
Change in fair value of warrant liability	—	(1,475)
Warrant valuation expense	—	67
Changes in assets and liabilities:		
Accounts receivable	(241)	(263)
Inventories	(70)	(911)
Other current assets	(67)	1
Other assets and liabilities	(14)	—
Accounts payable and accrued expenses	545	(1,176)
Net cash used in operations	(14,560)	(11,920)
Investing activities:		
Purchase of property and equipment	(198)	(259)
Net cash used in investing activities	(198)	(259)
Financing activities:		
Net proceeds from public stock offerings	4,647	24,281
Net proceeds from exercise of warrants	—	1,989
Net proceeds from the sale of preferred stock, common stock and warrants	—	184
Net cash provided by financing activities	4,647	26,454
Effect of exchange rate changes on cash	(4)	(3)
Net increase (decrease) in cash and cash equivalents	(10,115)	14,272
Cash and cash equivalents—beginning of period	15,595	1,323
Cash and cash equivalents—end of period	$ 5,480	$ 15,595
Supplemental schedule of non-cash activities		
Financing fees incurred for subsequent equity financing included in other assets and accounts payable	$ 78	$ —
Warrants issued as inducement to warrant exercise	$ —	$ 509
Conversion of temporary equity to permanent equity	$ —	$ 485
Supplemental cash flow information		
Cash paid for income taxes	$ 2	$ 6

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. In August 2016, the Company acquired the Aquadex FlexFlow 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''). In September 2016, the Company announced a strategic refocus of its strategy that included halting all clinical evaluations of its C-Pulse related technology to fully focus all of its resources on its recently acquired Aquadex Business.

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.

In December 2018, the Company's stockholders approved a reverse split of its outstanding common stock at a ratio in the range of 1-for-2 to 1-for-14 and, in January 2019, the board of directors approved a 1-for-14 reverse split of the Company's outstanding common stock that became effective after trading on January 2, 2019. In addition, during 2017, the Company's stockholders and board of directors approved two reverse stock splits. 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. These reverse stock splits did not change 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. 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, 2018 and 2017, 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, 2018, the Company had an accumulated deficit of $199.4 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 system. This will require the Company to succeed in 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 the Company will succeed in these activities, and it may never generate revenues sufficient to achieve profitability.

On April 24, 2017, November 27, 2017, and on July 3, 2018, the Company closed on underwritten public equity offerings for aggregate net proceeds of approximately $28.8 million after deducting the underwriting discounts

and commissions and other costs associated with the offerings (see Note 6 – Shareholder's Equity).
The Company will 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 of America 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, 2018 or 2017.

Inventories

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

	2018	2017
Finished Goods	$ 517	$ 902
Work in Process	34	217
Raw Materials	1,107	469
Total	$1,658	$1,588

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

Depreciation expense was $232,000 and $229,000 for the years ended December 31, 2018, and 2017, 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 periodically reviews its property and equipment for potential impairment and determines if the fair value of property and equipment equals or exceeds its carrying value. There have been no impairment losses recognized for the years ended December 31, 2018 or 2017.

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 reviewed its definite lived intangible assets for impairment when impairment indicators existed. When impairment indicators existed, the Company determined if the carrying value of the intangible assets exceeded the related undiscounted cash flows. In cases where the carrying value exceeded the undiscounted cash flows, and the carrying amount was not considered recoverable, the carrying value was written down to its fair value, generally using a discounted cash flow analysis. An impairment loss was recognized for the amount that the intangible assets exceeded 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 definite lived intangible assets.

The Company had 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 included assumptions related to the Company's product revenues, 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 reflected these uncertainties by assigning future cash flow estimations probability factors and an overall discount rate of 30%.

Amortization expense was $0 and $540,000 for the years ended December 31, 2018 and 2017, respectively.

Goodwill

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

The Company evaluated its recorded 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 was then compared to the actual carrying amount of the goodwill for the reporting unit. To the extent the carrying amount of goodwill exceeded the implied goodwill, the difference was the amount of the goodwill impairment. The Company's annual impairment test on November 1, 2017, resulted in $0.2 million of impairment charges related to goodwill.

