As filed with the Securities and Exchange Commission on December 20, 2019

Registration No. 333-235385

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Amendment No. 1 to

FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

CHF SOLUTIONS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

Copies to:

Phillip D. Torrence	**Thomas Lynch**	**Michael F. Nertney**
Honigman LLP	**General Counsel**	**Ellenoff Grossman & Schole LLP**
650 Trade Centre Way, Suite 200	**CHF Solutions, Inc.**	1345 Avenue of the Americas
Kalamazoo, MI 49002	12988 Valley View Road	New York, NY 10105-0302
Tel: (269) 337-7700	Eden Prairie, Minnesota 55344	Tel: (212) 370-1300
Fax: (269) 337-7703	Tel: (952) 345-4200	Fax: (212) 401-4741

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

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

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

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

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

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

Large accelerated filer o Accelerated filer o Non-accelerated filer ☒ Smaller reporting company ☒

Emerging growth company o

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 to Section 7(a)(2)(B) of the Securities Act. o

CALCULATION OF REGISTRATION FEE

Title of securities to be registered[1]	**Proposed maximum aggregate offering price[1]**	**Amount of Registration Fee[2]**
Class A Units consisting of:	$	$
(i) Shares of common stock, par value $0.0001 per share		
(ii) Warrants to purchase common stock[3]		
Class B Units consisting of:	$	$
(i) Series H Convertible Preferred Stock		
(ii) Common stock issuable upon conversion of Series H Convertible Preferred Stock[3]		
(iii) Warrants to purchase common stock[3]		
Common Stock issuable on exercise of Warrants	$	$
Total	$ 5,000,000	$ 649[4]

(1) Estimated solely for the purpose of computing the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended (the "Act"). Pursuant to Rule 416 under the Act, the securities registered also include such indeterminate amounts and numbers of shares of common stock issuable to cover additional securities that may be offered or issued to prevent dilution resulting from stock splits, stock dividends or similar transactions. Also includes the offering price of additional units that the underwriters have the option to purchase.

(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price of all securities being registered.

(3) No separate fee is required pursuant to Rule 457(g) or Rule 457(i) under the Securities Act.

(4) Previously paid with the original filing of this registration statement.

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

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED DECEMBER 20, 2019

PRELIMINARY PROSPECTUS

CHF SOLUTIONS, INC.

[ ] Class A Units consisting of shares of common stock and warrants and [ ] Class B Units consisting of Series H convertible preferred stock and warrants (and shares of common stock underlying such warrants)

We are offering [ ] Class A Units, with each Class A Unit consisting of one share of common stock, par value $0.0001 per share, and one warrant to purchase one share of our common stock (together with the shares of common stock underlying such warrants, the "Class A Units") at a public offering price of $[ ] per Class A Unit. Warrants included in the Class A Units have an exercise price of $[ ] per whole share.

We are also offering [ ] Class B Units to purchasers who prefer not to beneficially own more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering. Each Class B Unit will consist of one share of Series H Convertible Preferred Stock, par value $0.0001 per share (the "Series H Preferred Stock"), convertible at any time at the holder's option into a number of shares of common stock equal to $[ ] divided by the conversion price of $[ ] (the "Conversion Price") and warrants to purchase a number of shares of our common stock equal to $[ ] divided by the Conversion Price (together with the shares of common stock underlying such shares of Series H Preferred Stock and such warrants, the "Class B Units" and, together with the Class A Units, the "Units") at a public offering price of $[ ] per Class B Unit. Each warrant included in the Class B Units entitles its holder to purchase a number of shares of common stock equal to 100% of the shares of common stock issuable upon conversion of the Series H Preferred Stock included in such units at an exercise price of $[ ] per share.

The Class A Units and Class B Units will not be certificated and the shares of common stock, Series H Preferred Stock and warrants comprising such Units are immediately separable and will be issued separately in this offering.

The price of our common stock on The Nasdaq Capital Market during recent periods will only be one of many factors in determining the public offering price. Other factors to be considered in determining the public offering price include our history, our prospects, the industry in which we operate, our past and present operating results, the previous experience of our executive officers, the general condition of the securities markets at the time of this offering and discussions between the underwriters and prospective investors. The recent market price used throughout this prospectus may not be indicative of the final offering price. All share numbers included in this prospectus are based upon an assumed conversion price of $0.89, the closing price of our common stock on December 4, 2019.

Our common stock trades on The Nasdaq Capital Market under the ticker symbol "CHFS". See "Prospectus Summary—Recent Developments" in this prospectus for important information about the listing of our common stock on The Nasdaq Capital Market. We do not intend to list the warrants or preferred stock to be sold in this offering on any stock exchange or other trading market.

Investing in our common stock involves a high degree of risk. Before making any investment in our securities, you should read and carefully consider the risks described in this prospectus under the section of this prospectus entitled "Risk Factors" on page 7 of this prospectus.

	Per Class A Unit	Per Class B Unit[1]	Total	Total
Public offering price				
Underwriting discounts[2]				
Proceeds, before expenses, to CHF Solutions, Inc.				

(1) The public offering price and underwriting discount corresponds to (x) in respect of the Class A Units (i) a public offering price per share of common stock of $[ ] and (ii) a public offering price per warrant of $[ ] and (y) in respect of the Class B Units (i) a public offering price per share of Series H Preferred Stock of $[ ] and (ii) a public offering price per warrant to purchase one share of common stock of $[ ].

(2) We have agreed to pay certain expenses of the underwriters in this offering. We refer you to "Underwriting" on page 71 for additional information regarding underwriting compensation.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriter has the option to purchase up to (i) [____] additional shares of common stock, and/or (ii) additional warrants to purchase up to [____] additional shares of common stock solely to cover over-allotments, if any, at the public offering price per share of common stock and the public offering price per warrant set forth above less the underwriting discounts and commissions. The over-allotment option may be used to purchase shares of common stock and/or warrants, or any combination thereof, as determined by the underwriter, but such purchases cannot exceed an aggregate of 15% of the number of shares of common stock (including the number of shares of common stock issuable upon conversion of shares of Series H Preferred Stock) and 15% of the warrants sold in the primary offering. The over-allotment option is exercisable for 45 days from the date of this prospectus.

The underwriters expect to deliver the securities to purchasers on [_____], 2019.

Sole Book-Running Manager

Ladenburg Thalmann

The date of this prospectus is [_____], 2019.

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You should rely only on the information contained in this prospectus and any free-writing prospectus that we authorize to be distributed to you. We have not, and the underwriters have not, authorized anyone to provide you with information different from or in addition to that contained in this prospectus or any related free-writing prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. We are offering to sell, and are seeking offers to buy, the securities offered by this prospectus only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the securities. Our business, financial conditions, results of operations and prospects may have changed since that date. You should also read and consider the information in the documents to which we have referred you under the caption "Where You Can Find Additional Information" in this prospectus.

We have not, and the underwriter has not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to the offering of the securities and distribution of this prospectus outside the United States.

We obtained industry and market data used throughout and incorporated by reference into this prospectus through our research, surveys and studies conducted by third parties and industry and general publications. We have not independently verified market and industry data from third-party sources.

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-1 that we filed with the Securities and Exchange Commission ("SEC"). It omits some of the information contained in the registration statement and reference is made to the registration statement for further information with regard to us and the securities being offered hereby. You should review the information and exhibits in the registration statement for further information about us and the securities being offered hereby. Statements in this prospectus concerning any document we filed as an exhibit to the registration statement or that we otherwise filed with the SEC are not intended to be comprehensive and are qualified by reference to the filings. You should review the complete document to evaluate these statements.

You should read this prospectus, any documents that we incorporate by reference in this prospectus and the additional information described below under "Where You Can Find Additional Information" and "Information Incorporated By Reference" before making an investment decision. You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized any other person to provide you with different information. If anyone provides you with additional, different or inconsistent information, you should not rely on it. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

You should not assume that the information in this prospectus or any documents we incorporate by reference herein is accurate as of any date other than the date on the front of such document. Our business, financial condition, results of operations and prospects may have changed since those dates.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We file reports, proxy statements and other information with the SEC in accordance with the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Our reports, proxy statements and other information filed with the SEC are available free of charge to the public over the Internet at the SEC's website at http://www.sec.gov. These documents may also be accessed on our website at www.chf-solutions.com. Information contained in, or accessible through, our website is not a part of this prospectus.

INFORMATION INCORPORATED BY REFERENCE

SEC rules allow us to "incorporate by reference" into this prospectus much of the information we file with the SEC, which means that we can disclose important information to you by referring you to those publicly available documents. The information that we incorporate by reference into this prospectus plus consolidated financial statements included in this prospectus is considered to be part of this prospectus. These documents may include Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as proxy statements. You should read the information incorporated by reference because it is an important part of this prospectus.