The Company had 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 included assumptions related to the Company's product revenues, 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 reflected 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 in August 2016, the Company has an obligation to pay additional consideration that is contingent upon the occurrence of certain future events (see Note 10- Commitments and Contingencies). 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. As of December 31, 2018, the contingent consideration was recorded in current liabilities in the accompanying balance sheet to reflect its maturity during 2019.

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 was remeasured to its estimated fair value at the end of each reporting period with changes recorded to earnings.

Revenue Recognition

The Company recognizes revenue in accordance with Accounting Standards Codification (''ASC''), Topic 606, *Revenue from Contracts with Customers*, which the Company adopted effective January 1, 2018. Accordingly, the Company recognizes revenue when its customers obtain control of their products or services, in an amount that reflects the consideration that the Company expects to receive in exchange for those goods and services. See Note 2 – Revenue Recognition for additional accounting policies and transition disclosures.

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 consolidated statements of operations and other comprehensive loss 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 or warrants to purchase shares of the Company's common stock. These RSUs or warrants 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. The Tax Reform Act was enacted December 22, 2017. The new legislation made significant changes to U.S. tax law including 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 reduced the U.S corporate income tax rates from 34% to 21%. As a result of the enacted law, the Company was required to revalue its deferred tax assets and liabilities at the new enacted rate. There was no income tax impact from the re-measurement 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 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 for the year ended December 31, 2017, 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. (See Note 6). There were no deemed dividends during 2018.

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 shares underlying outstanding convertible preferred stock, 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 year presented:

	December 31,	
	2018	2017
Stock options	140,546	2,766
Restricted stock units	3	15
Warrants to purchase common stock	599,293	608,787
Series F convertible preferred stock	18,190	60,480
Total	758,032	672,048

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)	2018	2017
Net loss	$(17,032)	$(13,382)
Deemed dividend to preferred shareholders (see Note 6)	—	(11,590)
Net loss after deemed dividend	(17,032)	(24,972)
Weighted average shares outstanding	404	48
Basic and diluted loss per share	$ (42.14)	$(525.01)

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.

Recent Accounting Pronouncements

In May 2014, August 2015, March 2016, April 2016 and May 2016, the Financial Accounting Standards Board (“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 Company adopted this new standard on January 1, 2018, utilizing the modified retrospective approach. There was no impact to the amount or timing of revenue that the Company had recognized in prior periods. See Note 2 - Revenue Recognition for additional accounting policy and transition disclosures.

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 was 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 during the year ended December 31, 2017, and recognized a $0.2 million impairment loss related to its goodwill.

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. The original guidance required application on a modified retrospective basis with the earliest period presented. In August 2018, the FASB issued new guidance which includes an option to not restate comparative periods in transition. This guidance is effective for the Company's annual and quarterly periods beginning January 1, 2019. The Company has nearly completed evaluating the impact that the adoption of this standard will have on its consolidated financial statements. The Company expects that the adoption of this guidance will result in an increase in both the assets and liabilities recorded on its consolidated balance sheets in an amount ranging from $575,000 to $625,000. The Company does not expect that the adoption of this standard will have a material impact on the consolidated statement of operations and comprehensive loss or in the statement of cash flows. We do expect to include additional qualitative and quantitative disclosures as required. The Company expects to use the effective date of this standard as the date of initial application, with no retrospective adjustments to prior comparative periods.

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 – Revenue Recognition

Net Sales

The Company sells its products in the United States primarily through a direct sales force. Customers who purchase the Company's products include hospitals and clinics throughout the United States. In countries outside the United States, the Company sells its products through a limited number of specialty healthcare distributors in the United Kingdom, Italy, Spain, Germany, Southeast Asia, Brazil and India. The majority of these distributors resell the Company's products to hospitals and clinics in their respective geographies.

Revenue from product sales are recognized when the customer or distributor obtains control of the product, which occurs at a point in time, most frequently upon shipment of the product or receipt of the product, depending on shipment terms. The Company's standard shipping terms are FOB shipping point, unless the customer requests that control and title to the inventory transfer upon delivery. Revenue includes shipment and handling fees charged to customers.