This prospectus incorporates by reference the documents listed below, other than those documents or the portions of those documents deemed to be furnished and not filed in accordance with SEC rules:

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on February 21, 2019;
- our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2019, filed with the SEC on May 9, 2019, for the quarter ended June 30, 2019, filed with the SEC on August 8, 2019, and for the quarter ended September 30, 2019, filed with the SEC on November 8, 2019;
- our Current Reports on Form 8-K filed with the SEC on January 2, 2019, January 25, 2019, March 13, 2019, May 24, 2019, September 4, 2019, September 27, 2019, October 23, 2019, and November 4, 2019;
- the information specifically incorporated by reference into our Annual Report on Form 10-K for the year ended December 31, 2018 from our definitive proxy statement for the annual meeting of stockholders held on May 23, 2019, filed with the SEC on April 9, 2019;
- the description of our common stock in our registration statement on Form 10 filed with the SEC on September 30, 2011, including any amendment or report filed for the purpose of updating such description; and
- the description of our Series A Junior Participating Preferred Stock, par value $0.0001 per share, in our registration statement on Form 8-A filed with the SEC on June 14, 2013.

Any statement contained in any document incorporated by reference herein shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or any prospectus modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

We also incorporate by reference any future filings, other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items, made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, in each case, other than those documents or the portions of those documents deemed to be furnished and not filed in accordance with SEC rules, until the offering of the securities under the registration statement of which this prospectus forms a part is terminated or completed. Information in such future filings updates and supplements the information provided in this prospectus. Any statements in any such future filings will be deemed to modify and supersede any information in any document we previously filed with the SEC that is incorporated or deemed to be incorporated herein by reference to the extent that statements in the later filed document modify or replace such earlier statements.

Because we are incorporating by reference future filings with the SEC, this prospectus is continually updated and later information filed with the SEC may update and supersede some of the information included or incorporated by reference in this prospectus. This means that you must look at all of the SEC filings that we incorporate by reference to determine if any of the statements in this prospectus or in any document previously incorporated by reference have been modified or superseded.

These documents may also be accessed on our website at www.chf-solutions.com. Information contained in, or accessible through, our website is not a part of this prospectus. We will provide without charge to each person, including any beneficial owners, to whom this prospectus is delivered, upon his or her written or oral request, a copy of any or all reports or documents referred to above which have been or may be incorporated by reference into this prospectus but not delivered with this prospectus, excluding exhibits to those reports or documents unless they are specifically incorporated by reference into those documents. You may request a copy of these documents by writing or telephoning us at the following address.

CHF Solutions, Inc.
12988 Valley View Road
Eden Prairie, Minnesota 55344
(952) 345-4200
ir@chf-solutions.com
Attention: Claudia Drayton
Chief Financial Officer

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before deciding to invest in our securities, you should read this entire prospectus carefully, including our financial statements and related notes, the information in the section "Risk Factors" and our filings incorporated by reference herein to which we have referred you in the sections "Where You Can Find Additional Information" and "Information Incorporated by Reference." Unless the context otherwise requires, references in this prospectus to the "Company," "CHFS," "we," "us", and "our" refer to CHF Solutions, Inc.

Company Overview

We are a medical device company dedicated to changing the lives of patients suffering from fluid overload through science, collaboration, and innovative technology. The company is focused on developing, manufacturing, and commercializing the Aquadex FlexFlow® system for ultrafiltration 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.

The Aquadex FlexFlow System

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

- Provides complete control over rate and total volume of fluid removed by allowing a medical practitioner to specify the amount of fluid to be removed from each individual patient;
- Aquapheresis therapy can be performed via peripheral or central venous access;
- Removes isotonic fluid (extracts sodium while sparing potassium and magnesium)[2];
- Following ultrafiltration, neurohormonal activation is reset toward a more physiological condition and diuretic efficacy is restored[3];
- Provides highly automated operation with only one setting required to begin;
- Utilizes a single-use, disposable auto-loading blood filter circuit that facilitates easy set-up;
- The console guides medical practitioner through the setup and operational process; and
- Decreased hospital readmissions and duration[4] resulting in cost savings at 90 days[5].

[1] SAFE Trial: Jaski BE, et al. J Card Fail. 2003 Jun; 9(3): 227-231; RAPID Trial: Bart BA, et al. J Am Coll Cardiol. 2005 Dec 6; 46(11): 2043-2046

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

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

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

[5] Costanzo MR, et al. Ultrafiltration vs. Diuretics for the Treatment of Fluid Overload in Patients with Heart Failure: A Hospital Cost Analysis.

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 FlexFlow blood set is proprietary and the Aquadex FlexFlow system can only be used with the Aquadex FlexFlow blood 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.

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

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.

Recent Developments

Nasdaq Notice

On December 17, 2019, we received a letter (the "Notice") from The Nasdaq Stock Market ("Nasdaq") advising that for 30 consecutive trading days preceding the date of the Notice, the bid price of our common stock had closed below the $1.00 per share minimum required for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). The Notice has no effect on the listing of our common stock at this time, and our common stock continues to trade on the Nasdaq Capital Market under the symbol "CHFS." Under Nasdaq Listing Rule 5810(c)(3)(A), if during the 180 calendar day period following the date of the Notice (the "Compliance Period"), the closing bid price of our common stock is at or above $1.00 for a minimum of 10 consecutive business days, we will regain compliance with the Minimum Bid Price Requirement and our common stock will continue to be eligible for listing on the Nasdaq Capital Market, absent noncompliance with any other requirement for continued listing. If we do not regain compliance with the Minimum Bid Price Requirement by the end of the Compliance Period (or the Compliance Period as may be extended) the Company's common stock will be subject to delisting. We intend to monitor the closing bid price of our common stock and may, if appropriate, consider implementing available options to regain compliance with the Minimum Bid Price Requirement under the Nasdaq Listing Rules.

Pediatrics

On September 30, 2019, the Company submitted an application to the FDA requesting for 510(k) clearance of the Aquadex FlexFlow system to include pediatric patients who weigh 20kg or more. 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[6], extracorporeal membrane oxygenation (ECMO) therapy[7], solid organ transplantation[8], and kidney replacement therapy for neonatal patients. 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. Subject to FDA review, the Company expects clearance for this pediatric population in early 2020.

Public Offering

On March 12, 2019, we closed on an underwritten public offering of 455,178 shares of common stock, approximately 1.9 million shares of Series G Convertible Preferred Stock, and warrants to purchase approximately 4.7 million shares of common stock, which includes the full exercise of the underwriter's over-allotment option, for gross proceeds of $12.4 million. Net proceeds totaled approximately $11.0 million after deducting the underwriting discounts and commissions and other costs associated with the offering.

Registered Direct Offering

On October 25, 2019, we closed on a registered direct offering of 575,830 shares of common stock, for gross proceeds of approximately $660,000, prior to deduction of commissions and offering expenses. In a concurrent private placement, we agreed to issue to the investors in the registered direct offering, unregistered warrants to purchase up to 575,830 shares of our common stock. On November 6, 2019, we closed on a registered direct offering of 1,219,076 shares of common stock and pre-funded warrants, for gross proceeds of approximately $1.36 million, prior to deduction of commissions and offering expenses. In a concurrent private placement, we agreed to issue to the investors in the registered direct offering, unregistered warrants to purchase up to 1,219,076 shares of our common stock.

Reverse Stock Split

On January 2, 2019, we effected a 1-for-14 reverse split of our outstanding common stock. This reverse stock split 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 have been retroactively adjusted to reflect the reverse stock split for all periods presented.

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

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

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

The Offering	
Issuer	CHF Solutions, Inc.
Class A Units Offered	We are offering **[ ]** Class A Units. Each Class A Unit consists of one share of common stock and a warrant to purchase one share of our common stock (together with the shares of common stock underlying such warrants).
Offering Price per Class A Unit	$[ ] combined price for each Class A Unit based upon an assumed offering price of $[ ], the closing price of our common stock on [ ].
Class B Units Offered	We are also offering **[ ]** Class B Units to purchasers who prefer not to beneficially own more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering. Each Class B Unit will consist of one share of Series H Preferred Stock, par value $0.0001 per share, convertible into a number of shares of common stock equal to $[ ] divided by a conversion price of $[ ] (the "Conversion Price") and warrants to purchase a number of shares of our common stock equal to $[ ] divided by the Conversion Price (together with the shares of common stock underlying such shares of Series H Preferred Stock and such warrants).
Offering Price per Class B Unit	$[ ] combined price for each Class B Unit.
Description of warrants	The warrants will be exercisable beginning on the closing date and expire on the fifth anniversary of the closing date and have an assumed initial exercise price per share equal to $[ ] per share, subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock
Description of Series H Preferred Stock	Each share of Series H Preferred Stock is convertible at any time at the holder's option into a number of shares of common stock equal to $[ ] divided by the Conversion Price. Notwithstanding the foregoing, we shall not effect any conversion of Series H Preferred Stock, with certain exceptions, to the extent that, after giving effect to an attempted conversion, the holder of shares of Series H Preferred Stock (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of our common stock in excess of 4.99% (or, upon election by a holder prior to the issuance of any Series H Preferred Stock, 9.99%) of the shares of our common stock then outstanding after giving effect to such exercise. For additional information, see "Description of Securities—Description of Capital Stock—Preferred Stock—Series H Convertible Preferred Stock Being Offered Pursuant to this Prospectus" on page 65 of this prospectus.