Revenue is measured as the amount of consideration the Company expects to receive, adjusted for any applicable estimates of variable consideration and other factors affecting the transaction price, which is based on the invoiced price, in exchange for transferring products. All revenue is recognized when the Company satisfies its performance obligations under the contract. The majority of the Company's contracts have a single performance obligation and are short-term in nature. The Company has entered into extended service plans with customers that are recognized over time. Revenue from extended service plans represented less than 1% of net sales during each of the years ended December 31, 2018 and 2017. The unfulfilled performance obligations related to these extended service plans is included in deferred revenue in the amount of $43,000 and $38,000 as of December 31, 2018 and 2017, respectively. Deferred revenue is included in other current liabilities on the consolidated balance sheets. The majority of the deferred revenue is expected to be recognized within one year.

Sales taxes and value added taxes in foreign jurisdictions that are collected from customers and remitted to governmental authorities are accounted for on a net basis and therefore are excluded from net sales. Revenue includes shipment and handling fees charged to customers. Shipping and handling costs associated with outbound freight after control over a product has transferred to a customer are accounted for as a fulfillment cost and are included in cost of goods sold.

Product Returns: The Company offers customers a limited right of return for its product in case of non-conformity or performance issues. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized. The Company currently estimates product return liabilities using available industry data and its own historical sales and returns information. The Company has not received any returns to date and believes that future returns of its products will be minimal. Therefore, revenue recognized is not currently impacted by variable consideration related to product returns.

Note 3—Property, Plant and Equipment

Property, plant and equipment were as follows:

(in thousands)	December 31, 2018	December 31, 2017
Office Furniture & Fixtures	$ 291	$ 287
Leasehold Improvements	224	224
Software	142	129
Production Equipment	991	926
Computer Equipment	357	277
Capital Lease Asset	309	307
Total	2,314	2,150
Accumulated Depreciation	(1,778)	(1,580)
	$ 536	$ 570

Note 4—Intangible Assets

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 definite 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 included assumptions related to the Company's product revenues, 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 reflected these uncertainties by assigning future cash flow estimations probability factors and an overall discount rate of 30%.

Note 5—Debt

On August 5, 2016, the Company entered into a loan and security agreement with Silicon Valley Bank (the Bank). Under the 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. The Term Loan expired unused on November 30, 2016. Advances under the Revolving Line, if any, 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, 2018 or 2017.

Warrants: In connection with the funding of term loans under prior agreements, the Company issued warrants to the Bank and one of its affiliates to purchase 9 shares of common stock at an exercise price of $43,848 per share and warrants to purchase 4 shares of common stock at an exercise price of $30,912 per share. The Company valued these warrants at $32,424 per share and $22,764 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 were fully vested on the date of grant and expire on February 2025, and June 2025, respectively.

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 Series B issued under the securities purchase agreement was exchanged for Series B-1 Convertible Preferred Stock on October 30, 2016. The Series B-1 Convertible Preferred Stock was non-voting and was convertible into shares of common stock at the holder's election at any time. Approximately $1.6 million of the proceeds were allocated to the preferred stock, representing the residual proceeds after the warrants were recorded at fair value (see below.) As of both December 31, 2018, and 2017, all Series B/B-1-Convertible Preferred Stock had been converted into common stock and none were outstanding.

Series C and D Convertible Preferred Stock: 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 the second closing occurred on January 10, 2017, whereby the Company received 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 both December 31, 2018, and 2017, all shares of the Series C and D Convertible Preferred Stock had been converted into shares of common stock and none remained outstanding.

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 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 both December 31, 2018. and 2017, all shares of the Series E Convertible Preferred Stock had been converted into 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 an initial conversion price of $63.00 per share. Each share of Series F preferred stock was accompanied by a Series 1 warrant, which was to expire on the first anniversary of its issuance, to purchase 16 shares of the Company's common stock at an exercise price of $63.00 per share, and a Series 2 warrant, which expires on the seventh anniversary of its issuance, to purchase 16 shares of the Company's common stock at an exercise price of $63.00 per share. The Series F preferred stock and the warrants were immediately separable and were issued separately. The conversion price of the Series F preferred stock will be adjusted in the event of a stock split, combination, reclassification or stock dividend or if the Company consummates a fundamental transaction. The Series F preferred stock also has full ratchet price based anti-dilution protection, subject to customary carve outs, in the event of a down-round financing at a price per share below the conversion price of the Series F preferred stock (which protection will expire if, during any 20 of 30 consecutive trading days, the volume weighted average price of the Company's common stock exceeds 300% of the then-effective conversion price of the Series F preferred stock and the daily dollar trading volume for each trading day during such period exceeds $200,000). 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 stock splits, combinations, reclassifications, stock dividends or fundamental transactions. A total of 18,000 shares of Series F Convertible Preferred Stock initially convertible into 286,714 shares of common stock and warrants to purchase