Shares of common stock underlying the warrants	**[ ]** shares.
Shares of common stock outstanding before this offering	4,674,068 shares as of December 4, 2019.
Shares of common stock to be outstanding after this offering	**[ ]** shares (**[ ]** shares on an as-converted basis, assuming the conversion of the Series H Preferred Stock in full).
Shares of Preferred Stock outstanding before this offering	We have no shares of Series H Preferred Stock outstanding prior to this offering; we have 535 shares of Series F convertible preferred stock (the "Series F Preferred Stock") outstanding prior to this offering as of December 4, 2019.
Shares of Preferred Stock to be outstanding after this offering	[ ] shares of Series H Preferred Stock; 535 shares of Series F Preferred Stock.
Over-allotment option	We have granted the representative an option to purchase additional shares of common stock equal to 15% of the shares (including shares of common stock underlying the Series H Preferred Stock) in the offering and/or additional warrants equal to 15% of the warrants in the offering at the assumed public offering price per share of common stock and the assumed public offering price per warrant set forth on the cover page hereto less the underwriting discounts and commission. This option is exercisable, in whole or in part, for a period of 45 days from the date of this prospectus.
Market for the common stock	Our common stock is listed on The Nasdaq Capital Market under the symbol "CHFS". See "—Recent Developments" above for important information about the listing of our common stock on The Nasdaq Capital Market.
Use of Proceeds	We intend to use the net proceeds of this offering for general corporate purposes, including for continued investments in our commercialization efforts. See "Use of Proceeds" herein.
No listing of warrants	We do not intend to apply for listing of the warrants on any securities exchange or trading system.
No listing of Series H Preferred Stock	We do not intend to apply for listing of the Series H Preferred Stock on any securities exchange or trading system.
Risk Factors	See "Risk Factors" beginning on page 7 and other information included in this prospectus for a discussion of factors that you should consider carefully before deciding to invest in this offering.

Except as otherwise indicated, all information in this prospectus is based on 4,674,068 shares of common stock outstanding as of December 4, 2019 and excludes the shares of common stock being offered by this prospectus or issuable upon conversion of the Series H Preferred Stock or warrants being offered by this prospectus and also excludes the following:

- 409,468 shares of common stock issuable upon the exercise of outstanding stock options, having a weighted average exercise price of $21.75 per share;
- 6,948,466 shares of our common stock issuable upon the exercise of outstanding warrants (other than the warrants offered hereby) with a weighted-average exercise price of $7.06 per share;
- 538,210 shares of common stock issuable upon the conversion of the 535 outstanding shares of our Series F Preferred Stock (excluding additional shares of common stock that we may be required to issue upon such conversion due to the full ratchet anti-dilution price protection in the certificate of designation for the Series F Preferred Stock as described in the following bullet);
- 63,130 additional shares of common stock that we will be required to issue to the holders of our Series F Preferred Stock upon conversion thereof if the effective price per share of common stock in this offering is lower than $0.9942, the current conversion price of the Series F Preferred Stock, as a result of the reduction of such conversion price to the per share price in this offering due to the full ratchet anti-dilution price protection in the certificate of designation for the Series F Preferred Stock (assuming a per share price of $0.89, the closing price of our common stock on December 4, 2019); and
- 159,825 shares of our common stock reserved for future issuance under our equity incentive plans.

All share and per share amounts for all periods presented in this prospectus and the registration statement of which it forms a part have been retroactively adjusted to reflect the reverse stock splits we previously effected on January 12, 2017, October 12, 2017 and January 2, 2019.

RISK FACTORS

An investment in our securities has a high degree of risk. Before you invest you should carefully consider the risks and uncertainties described below and the other information in this prospectus. Any of the risks and uncertainties set forth herein could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the trading price or value of our securities. Additional risks not currently known to us or which we consider immaterial based on information currently available to us may also materially adversely affect us. As a result, you could lose all or part of your investment.

Risks Related to Our Business

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

Prior to our acquisition of the Aquadex FlexFlow 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, and $13.7 million for the nine-months ended September 30, 2019. As of September 30, 2019, our accumulated deficit was $213.1 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 business associated with the Aquadex FlexFlow system (herein referred to as the “Aquadex Business”) from Baxter International, Inc. (herein referred to as “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 2020. 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 2020. 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 48.7% of our revenues in the year ended December 31, 2018, and first nine months of 2019, respectively, with our largest customer representing 10.1% and 10.2%, 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 services 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 submitted an application to the FDA requesting for 510(k) clearance of the Aquadex FlexFlow system to include pediatric patients who weigh 20kg or more, in September 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. However, based on their clinical expertise and medical judgement, physicians are permitted to prescribe the Aquadex FlexFlow system for use in pediatric patients. Because we submitted our application in September 2019, we anticipate receiving clearance from the FDA in early 2020. However, 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. 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 had previously expired. We received renewal for the Aquadex FlexFlow circuit in the second quarter of 2019 and expect to receive renewal for the Aquadex FlexFlow console in the first quarter of 2020. We cannot import addition console inventory into the EU until the CE Mark is received. While we believe that we currently have sufficient inventory of consoles 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. In 2019, our manufacturing facility was inspected 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 continue to comply with their respective requirements on a timely basis or at all, which could delay or prevent our obtaining or maintaining 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 to 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 intangible 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 November 30, 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

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 December 17, 2019, we received a letter (the "Notice") from Nasdaq advising that for 30 consecutive trading days preceding the date of the Notice, the bid price of our common stock had closed below the $1.00 per share minimum required for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). The Notice has no effect on the listing of our common stock at this time, and our common stock continues to trade on the Nasdaq Capital Market under the symbol "CHFS." Under Nasdaq Listing Rule 5810(c)(3)(A), if during the 180 calendar day period following the date of the Notice (the "Compliance Period"), the closing bid price of our common stock is at or above $1.00 for a minimum of 10 consecutive business days, we will regain compliance with the Minimum Bid Price Requirement and our common stock will continue to be eligible for listing on the Nasdaq Capital Market, absent noncompliance with any other requirement for continued listing. If we do not regain compliance with the Minimum Bid Price Requirement by the end of the Compliance Period (or the Compliance Period as may be extended) the Company's common stock will be subject to delisting. We intend to monitor the closing bid price of our common stock and may, if appropriate, consider implementing available options to regain compliance with the Minimum Bid Price Requirement under the Nasdaq Listing Rules.

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.

On January 2, 2019, we effected a 1-for-14 reverse split of our outstanding common stock. This reverse stock split 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.

If our common stock is delisted, 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. Further, if the effective price per share of common stock in this offering is less than the current conversion price of our Series F Preferred Stock, we will be required to issue additional shares of common stock to the holders of such preferred stock upon conversion thereof. Conversion or exercise of such outstanding convertible securities will cause dilution to holders of our common stock, including investors in this offering, 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 December 4, 2019, we have warrants to purchase 6,948,466 shares of common stock outstanding, with exercise prices ranging from $0.9942 to $43.848 with a weighted-average exercise price of $7.06.

Through December 4, 2019, shares of our Series F Preferred Stock have been converted into 53,019 shares of our common stock. As of December 4, 2019, there were 535 shares of Series F Preferred Stock outstanding, convertible into an aggregate of 538,210 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. As a result of this obligation, if the public offering price of our common stock in this offering is less than $0.9942, the current conversion price of our Series F Preferred Stock, the conversion price shall be

reduced to the effective price per share of common stock in this offering. This reduction in the conversion price will result in a greater number of shares of common stock being issuable upon conversion of the Series F Preferred Stock for no additional consideration, causing greater dilution to our stockholders and investors in this offering. In addition, should we issue any securities following this offering at an effective common stock purchase price that is less than the then effective conversion price of our Series F Preferred Stock, we will be required to further reduce the conversion price of our Series F Preferred Stock, which will result in a greater dilutive effect on our stockholders.

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 December 4, 2019. The rights, preferences and privileges of our Series F Preferred Stock are described under “Description of Securities—Description of Capital Stock—Preferred Stock—Outstanding Series F Convertible Preferred Stock”. 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.

On January 2, 2019, we effected a 1-for-14 reverse split of our outstanding common stock. This reverse stock split 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. Because the number of authorized shares of our common stock was not reduced proportionately, the reverse stock split increased our board of directors’ ability to issue authorized and unissued shares without further stockholder action. As of December 4, 2019, our certificate of incorporation provides for 100,000,000 shares of authorized common stock and 40,000,000 shares of authorized preferred stock, 30,000 of which are designated Series A Junior Participating Preferred Stock and 535 of which are designated Series F Preferred Stock and we have 4,674,068 shares of common stock outstanding, 7,896,144 shares reserved for issuance upon the conversion, exercise or vesting of outstanding preferred stock, warrants and options, and 159,825 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 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 $120.1 million for U.S. income tax purposes, which expire from 2024 through 2037. To the extent these NOL carryforwards are available, we intend to use them to reduce any corporate income tax liability associated with our operations that we might have in the future. Section 382 of the U.S. Internal Revenue Code of 1986, as amended (the "Internal Revenue Code"), generally imposes an annual limitation on the amount of NOL carryforwards that might be used to offset taxable income when a corporation has undergone significant changes in stock ownership. During 2017, we experienced an ownership change as defined in Section 382 of the Internal Revenue Code which will limit our ability to utilize the our NOLs.

We may have experienced additional ownership changes 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, including due to this offering, could put limitations on the availability of our NOL carryforwards. In addition, our ability to utilize the current NOL carryforwards might be further limited by future issuances of our common stock.

As of December 31, 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 SOX and the listing requirements of The Nasdaq Capital Market. We expect these rules and regulations will continue to increase our legal and financial compliance costs and make some activities more time-consuming and costly, and these activities may increase general and administrative expenses and divert management's time and attention away from revenue-generating activities. Furthermore, now that we are a revenue-generating company following the acquisition of the Aquadex Business in August 2016, our costs to comply with regulations applicable to U.S. reporting companies may further increase. We also expect these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers.

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

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 Fourth Amended and Restated Certificate of Incorporation, as amended, 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 substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our Fourth Amended and Restated Certificate of Incorporation, as amended, 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 exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law; or any action asserting a claim against us that is governed by the internal affairs doctrine. This choice of forum provision does not preclude or contract the scope of exclusive federal or concurrent jurisdiction for any actions brought under the Securities Act or the Exchange Act. Accordingly, our exclusive forum provision will not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations.

Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees.

If a court were to find the choice of forum provision contained in our Fourth Amended and Restated Certificate of Incorporation, as amended, to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and 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.

Risks Relating to this Offering

Because our management will have broad discretion and flexibility in how the net proceeds from this offering are used, our management may use the net proceeds in ways with which you disagree or which may not prove effective.

We currently intend to use the net proceeds from this offering as discussed under "Use of Proceeds" in this prospectus. We have not allocated specific amounts of the net proceeds from this offering for any of the foregoing purposes. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds of this offering. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the net proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for us. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flow.

If you purchase Units in this offering, you may incur immediate and substantial dilution in the net tangible book value of your shares.

The assumed public offering price of the Units is substantially higher than the net tangible book value per share of our common stock. Investors purchasing Units in this offering may pay a price per share of common stock that may substantially exceed the pro forma book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing Units in this offering may incur immediate dilution of $**[ ]** per share of common stock, based on an assumed public offering of $**[ ]** per Class A Unit. See "Dilution."

As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of a liquidation of our company.

The Series H Preferred Stock and the warrants are unlisted securities and there is no public market for them.

There is no established public trading market for the Series H Preferred Stock or the warrants, and we do not expect a market to develop. In addition, neither the Series H Preferred Stock nor the warrants are listed, and we do not intend to apply for listing of the Series H Preferred Stock or the warrants on any securities exchange or trading system. Without an active market, the liquidity of the Series H Preferred Stock and the warrants is limited, and investors may be unable to liquidate their investments in the Series H Preferred Stock or the warrants.

The value of our Series H Preferred Stock is directly tied to the value of our common stock, and any change in the value of our common stock will be reflected in the value of our Series H Preferred Stock.

There is no established public trading market for the Series H Preferred Stock, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series H Preferred Stock on any national securities exchange or other nationally recognized trading system. As a result, because each share of Series H Preferred Stock

is initially convertible into a number of shares of our common stock equal to $[ ] divided by the conversion price, subject to certain beneficial ownership limitations, we expect the value of the Series H Preferred Stock to have a value directly tied to the value of our common stock. Accordingly, any change in the trading price of our common stock will be reflected in the value of our Series H Preferred Stock, and the price of our common stock may be volatile as described above.

The warrants may not have any value.

The warrants will be exercisable for five years from the closing date at an initial exercise price of $[ ] per share. In the event that the price of a share of our common stock does not exceed the exercise price of the warrants during the period when the warrants are exercisable, the warrants may not have any value.

The warrants purchased in this offering do not entitle the holder to any rights as common stockholders until the holder exercises the warrant for shares of our common stock.

Until you acquire shares of our common stock upon exercise of your warrants purchased in this offering, such warrants will not provide you any rights as a common stockholder, except as set forth in the warrants. Upon exercise of your warrants purchased in this offering, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs on or after the exercise date.

Purchasers in this offering may experience additional dilution of their investment in the future.

Subject to lock-up provisions described under “Underwriting,” we are generally not restricted from issuing additional securities, including shares of common stock, securities that are convertible into or exchangeable for, or that represent the right to receive, common stock or substantially similar securities. The issuance of securities may cause further dilution to our stockholders, including investors in this offering. In order to raise additional capital, such securities may be at prices that are not the same as the price per share in this offering. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders, including investors who purchase securities in this offering. The price per share at which we sell additional shares of our common stock or securities convertible into common stock in future transactions may be higher or lower than the price per share in this offering. The exercise of outstanding stock options or warrants and the vesting of outstanding restricted stock units may also result in further dilution of your investment.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but are not always, made through the use of words or phrases such as “anticipates,” “estimates,” “plans,” “projects,” “continuing,” “ongoing,” “expects,” “management believes,” “we believe,” “we intend” and similar words or phrases. Accordingly, these statements involve estimates, assumptions and uncertainties which could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this prospectus, and in particular those factors included in the section entitled “Risk Factors.”

Because the factors referred to in the preceding paragraph could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements we make, you should not place undue reliance on any such forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

You should carefully read this prospectus and any related free writing prospectus and with the understanding that our actual future results may materially differ from what we expect.

Except as required by law, forward-looking statements speak only as of the date they are made, and we assume no obligation to update any forward-looking statements publicly, or to update the reasons why actual results could differ materially from those anticipated in any forward-looking statements, even if new information becomes available.

USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of the securities offered by this prospectus in this offering will be approximately $[_____] million (or $[_____] million if the underwriters fully exercise their overallotment option) after deducting commissions and estimated offering expenses payable by us.

We currently intend to use the net proceeds from this offering for general corporate purposes, including for continued investments in our commercialization efforts. We may use a portion of the net proceeds for the acquisitions of businesses, products, technologies or licenses that are complementary to our business, although we have no present commitments or agreements to do so.

The allocation of the net proceeds of the offering set forth above represents our estimates based upon our current plans and assumptions regarding industry and general economic conditions, our future revenues and expenditures.

The amounts and timing of our actual expenditures may vary significantly and will depend on numerous factors, including market conditions, cash generated or used by our operations, business developments and opportunities that may arise and related rate of growth. We may find it necessary or advisable to use portions of the proceeds from this offering for other purposes.

Circumstances that may give rise to a change in the use of proceeds and the alternate purposes for which the proceeds may be used include:

- the existence of other opportunities or the need to take advantage of changes in timing of our existing activities;
- the need or desire on our part to accelerate, increase or eliminate existing initiatives due to, among other things, changing market conditions and competitive developments; and/or
- if strategic opportunities present themselves (including acquisitions, joint ventures, licensing and other similar transactions).

From time to time, we evaluate these factors and other factors and we anticipate continuing to make such evaluations to determine if the existing allocation of resources, including the proceeds of this offering, is being optimized. Pending the application of the net proceeds as described above, we will hold the net proceeds from this offering in short-term, interest-bearing, securities.

We believe that the net proceeds of this offering, together with cash on hand, will be sufficient to fund our operations through 2020, and we believe that we will need to raise additional capital to fund our operations thereafter if warrant exercises for cash do not materialize. Additional capital may not be available on terms favorable to us, or at all. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve restrictive covenants or additional security interests in our assets. Any additional debt or equity financing that we complete may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or products or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to delay, reduce the scope of, or eliminate some or all of, our development programs or liquidate some or all of our assets.

MARKET INFORMATION AND DIVIDEND POLICY

Our common stock is currently listed on The Nasdaq Capital Market under the symbol "CHFS." See "Prospectus Summary—Recent Developments" in this prospectus for important information about the listing of our common stock on The Nasdaq Capital Market. Neither the Series H Preferred Stock nor the warrants will be traded on a national securities exchange.

As of December 4, 2019, the last reported sale price of our common stock on The Nasdaq Capital Market was $0.89.

As of December 4, 2019, there were approximately 21 stockholders of record for our common stock. A substantially greater number of stockholders may be "street name" or beneficial holders, whose shares are held of record by banks, brokers and other financial institutions.

We have 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 capital 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.

Our transfer agent is American Stock Transfer & Trust Company LLC, 6201 15th Avenue, Brooklyn, New York 11219; Telephone: 800-937-5449.

The following table sets forth certain information as of December 4, 2019 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	116,567(1)	$ 7.28(2)	94,263(3)
Equity compensation plans not approved by security holders	292,901(4)	$ 58.11	65,562(5)
Total	**409,468**	**$ 21.75**	**159,825**

(1) Consists of shares of our common stock that may be issued pursuant to outstanding stock options 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 78,172 shares of our common stock remaining available for future issuance under the 2017 Equity Incentive Plan (the "2017 Plan") and 16,091 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 65,562 shares remaining available for future issuance under the New-Hire Plan.