approximately 573,310 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 noted below, effective July 3, 2018, the conversion price of the Series F preferred stock was reduced from $63.00 to $29.68, the per share price to public in the July 2018 Offering described below, and now each share of the remaining Series F preferred stock is convertible into 34 shares of the Company's common stock. As of December 31, 2018, and 2017, 17,465 and 14,220 shares of the Series F Convertible Preferred Stock had been converted into an aggregate of 279,526 and 226,504 shares of common stock and 535 and 3,780 remained outstanding, respectively.

July 2018 Offering: On July 3, 2018, the Company closed on an underwritten public offering of 181,941 shares of its common stock at a public offering price of $29.68 per share, for gross proceeds of $5.4 million, including the full exercise of the underwriters' over-allotment option to purchase additional shares of the Company's common stock, prior to deducting underwriting discounts and commissions and offering expenses (the ''July 2018 Offering'').

In connection with the July 2018 Offering, and to induce certain institutional investors who hold warrants issued by the Company in November 2017 (''November 2017 Warrants'') to participate in the July 2018 Offering, the Company entered into letter agreements with such institutional investors. Pursuant to the terms of these agreements, the Company agreed, effective July 3, 2018, to reduce the per share exercise price of the November 2017 Warrants held by such institutional investors to $29.68 and to extend the expiration date of the warrants that were to expire on November 27, 2018 to November 27, 2019. The number of common shares underlying the warrants that were repriced did not change. The repriced warrants are exercisable for 554,322 shares of common stock in the aggregate, of which, following such amendment, half expire on November 27, 2019 and half expire on November 27, 2024. The repricing of the warrants was accounted as an equity financing cost, with no impact to net proceeds from the offering.

As noted above, the Company's outstanding Series F preferred stock is subject to full-ratchet anti-dilution protection in the event the Company sells any common stock at a price lower than the then-conversion price of the Series F preferred stock. As a result of the July 2018 Offering, effective July 3, 2018, the conversion price of the Series F preferred stock was reduced from $63.00 to $29.68, the per share price to public in the July 2018 Offering.

Placement Agent Fees 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 financings completed in April 2017, November 2017, and July 2018, the Company paid the placement agent an aggregate cash placement fee equal to 9%, 8%, 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 440 shares of common stock at an exercise price of $7,896 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 $1,428 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 2,522 shares of common stock at an exercise price of $1,512 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 141 shares of common stock at an exercise price of $1,512 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 3,105 Replacement Warrants with exercise prices ranging from $484.4 per share to $1,397.2 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, 2018, and 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. There were no warrants outstanding at December 31, 2018 or 2017 that were accounted for as liabilities.

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 stock-based compensation expense related to grants of stock options, RSUs and common stock awards to employees, directors and consultants of $2.1 million, and $0.5 million during the years ended December 31, 2018 and 2017, 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)	2018	2017
Selling, general and administrative	$1,958	$452
Research and development	129	50
Total	$2,087	$502

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. Stock-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:

	2018		2017	
	Options Outstanding	Weighted Average Exercise Price	Options Outstanding	Weighted Average Exercise Price
Beginning Balance	2,562	$1,049.93	272	$31,021.57
Granted	163,997	45.76	2,461	167.30
Exercised	—	—	—	—
Forfeited/expired	(26,013)	61.01	(171)	36,429.90
Outstanding at December 31	140,546	$ 61.25	2,562	$ 1,049.93
Vested at December 31	16,206	$ 169.07	148	$11,338.37

For options outstanding and vested at December 31, 2018, the weighted average remaining contractual life was 9.12 years and 9.07 years, respectively. There were no option exercises in 2018 or 2017. The total fair value of options that vested in 2018 and 2017 was $0.9 million, and $0.7 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 weighted average assumptions used in the Black-Scholes option pricing model for the years ended December 31:

	2018	2017
Expected dividend yield	0%	0%
Risk-free interest rate	2.49%	1.97%
Expected volatility	120.54%	103%
Expected life (in years)	6.23	6.25

The weighted-average fair value of stock options granted in 2018 and 2017 was $41.04 and $167.3, respectively. As of December 31, 2018, the total compensation cost related to all non-vested stock option awards not yet recognized was approximately $3.9 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 2018 and 2017:

	2018		2017	
	RSUs	Weighted Average Grant Price	RSUs	Weighted Average Grant Price
Nonvested, beginning balance	15	$7,297.22	33	$9,052.37
Granted	—	—	11	1,514.80
Vested	(12)	7,297.22	(29)	1,854.56
Forfeited	—	—	—	—
Nonvested at December 31	3	$7,297.22	15	$7,297.22

Warrants

Warrants to purchase 599,293, and 608,764 shares of common stock were outstanding at December 31, 2018 and 2017, respectively. As of December 31, 2018, warrants outstanding were exercisable at prices ranging from $29.68 to $43,848 per share, and are exercisable over a period ranging from eleven months to 6.5 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 was classified as Level 3 in the fair value hierarchy.

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

(in thousands)	
Balance December 31, 2016	$ 1,843
Change in fair value	(1,475)
Exercise of warrants	(368)
Balance as of December 31, 2017	$ —

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, 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, 2018 and 2017. 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)	2018	2017
Domestic	$(17,027)	$(13,367)
Foreign	1	(9)
Loss before income taxes	$(17,026)	$(13,376)

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

(in thousands)	2018	2017
Current:		
United States and state	$—	$—
Foreign, net	(6)	(6)
Deferred:		
United States and state	—	—
Foreign	—	—
Total income tax expense	$ (6)	$ (6)

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

(in thousands)	2018	2017
Statutory federal income tax benefit	$ 3,578	$ 4,548
State tax benefit, net of federal taxes	45	48
Foreign tax	(2)	—
Foreign deferred exchange rate adjustments	(1,112)	899
Nondeductible/nontaxable items	(259)	(114)
New federal rate adjustment	—	(16,081)
Other	(72)	(1,085)
Valuation allowance decrease (increase)	(2,184)	11,779
Total income tax benefit expense	$ (6)	$ (6)

Deferred taxes consist of the following as of December 31:

(in thousands)	2018	2017
Deferred tax assets:		
Noncurrent:		
Accrued leave	$ 50	$ 32
Other accrued expenses	—	28
Stock based compensation	483	336
Net operating loss carryforward	41,032	38,947
Other	125	115
Intangibles	847	895
R&D credit carryforward	531	531
Total deferred tax assets	43,068	40,884
Less: valuation allowance	(43,068)	(40,884)
Total	$ —	$ —

As of December 31, 2017, the Company had federal net operating loss (''***NOLs***'') carryforwards of approximately $135.2 million and $29.5 million of state NOL carryforwards., Approximately $120.1 million of federal NOL carryforwards will expire between 2024 and 2037. Pursuant to the Tax Cuts and Jobs Act of 2017, the NOL generated during the current year of approximately $15.1 million does not expire. The expiration of state NOL carryforwards will vary by jurisdiction. As of December 31, 2018, the Company had tax losses in the Commonwealth of Australia of approximately AU$49.0 million which can carry forward indefinitely. Federal or state 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 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 consolidated financial statements. For the year ended December 31, 2018, the valuation allowance increased by $2.2 million primarily due to current year operating losses. For the year ended December 31, 2017, the valuation allowance decreased by $11.8 million primarily as result of the impact of the 2017 tax reform re-measurement of deferred tax assets.

During 2017 and 2018, the Company believes it 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, 2018 or 2017.

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, 2018 and 2017, the Company recorded no accrued interest or penalties related to uncertain tax positions.

The tax years ended December 31, 2015 through December 31, 2018 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 2022. In August 2018, the Company entered into a Third Amendment to the lease, extending the term of the lease from March 31, 2019 to March 31, 2022. Beginning on April 1, 2019, the annual base rent shall be $9.00 per square foot, subject to annual increases of $0.25 per square foot. 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 September 2020.