CAPITALIZATION

The following table sets forth our actual cash and cash equivalents and our capitalization as of September 30, 2019 and on an adjusted basis to give effect to the sale of the securities offered hereby and the use of proceeds, as described in the section entitled "Use of Proceeds."

You should read this information in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes appearing in our Annual Report on Form 10-K for the year ended December 31, 2018, which is incorporated by reference in this prospectus. The information provided below has been adjusted to reflect our 1-for-14 reverse stock split that was effected after trading on January 2, 2019. The information below has also been adjusted to reflect (i) the effect of our registered direct offerings and private placements on October 25, 2019 and November 6, 2019 and (ii) the effect of this current offering.

The pro forma information set forth in the table below is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

	As of September 30, 2019 (in thousands, except share and per share data)		
	Actual	As Adjusted	Pro Forma As Adjusted
Cash and cash equivalents	$ 3,634	$ 5,394	
Stockholders' equity:			
Series A junior participating preferred stock, par value $0.0001 per share; authorized 30,000 shares, none outstanding	—	—	
Series F convertible preferred stock, par value $0.0001 per share; authorized 535 shares, issued and outstanding 535 shares	—	—	
Series H convertible preferred stock, par value $0.0001 per share; authorized none and [ ] shares, respectively, issued and outstanding none and [ ] shares, respectively	—	—	
Preferred stock, par value $0.0001 per share; authorized 39,969,465 shares, respectively, none outstanding			
Common stock, par value $0.0001 per share; authorized 100,000,000 shares, issued and outstanding 2,879,162 shares	—	[__]	
Additional paid-in capital	216,173	217,933	
Accumulated other comprehensive income:			
Foreign currency translation adjustment	1,219	1,219	
Accumulated deficit	(213,054)	(213,054)	
Total stockholders' equity	4,338	6,098	

The as adjusted column reflects our registered direct offerings and private placements in October and November of 2019 and the pro forma as adjusted column above reflects our sale of Series H Preferred Stock, common stock and warrants in this offering at an assumed public offering price of $0.89, the closing price of our common stock on December 4, 2019, per Class A Unit and an assumed public offering price of $[ ] per Class B Unit. The above discussion and table are based on 2,879,162 shares of common stock outstanding as of September 30, 2019 and excludes:

- 332,722 shares of common stock issuable upon the exercise of outstanding stock options, having a weighted average exercise price of $26.82 per share;
- 5,430,721shares of our common stock issuable upon the exercise of outstanding warrants (other than the warrants offered hereby) with a weighted-average exercise price of $10.18 per share;
- 102,185 shares of common stock issuable upon the conversion of the 535 outstanding shares of our Series F Preferred Stock (excluding additional shares of common stock that we may be required to issue upon such conversion due to the full ratchet anti-dilution price protection in the certificate of designation for the Series F Preferred Stock as described in the following bullet);

- 499,155 additional shares of common stock that we will be required to issue to the holders of our Series F Preferred Stock upon conversion thereof if the effective price per share of common stock in this offering is lower than $5.25, the conversion price of the Series F Preferred Stock on September 30, 2019, as a result of the reduction of such conversion price to the per share price in this offering due to the full ratchet anti-dilution price protection in the certificate of designation for the Series F Preferred Stock (assuming a per share price of $0.89, the closing price of our common stock on December 4, 2019); and
- 166,571 shares of our common stock reserved for future issuance under our equity incentive plans.

DILUTION

A purchaser of our securities in this offering will be diluted to the extent of the difference between the price you may for each share of our common stock and the net tangible book value per share of our common stock after this offering. Our net tangible book value as of September 30, 2019 was approximately $4.3 million, or $1.51 per share of our common stock. Net tangible book value per share is equal to our total tangible assets minus total liabilities, all divided by 2,879,162 shares of common stock outstanding at September 30, 2019.

After giving effect to our sale in this offering of [ ] shares of common stock, inclusive of the [ ] shares of common stock that the Series H Preferred Stock to be issued is convertible into, at an assumed public offering price of $[__] per Class A Unit, excluding shares that may be issued upon exercise of the underwriters' overallotment option and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our net tangible book value as of September 30, 2019 would have been approximately $[ ] million, or $[ ] per share of our common stock. This amount represents an immediate [increase][decrease] of net tangible book value to our existing stockholders of $[ ] per share and an immediate dilution of $[ ] per share to the new investors purchasing securities in this offering. For the Class B Units, we determine dilution by subtracting the adjusted net tangible book value per share after this offering from the conversion price per share of our common stock. The following table illustrates the dilution in net tangible book value per share to new investors:

Assumed public offering price per Class A Unit and conversion price per share of Series H Preferred Stock	$	[ ]
Historical net tangible book value per share at September 30, 2019	$	1.51
[Increase][Decrease] per share attributable to investors purchasing securities in this offering	$	[ ]
Net tangible book value per share, as adjusted to give effect to this offering	$	[ ]
Dilution per share to investors in this offering	$	[ ]

The information above is illustrative only and will change based on actual pricing and other terms of this offering determined at pricing.

The above discussion and table are based on 2,879,162 shares of common stock outstanding as of September 30, 2019 and excludes:

- 3,589,812 shares of common stock issued and underlying warrants to purchase common stock issued in our October and November 2019 registered direct offerings;
- 332,772 shares of common stock issuable upon the exercise of outstanding stock options, having a weighted average exercise price of $26.82 per share;
- 5,430,721 shares of our common stock issuable upon the exercise of outstanding warrants (other than the warrants offered hereby) with a weighted-average exercise price of $10.18 per share;
- 102,185 shares of common stock issuable upon the conversion of the 535 outstanding shares of our Series F Preferred Stock (excluding additional shares of common stock that we may be required to issue upon such conversion due to the full ratchet anti-dilution price protection in the certificate of designation for the Series F Preferred Stock as described in the following bullet);
- 499,155 additional shares of common stock that we will be required to issue to the holders of our Series F Preferred Stock upon conversion thereof if the effective price per share of common stock in this offering is lower than $5.25, the conversion price of the Series F Preferred Stock in effect on September 30, 2019, as a result of the reduction of such conversion price to the per share price in this offering due to the full ratchet anti-dilution price protection in the certificate of designation for the Series F Preferred Stock (assuming a per share price of $0.89, the closing price of our common stock on December 4, 2019); and
- 166,571 shares of our common stock reserved for future issuance under our equity incentive plans.

To the extent that outstanding convertible preferred stock, options or warrants are converted or exercised, you could experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of additional equity, the issuance of these shares could result in further dilution to our stockholders.

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 in conjunction with our interim condensed consolidated financial statements and related notes appearing in our Quarterly Report on Form 10-Q for the period ended September 30, 2019 and our audited consolidated financial statements and related notes appearing in our Annual Report on Form 10-K for the year ended December 31, 2018, each of which are incorporated by reference in this prospectus.

OVERVIEW

About CHF Solutions

We are a medical device company dedicated to changing the lives of patients suffering from fluid overload through science, collaboration, and innovative technology. The company is focused on developing, manufacturing, and commercializing the Aquadex FlexFlow® system for ultrafiltration therapy. 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 510(k) clearance from the FDA to market and sell the Aquadex FlexFlow system to adults. We have submitted an application to the FDA requesting for 510(k) clearance of the Aquadex FlexFlow system to include pediatric patients who weigh 20kg or more, which we expect to receive in early 2020. In the European Union ("EU"), we are required to hold a CE Mark to import our product into the EU. The CE Mark for the Aquadex FlexFlow system had previously expired. We received renewal for the Aquadex FlexFlow circuit in the second quarter of 2019 and expect to receive renewal for the Aquadex FlexFlow console in the first quarter of 2020, which would allow us to import additional console inventory into the EU. We believe that we currently have sufficient inventory of consoles already available for sale in the EU market and the timing of the receipt of the CE Mark for the console will not have a material impact on our revenue.

Previously, 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 Business from a subsidiary of Baxter

Recent Developments

Nasdaq Notice

On December 17, 2019, we received a letter (the "Notice") from The Nasdaq Stock Market ("Nasdaq") advising that for 30 consecutive trading days preceding the date of the Notice, the bid price of our common stock had closed below the $1.00 per share minimum required for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). The Notice has no effect on the listing of our common stock at this time, and our common stock continues to trade on the Nasdaq Capital Market under the symbol "CHFS." Under Nasdaq Listing Rule 5810(c)(3)(A), if during the 180 calendar day period following the date of the Notice (the "Compliance Period"), the closing bid price of our common stock is at or above $1.00 for a minimum of 10 consecutive business days, we will regain compliance with the Minimum Bid Price Requirement and our common stock will continue to be eligible for listing on the Nasdaq Capital Market, absent noncompliance with any other requirement for continued listing. If we do not regain compliance with the Minimum Bid Price Requirement by the end of the Compliance Period (or the Compliance Period as may be extended) the Company's common stock will be subject to delisting. We intend to monitor the closing bid price of our common stock and may, if appropriate, consider implementing available options to regain compliance with the Minimum Bid Price Requirement under the Nasdaq Listing Rules.