Rent expense related to operating leases was approximately $293,000, and $290,000 for the years ended December 31, 2018 and 2017, respectively. Future minimum lease payments under non-cancelable operating leases as of December 31, 2018, were approximately $217,000, $220,000, $219,000, $55,000, and $0 for each of the years ended December 31, 2019, through 2023, 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 $197,000 and $138,000 for the years ended December 31, 2018 and 2017, respectively.

Contingent Consideration

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 of the purchase of the Aquadex Business, 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, 2018, long-lived assets were located primarily in the United States.

Note 12 – Subsequent Event

The Company filed an S-1 on December 31, 2018, which was amended January 22, 2019, to raise additional capital. Changing circumstances may cause the Company to consume capital significantly faster than it currently anticipates and could adversely affect the Company's ability to raise additional capital. Additional financing may not be available when the Company needs it or may not be available on favorable terms.

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, 2018, 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, 2018.

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, 2018, 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, 2018.

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, 2018 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 2019 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."

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	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	January 2, 2019	3.1	
3.6	Second Amended and Restated Bylaws	8-K	001-35312	May 23, 2017	3.2	
3.7	Form of Certificate of Designation of Series A Junior Participating Preferred Stock	8-K	001-35312	June 14, 2013	3.1	
3.8	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				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
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	
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	

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
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	
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	

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
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	
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	Third Amendment to Lease, dated as of August 3, 2018, by and between the Company and Capital Partners Industrial Fund I, LLLP	10-Q	001-35312	November 7, 2018	10.2	

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
10.32	Separation and Release Agreement between the Company and David A. Rosa, dated November 30, 2015†	8-K	001-35312	November 30, 2015	99.1	
10.33	Executive Employment Agreement between Sunshine Heart, Inc. and John L. Erb, dated March 1, 2016†	8-K	001-35312	March 2, 2016	10.1	
10.34	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	
10.35	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	
10.36	Claudia Drayton Retention Bonus Letter, dated as of December 12, 2016†	8-K	001-35312	December 16, 2016	10.1	
10.37	Molly Wade Retention Bonus Letter, dated as of December 12, 2016†	S-1	333-221010	October 18, 2017	10.35	
10.38	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	
10.39	Offer Letter by and between the Company and Jim Breidenstein dated April 12, 2017†	10-Q	001-35312	May 12, 2017	10.4	
10.40	Separation and Release Agreement, dated as of August 6, 2018, between the Company and James Breidenstein†	10-Q	001-35312	November 7, 2018	10.1	
10.41	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	
10.42	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	
10.43	Form of Warrant Reprice Agreement	8-K	001-35312	June 29, 2018	10.1	

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
10.44	Consulting Agreement, dated as of January 28, 2019, between CHF Solutions, Inc. and Steve Brandt†					X
21	List of Subsidiaries					X
23.1	Consent of Baker Tilly Virchow Krause, 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: February 21, 2019

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)	February 21, 2019
/S/ CLAUDIA DRAYTON Claudia Drayton	Chief Financial Officer (principal financial and accounting officer)	February 21, 2019
/S/ STEVEN BRANDT Steven Brandt	Director	February 21, 2019
/S/ MATTHEW LIKENS Matthew Likens	Director	February 21, 2019
/S/ JON W. SALVESON Jon W. Salveson	Director	February 21, 2019
/S/ GREGORY D. WALLER Gregory D. Waller	Director	February 21, 2019
/S/ WARREN S. WATSON Warren S. Watson	Director	February 21, 2019

EXHIBIT 21

SUBSIDIARIES

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

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, 333-221716 and 333-229102), Form S-3 (File No. 333-224881) and Form S-8 (File No. 333-223879, 333-218464, 333-210215, 333-202904, 333-194642, 333-190499, 333-188935, 333-183925, and 333-183924) of CHF Solutions, Inc. of our report dated February 21, 2019, 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 43 of this annual report on Form 10-K for the year ended December 31, 2018.

/s/ BAKER TILLY VIRCHOW KRAUSE, LLP

Minneapolis, Minnesota
February 21, 2019

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: February 21, 2019

/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: February 21, 2019

/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, 2018 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: February 21, 2019

/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, 2018 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: February 21, 2019

/S/ CLAUDIA DRAYTON

Claudia Drayton
Chief Financial Officer

[THIS PAGE INTENTIONALLY LEFT BLANK]

[THIS PAGE INTENTIONALLY LEFT BLANK]

CHF SOLUTIONS BUSINESS OVERVIEW

AQUADEX FLEXFLOW® SYSTEM

The Aquadex FlexFlow System is designed and clinically proven 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.