Pediatrics

On September 30, 2019, the Company submitted an application to the FDA requesting for 510(k) clearance of the Aquadex FlexFlow system to include pediatric patients who weigh 20kg or more. 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[9], extracorporeal membrane oxygenation (ECMO) therapy[10], solid organ transplantation[11], and kidney replacement therapy for neonatal patients. 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. Subject to FDA review, the Company expects clearance for this pediatric population in early 2020.

Public Offerings

On October 25, 2019, we closed on a registered direct offering of 575,830 shares of common stock at a price of $1.15 per share, for gross proceeds of approximately $660,000, prior to deducting commissions and expenses related to the transaction. In a concurrent private placement, we agreed to issue to the investors in the registered direct offering unregistered warrants to purchase up to 575,830 shares of our common stock at an exercise price of $1.41 per share, which will be exercisable six months from the date of issuance, and will expire five years from the initial exercise date.

Additionally, our outstanding Series F preferred stock is subject to full-ratchet anti-dilution protection in the event we sell any common stock at a price lower than the then-conversion price of the Series F preferred stock. As a result of this offering, effective October 25, 2019, the conversion price of the Series F preferred stock was reduced from $5.25 to $1.15 per share, the per share price to the public in this transaction.

On November 6, 2019, we closed on a registered direct offering of 1,219,076 shares of common stock, or common equivalents, at a price of $1.12 per share, for gross proceeds of approximately $1.36 million prior to deduction of commissions and offering expenses related to the transaction. In a concurrent private placement, we agreed to issue to the investors in the registered direct offering unregistered warrants to purchase up to 1,219,076 shares of our common stock at an exercise price of $0.9942 per share, which will be exercisable upon the date of issuance, and will expire five years from the initial exercise date. Effective November 6, 2019, the conversion price of the Series F preferred stock was reduced from $1.15 to $0.9942, the exercise price of the warrants issued in connection with this financing.

On March 12, 2019, we closed on an underwritten public offering of 455,178 shares of common stock, approximately 1.9 million shares of Series G Convertible Preferred Stock, and warrants to purchase approximately 4.7 million shares of common stock, which includes the full exercise of the underwriter’s over-allotment option, for gross proceeds of $12.4 million. Net proceeds totaled approximately $11.0 million after deducting the underwriting discounts and commissions and other costs associated with the offering.

Reverse Stock Split

On January 2, 2019, we effected a 1-for-14 reverse split of our outstanding common stock. This reverse stock split 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 have been retroactively adjusted to reflect the reverse stock split for all periods presented.

Critical Accounting Policies and Estimates

We have adopted various accounting policies to prepare the condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States. (U.S. GAAP). Our most significant accounting policies are disclosed in Note 1 to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2018, which is incorporated by reference in this prospectus.

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

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

[10] Selewski Dt, el al. Crit Care Med. 2012 September ; 40(9): 2694-2699. doi:10.1097/CCM.0b013e318258ff01.

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

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 its products or services, in an amount that reflects the consideration that we expect to receive in exchange for those goods and services. See Notes 1 and 2 to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2018, which is incorporated by reference in this prospectus. For the three months ended September 30, 2019, three customers represented 11%, 12% and 12% of net sales. For the nine months ended September 30, 2019, one customer represented 10% of net sales. For the three months ended September 30, 2018, two customers represented 15% and 10% of net sales. For the nine months ended September 30, 2018, one customer represented 10% of net sales.

Accounts Receivable: Accounts receivable are unsecured, 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 collectability, 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 the aging of its accounts receivable, and therefore, no allowance for doubtful accounts was considered necessary as of September 30, 2019 or December 31, 2018. As of September 30, 2019, two customers represented 14% and 12% of the accounts receivable balance. As of December 31, 2018, three customers represented 18%, 13% and 13% of the accounts receivable balance.

Inventories: Inventories consist of 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. Overhead is allocated to manufactured finished goods inventory based on the normal capacity of the Company's production facilities. Abnormal amounts of overhead, if any, are expensed as incurred. Inventories consisted of the following:

(in thousands)	September 30, 2019	December 31, 2018
Finished Goods	$ 468	$ 517
Work in Process	185	34
Raw Materials	959	1,107
Total	$ 1,612	$ 1,658

Contingent consideration: In connection with the purchase of the Aquadex Business, we had an obligation to pay additional consideration that was contingent upon the occurrence of certain future events. See Note 9 to the condensed consolidated financial statements (unaudited) included in our Quarterly Report for the three months ended September 30, 2019, which is incorporated by reference in this prospectus. Contingent consideration was recognized at the acquisition date at $126,000, the estimated fair value of the contingent milestone payments. The fair value of the contingent consideration was remeasured to its estimated fair value at the end of each reporting period, with changes recorded to earnings. As of September 30, 2019, this contingency had expired, therefore its fair value was $0.

Stock-Based Compensation: We recognize all share-based payments to employees and directors, including grants of stock options, warrants and common stock awards in the consolidated statement of operations and comprehensive loss as an operating expense based on their fair values as established at the grant date. Equity instruments issued to non-employees include common stock awards or warrants to purchase shares of our common stock. These common stock awards 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. In accordance with Accounting Standards Update 2018-07, unvested awards are no longer remeasured to fair value until vesting and rather the fair value is established at the grant date consistent with the treatment of employee director awards.

We compute the estimated fair values of stock options and warrants using the Black-Scholes option pricing model and market-based warrants using a Monte Carlo valuation 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 except for market-based warrants which are expensed based on the grant date fair value regardless of whether the award vests. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

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 nine months ended September 30, 2019, reflects a $4.5 million increase for the net deemed dividend to preferred stockholders provided in connection with the close of the March 2019 public offering, representing the intrinsic value of the preferred shares at the time of issuance. Diluted earnings per share is computed based on the net loss allocable to common stockholders for each period divided by the weighted average number of common shares outstanding, increased by the number of additional shares that would have been outstanding had the potentially dilutive common shares been issued, and reduced by the number of shares the Company could have repurchased from the proceeds from issuance of the potentially dilutive shares. Potentially dilutive shares of common stock include warrants, stock options and other stock-based awards granted under stock-based compensation plans. These potentially dilutive shares were excluded from the computation of loss per share as their effect was antidilutive due to our net loss in each of those periods.

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

	September 30	
	2019	2018
Warrants to purchase common stock	5,430,721	608,787
Series F convertible preferred stock	102,185	19,210
Stock options	332,722	139,439
Restricted stock units	—	3
Total	5,865,628	767,439

The following table reconciles reported net loss with reported net loss per share for the periods ended September 30, 2019:

(in thousands, except per share amounts)	Three months	Nine months
Net loss	$ (4,509)	$ (13,666)
Deemed dividend to preferred shareholders (see Note 4)	—	(4,509)
Net loss after deemed dividend	(4,509)	(18,175)
Weighted average shares outstanding	2,646	1,915
Basic and diluted loss per share	$ (1.70)	$ (9.49)

Going Concern: Our consolidated 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, and through September 30, 2019, we incurred losses from operations and net cash outflows from operating activities as disclosed in the condensed consolidated statements of operations and cash flows, respectively. As of September 30, 2019, we had an accumulated deficit of $213.1 million and we expect to incur losses for the immediate future. To date, we have been funded primarily by various 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 the next twelve months.

We became a revenue generating company only after acquiring the Aquadex Business in August 2016. We expect to incur additional losses in the near-term as we grow the Aquadex Business, including investments in expanding our sales and marketing capabilities, purchasing inventory, 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 in 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.

During 2017, 2018 and through November 6, 2019, we closed on registered direct and underwritten public equity offerings for net proceeds of approximately $41.4 million after deducting the underwriting discounts and commissions and other costs associated with the offering. We will 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 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 were no impacts to the amount or timing of revenue that we had recognized in prior periods. For additional accounting policy and transition disclosures, see Note 2 – Revenue Recognition to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2018, which is incorporated by reference in this prospectus.

In January 2017, the FASB issued amended guidance to simplify the accounting for goodwill impairment by removing Step 2 of the goodwill impairment test. A goodwill impairment will now be measured as the amount by which a reporting unit’s carrying value exceeds its fair value, limited to the amount of goodwill allocated to that reporting unit. This guidance is to be applied on a prospective basis effective for our interim and annual periods beginning after January 1, 2019, with early adoption permitted for any impairment tests performed after January 1, 2017. We adopted this guidance in 2017, and recognized $0.2 million of impairment losses related to our goodwill.

In February 2016, FASB issued updated guidance to improve financial reporting about leasing transactions. This guidance required 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 included an option to not restate comparative periods in transition. The Company adopted this new standard on January 1, 2019 with no retrospective adjustments to prior comparative periods. The adoption of this standard on January 1, 2019 resulted in an increase of approximately $0.6 million in the Company’s other long-term assets and in short and long-term liabilities recorded on its consolidated balance sheet. In addition, the Company elected the package of practical expedients permitted under the transition guidance within the new standard which allowed it to carry forward the historical lease classification. For additional qualitative and quantitative disclosures, see Note 7 - Operating Leases to the consolidated financial statements included in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, which is incorporated by reference in this prospectus.