AQUADEX FLEXFLOW FEATURES & BENEFITS

- Safe, effective, and clinically proven to remove excess salt and water from the body
- 40% more fluid removal than conventional diuretic drug therapy over the same period of time[1]
- No clinically significant impact on electrolyte balance, blood pressure, or heart rate[1,2]
- Prescribed by any medical specialty trained in extracorporeal therapy
- 53% reduction in the risk of HF rehospitaliztion than those treated soley with diuretics at 90 days[3]
- Fewer HF re-hospitalization days due to cardiovascular event[4]

Sources: [1]Bart BA, et al. Am Coll Cardiol. 2005;46:2043-6. [2]Jaski BE et al. J Card Fail. 2003; 9(3):227-231. [3]Costanzo MR, et al. J Am Coll Cardiol. 2007 Feb 13;49(6):675-683. [4]Costanzo MR, et al. J Am Coll Cardiol. 2005;46:2047-51.

FLUID OVERLOAD

Fluid overload is a condition in which there is too much fluid, primarily salt and water, throughout the body resulting in weight gain, breathing distress and emergency room admissions.

Causes of fluid overload include: heart failure, kidney failure, nephrotic syndrome, cirrhosis, or burn injuries/trauma. Individuals may also suffer from temporary fluid overload following certain surgical procedures, such as cardiac surgery. Fluid overload has a significant association with the combined events of death, infection, bleeding, arrhythmia, and pulmonary edema and is a leading cause of readmissions with patients following cardiac surgery and patients suffering from heart failure.

MARKET STRATEGY

Post Cardio Vascular Surgery: Aquadex FlexFlow System may be used to treat patients suffering from fluid overload following cardiac surgery procedures. We have expanded our commercial efforts in this therapeutic area, leveraging the synergies between heart failure cardiologists and cardiovascular surgeons, traditional technology adoption rates of cardiac surgeons, and product purchase cycle of the cardiac surgical centers.

Heart Failure Inpatient: Heart failure patients suffering from fluid overload may be treated in an inpatient setting, such as a hospital, extended care facility or nursing home. We continue to focus our traditional sales efforts on inpatient facilities, leveraging the clinical benefits and economic advantages of using the Aquadex FlexFlow System over diuretic therapy.

Heart Failure Outpatient: Heart failure patients suffering from fluid overload may also be treated in the outpatient setting, such as a clinic or hospital outpatient department (e.g. observation unit). While currently not reimbursed, outpatient clinics are still using the Aquadex FlexFlow System because there may be a financial benefit to use the Aquadex FlexFlow System without reimbursement rather than to incur Medicare penalties for readmission into the inpatient setting. We are supporting the development of new evidence regarding the economic impact of ultrafiltration in the outpatient setting and to seek reimbursement and gain broader adoption of the Aquadex FlexFlow System in the outpatient market.

Pediatrics: We are seeking a modification of the product label for our Aquadex FlexFlow System to allow commercial promotion in pediatric patients. Because our Aquadex FlexFlow system is not recommended for use in pediatric patients, we do not devote commercialization resources toward, nor promote, the use of the Aquadex FlexFlow system in pediatric patients. We believe that Aquadex FlexFlow System is currently being prescribed by physicians to treat various conditions in pediatric patients and began discussions with the FDA regarding a modification to the product label.

BOARD OF DIRECTORS

John L. Erb (Chairman)
Jon W. Salveson
Gregory D. Waller
Warren S. Watson
Matthew Likens
Steve Brandt

CORPORATE OFFICERS

John L. Erb
Chief Executive Officer

Claudia Napal Drayton
Chief Financial Officer

COMPANY SECRETARY

Thomas Lynch

TRANSFER AGENT AND REGISTRAR

American Stock Transfer & Trust
Company, LLC
6201 15th Avenue
Brooklyn, NY 11219
+1.800.937.5449
Amstock.com

ANNUAL MEETING

May 23rd, 2019

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.

chf solutions

12988 Valley View Road
Eden Prairie, MN 55344
+1.952.345.4200
www.chf-solutions.com