In August 2018, the FASB issued updated guidance to improve and simplify the disclosure requirements on fair value measurements for level 3 assets and liabilities valued at fair value. The Company early-adopted the guidance effective in its second quarter and the effect on the consolidated financial statements was not material.

Financial Overview

We are a medical device company focused on developing, manufacturing and commercializing the Aquadex 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. As of September 30, 2019, we had an accumulated deficit of $213.1 million and we expect to incur losses for the immediate 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, there can be no assurance that we will be able to do so or that we will ever operate profitably.

Results of Operations

Comparison of Three Months Ended September 30, 2019 to Three Months Ended September 30, 2018

Net Sales

(in thousands)

Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Increase (Decrease)	% Change
$1,252	$1,363	$(111)	(8.1)%

Revenue is generated mainly from the sale of disposable blood filters and catheters used in conjunction with the Aquadex FlexFlow consoles. We sell primarily in the United States to hospitals and clinics through our direct salesforce. We sell outside of the United States to independent specialty distributors who in turn sell to hospitals and clinics in their geographic regions. The decrease in net sales compared to the same period of 2018 is driven by a reorganization of our salesforce to best align experiences and competencies with our go-to market strategy around cardiac surgery and eventually pediatrics.

Costs and Expenses

Our costs and expenses were as follows:

(in thousands)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Increase (Decrease)	% Change
Cost of goods sold	$ 540	$ 915	$ (375)	(41.0)%
Selling, general and administrative	$ 4,107	$ 3,713	$ 394	10.6%
Research and development	$ 1,112	$ 985	$ 127	12.9%

Cost of Goods Sold

In connection with the acquisition of the Aquadex Business, we entered into a manufacturing and supply agreement with Baxter. In 2017, we provided notice to Baxter to cease the manufacturing of the Aquadex product line and we began transitioning activities in house. In August 2018, we announced that the transfer of all manufacturing activities was complete.

Cost of sales in 2018 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. In the first quarter of 2019, we began selling our internally manufactured inventory, driving the improvement in our gross margins. In future quarters, we expect our gross margins will continue to improve as volumes increase and we achieve larger efficiencies of scale.

Selling, General and Administrative

The increase in selling, general and administrative expense reflect primarily on-going investment in our commercial organization as we continue to expand our outreach in the field with incremental clinical specialists and marketing support. Our general and administrative costs have remained consistent with the prior year.

As we realign and grow our distribution footprint, we expect that our selling expenses will increase modestly in future quarters, and that general and administrative expenses will remain consistent to the current quarter.

Research and Development

The increase in research and development expenses relate to investments we are making to support our 510(k) submission for pediatric label modification, and to improve the functionality of our Aquadex system, including console software updates and catheter improvements. We expect that our research and development expenditures will decrease modestly in future quarters.

Comparison of Nine Months Ended September 30, 2019 to Nine Months Ended September 30, 2018

Net Sales

(dollars in thousands)

Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018	Increase (Decrease)	% Change
$4,144	$3,499	$645	18.4%

Revenue is generated mainly from the sale of disposable blood filters and catheters used in conjunction with our Aquadex FlexFlow consoles. We sell primarily in the United States to hospitals and clinics through our direct salesforce. We sell outside of the United States to independent specialty distributors who in turn sell to hospitals and clinics in their geographic regions. The change in net sales compared to the same period of 2018 is driven by the execution of our commercialization strategy which includes continued expansion of our commercial footprint by the hiring of new sales representatives, clinical specialists, and marketing personnel. In the fourth quarter of 2019, we announced a reorganization of our sales force to best align experiences and competencies with our go-to market strategy around cardiac surgery and eventually pediatrics.

Costs and Expenses

Our costs and expenses were as follows:

(dollars in thousands)	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018	Increase (Decrease)	% Change
Cost of goods sold	$ 1,987	$ 2,686	$ (699)	(26.0)%
Selling, general and administrative	$ 12,098	$ 11,489	$ 609	5.3%
Research and development	$ 3,719	$ 2,107	$ 1,612	76.5%

Cost of Goods Sold

In connection with the acquisition of the Aquadex Business, we entered into a manufacturing and supply agreement with Baxter. We provided notice to Baxter to cease the manufacturing of the Aquadex product line in 2017, and we began transitioning activities in house. In August 2018, we announced that the transfer of all manufacturing activities was complete.

Cost of sales in 2018 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. In the first quarter of 2019, we began selling our internally manufactured inventory, driving the improvement in our gross margins. In future quarters, we expect our gross margins will continue to improve as volumes increase and we achieve larger efficiencies of scale.

Selling, General and Administrative

The increase in selling, general and administrative expense reflect primarily on-going investment in our commercial organization as we continue 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.

As we continue to increase our distribution footprint, we expect that our selling expenses will continue to increase modestly in future quarters, and that general and administrative expenses will remain consistent to the current quarter.

Research and Development

The increase in research and development expenses relate to investments we are making to support our 510(k) submission for pediatric label modification, and to improve the functionality of our Aquadex system, including console software updates and catheter improvements. We expect that our research and development expenditures will decrease modestly in future quarters.

Comparison of Year Ended December 31, 2018 to Year Ended December 31, 2017

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.

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 4 – Equity, to the condensed consolidated financial statements (unaudited) included in our Quarterly Report for the three months ended September 30, 2019, which is incorporated by reference to this prospectus.

On March 12, 2019, we closed on an underwritten public offering for net proceeds totaling approximately $11.0 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 455,178 shares of common stock, approximately 1.9 million shares of Series G convertible preferred stock and warrants to purchase approximately 4.7 million shares of common stock. See Note 4 – Equity, to the condensed consolidated financial statements (unaudited) included in of our Quarterly Report for the three months ended September 30, 2019, which is incorporated by reference to this prospectus.

On October 25, 2019, we closed on a registered direct offering of common stock, for gross proceeds of approximately $660,000, prior to deducting commissions and expenses related to the transaction. In a concurrent private placement, we agreed to issue to the investors in the registered direct offering unregistered warrants to purchase up to 575,830 shares of our common stock. See Note 10 – Subsequent Events, to the condensed consolidated financial statements included in Part I, Item 1 of our Quarterly Report for the three months ended September 30, 2019, which is incorporated by reference to this prospectus.

On November 6, 2019, we closed on a registered direct offering of 1,219,076 shares of common stock, or common equivalents, at a price of $1.12 per share, for gross proceeds of approximately $1.36 million prior to deduction of commissions and offering expenses related to the transaction. In a concurrent private placement, we agreed to issue to the investors in the registered direct offering unregistered warrants to purchase up to 1,219,076 shares of our common stock at an exercise price of $0.9942 per share, which will be exercisable upon the date of issuance, and will expire five years from the initial exercise date. Effective November 6, 2019, the conversion price of the Series F preferred stock was reduced from $1.15 to $0.9942, the exercise price of the warrants issued in connection with this financing.

On August 5, 2016, we entered into a loan agreement with Silicon Valley Bank for proceeds of up to $5.0 million, including a $1.0 million revolving line of credit and a $4.0 million term loan. The term loan expired

unused on November 30, 2016 and the term loan is no longer available to be drawn. Under the revolving line, we may borrow the lesser of $1 million or 80% of our eligible accounts (subject to customary exclusions), minus the outstanding principal balance of any advances under the revolving line. Advances under the revolving line, if any, will accrue interest at a floating per annum rate equal to 1.75% or 1.0% above the prime rate, depending on liquidity factors. The loan agreement contains customary representations, as well as customary affirmative and negative covenants. Our obligations under the new loan agreement are secured by a security interest in our assets, excluding intellectual property and certain other exceptions. We are subject to a negative pledge covenant with respect to our intellectual property. Advances under the revolving line are subject to various conditions precedent, including our compliance with financial covenants relating to net liquidity relative to monthly cash burn. The revolving line of credit expires on March 31, 2020. We had no borrowings outstanding under the Silicon Valley Bank facility as of September 30, 2019 or December 31, 2018.

As of September 30, 2019, and December 31, 2018, cash and cash equivalents were $3.6 million and $5.5 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. 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 to seek financing in the future.

Cash Flows from Operating Activities

Net cash used in operating activities was $12.3 million and $11.8 million for the nine months ended September 30, 2019 and 2018, respectively. The net cash used in each of these periods primarily reflects the net loss for those periods, offset in part by stock-based compensation, depreciation and amortization, and the effects of changes in operating assets and liabilities.

Cash Flows from Investing Activities

Net cash used in investing activities was $464,000 and $177,000 for the nine months ended September 30, 2019 and September 30, 2018, respectively. The majority of cash used in investing activities was for internally manufactured equipment, and the purchase of manufacturing, laboratory and office equipment.

Cash Flows from Financing Activities

As described above, net cash provided by financing activities was $11.0 million and $4.6 million for the nine months ended September 30, 2019 and September 30, 2018, respectively.

Capital Resource Requirements

As of September 30, 2019, 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 would pay Baxter 40% of the amount of such excess. This commitment expired on August 6, 2019. In addition, we also agreed that, if shares of our common stock cease to be publicly traded on the Nasdaq Capital Market, Baxter has the option to require us to repurchase, in cash, all or any part of the common shares held by Baxter at a price equal to their fair market value, as determined by a third-party appraiser.

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

BUSINESS

Overview

We are a medical device company dedicated to changing the lives of patients suffering from fluid overload through science, collaboration, and innovative technology. We are focused on developing, manufacturing, and commercializing the Aquadex FlexFlow® system for ultrafiltration therapy. 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[12] 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.[13] 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.[14] These dramatic improvements include new medications and new technologies, such as ultrafiltration, to help treat fluid overload.

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.[15] Approximately 40% of heart failure patients have poor diuretic response.[16] 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.[17] 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.[18]

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

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

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

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

[16] 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.

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

[18] Costanzo MR, Ronco C, Abrahman WT, et al. Extracorporeal ultrafiltration for fluid overload in heart failure. J Am Coll Cardiol. 2017;69(19):2428-2445.

Nearly one-half of hospitalized patients with heart failure are discharged with residual fluid excess after receiving conventional diuretic therapies.[19] 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.[20] There is an association of chronic loop diuretic therapy and greater resource utilization at hospitals.[21] 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.[22] 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.[23]

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 clinically significant impact on electrolyte balance, blood pressure or heart rate.[24] 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);[25]
- Following ultrafiltration, neurohormonal activation is reset toward a more physiological condition and diuretic efficacy is restored;[26]
- 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;

[19] Gheorghiade M, Filippatos G. Reassessing treatment of acute heart failure syndromes: the ADHERE registry. Eur Heart J Suppl. 2005; 7:B13–19.

[20] Felker GM, Lee KL, Bull DA, et al. Diuretic strategies in patients with acute decompensated heart failure. N Engl J Med. 2011; 364:797–805.

[21] 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.

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

[23] 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.

[24] 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.

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

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

- The console guides medical practitioner through the setup and operational process; and
- Decreased hospital readmissions and duration resulting in cost savings at 90 days.[27] [28]

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: cardiac surgery and other areas of critical care, and heart failure. We are also preparing for commercial activities with pediatric patients, once the anticipated clearance from the U.S. Food and Drug Administration, or FDA, is received.

Post-Cardiovascular Surgery and Critical Care

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,[29] 180,000 valve procedures[30], and 3,000 ventricular assist device (VAD) implants[31]. 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.[32]

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.[33] 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.[34] 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

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

[28] Costanzo MR, et al. Ultrafiltration v. Diuretics for the Treatment of Fluid Overload in Patients with Heart Failure: A Hospital Cost Analysis. Poster presented at the ISPOR meeting, May 23, 2018, Baltimore, MD, USA.

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

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

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

[32] 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.

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

[34] 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.

estimated 70,000 fluid overload-related readmissions for CABG, valve, and VAD procedures per year in the United States.[35] 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.

Similar to cardiac surgery, patients may suffer from fluid overload in connection with other critical care procedures, such as organ transplants, extra corporeal membrane oxygenation (ECMO) therapy, dialysis, and treatment for sepsis and severe burns. The potential complications (e.g. renal failure, infection, or prolonged intubation) are reported to be associated with high mortality, particularly when renal replacement therapy is required. Many patients are fluid overloaded following a transplant procedure and require treatment to achieve fluid balance. Hospitals are currently using ultrafiltration in connection with organ transplant procedures.

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 that 6.5 million people in the United States, age 20 and over, had heart failure.[36] 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.[37] 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.[38] In addition, approximately 68% of patients are discharged with sub-optimal results.[39] 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.[40] 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 25% and 6-month readmissions of 50%, while 78% of patients are admitted directly to the Emergency Department as the first point of care.[41] [42]

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.[43] As the population ages, healthcare expenditures are expected to increase substantially.[44] Therefore, therapies aimed at treating congestion and fluid overload are essential from a patient care and health economic perspective.

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

[36] Benjamin EJ, et 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).

[37] Benjamin EJ, et 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).

[38] Costanzo MR, et al. J Am Coll Cardiol. 2017; 69(19): 2428-45.

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

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

[41] Costanzo MR, et al. J Am Coll Cardiol. 2017; 69(19): 2428-2445.

[42] 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.

[43] 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.

[44] 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.

To remove the excess fluid, 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.

Pediatrics

Many of the conditions and procedures faced by adult patients also occur in pediatric patients, such as cardiac surgery, organ transplants, heart failure and extracorporeal membrane oxygenation (ECMO) therapy. Similar to adult patients, these conditions and procedures may lead to fluid overload. While incidence data is not readily available, it is estimated that there are approximately 10,000 to14,000 pediatric patients with heart failure[45] and approximately 18,000 receiving cardiac surgery, ECMO therapy, and solid organ transplantation.[46, 47, 48] In addition to these conditions, babies born prematurely may not have functioning kidneys and need kidney replacement therapy for survival. It is estimated that approximately 11,000 newborn babies require neonatal kidney replacement therapy each year in the U.S.[49]

Our Strategy

Our vision is to change the lives of patients suffering from fluid overload through science, collaboration, innovation. We provide healthcare professionals with a reliable and 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. Our field-based employees include both sales representatives and clinical specialists in 13 sales territories in the U.S. We also have distribution agreements in several countries in Europe and Asia. We intend to focus on the acute needs of fluid overloaded patients in cardiac surgery and other areas of critical care, while continuing to support heart failure patients in the inpatient setting, and eventually the outpatient setting. Once we receive the anticipated clearance from the FDA, which is expected in the first quarter of 2020, we intend to expand our commercialization efforts to treatments for pediatric patients.

Post Cardiac Surgery and Critical Care: 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. In September 2019, we realigned our sales force to further focus on the acute needs of fluid overloaded patients in cardiac surgery and other areas of critical care, such as organ transplantation. We believe that we will continue to grow revenue in this faster growing segment of our business by 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 and other critical care centers at large hospitals.

Pediatrics: In September 2019, the Company submitted an application to the FDA requesting for 510(k) clearance of the Aquadex FlexFlow system to include pediatric patients who weigh 20kg or more. 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

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

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

[47] 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.

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

[49] https://www.ncbi.nlm.nih.gov/pubmed/23833312

by physicians to treat various conditions in pediatric patients, including heart failure, cardiac surgery[50], extracorporeal membrane oxygenation (ECMO) therapy[51], solid organ transplantation[52], and kidney replacement therapy for neonatal patients. Based on submitting our application in September 2019, we anticipate receiving clearance from the FDA in early 2020. 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. We expect to evaluate improvements to the Aquadex FlexFlow system to address the needs of the pediatric population.

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 support 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 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 was initiated by the Department of Veterans Affairs Medical Center in Tampa, Florida in the fourth 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.

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, Greece, 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. As we expand our commercialization efforts in the pediatric market, following FDA clearance, we expect to evaluate improvements to the Aquadex FlexFlow system to address the needs of the pediatric population.

Sales and Marketing

As of November 30, 2019, we had 34 full-time employees in sales and marketing. Our U.S. sales force includes account managers in 13 territories, 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 in August 2016, our direct sales force was focused initially 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, primarily in heart failure. In 2018, we expanded our commercialization efforts to include post-cardiac surgery. In September 2019, we realigned our sales force to further focus on the acute needs of fluid overloaded patients in cardiac surgery and other areas of critical care, such as organ transplantation, while still supporting heart failure.

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 represented 10.1% of our 2018 annual revenue. The loss of this customer would have a material adverse effect on our revenue.

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

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

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

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, Greece, 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 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 of the fourth quarter of 2019, we initiated 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 2020. As we expand our commercialization efforts in the pediatric market, following FDA clearance, we expect to evaluate improvements to the Aquadex FlexFlow system to address the needs of the pediatric population. In the future, we also 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

We manufacture the Aquadex FlexFlow system at our 23,000 square foot facility in Eden Prairie, Minnesota. Following the acquisition of the Aquadex Business in 2016, Baxter manufactured and supplied the Aquadex FlexFlow blood circuit sets and Aquadex FlexFlow catheters. We transferred manufacturing equipment for the Aquadex Business 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. We purchase parts and components for the Aquadex FlexFlow system from third-party manufactures and suppliers. We believe that our current manufacturing facility is suitable and adequate to meet anticipated manufacturing demands, and that, if necessary, suitable additional or substitute space will be available to accommodate expansion of our operations.

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 November 30, 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. In September 2019, we submitted an application to the FDA requesting for 510(k) clearance of the Aquadex FlexFlow system to include pediatric patients who weigh 20kg or more. We anticipate receiving clearance from the FDA in early 2020. 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.

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 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 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 an 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 had previously expired. We received renewal for the Aquadex FlexFlow circuit in the second quarter of 2019 and expect to receive renewal for the Aquadex FlexFlow console in the first quarter of 2020, which would allow us to import additional console inventory into the EU. 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.

Employees

As of November 30, 2019, we had 67 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 prospectus.

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.

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.

Legal Proceedings

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

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

We give careful attention to related person transactions because they may present the potential for conflicts of interest. Under SEC rules, a related person transaction is any transaction or series of transactions in which: the Company or a subsidiary is a participant; the amount involved exceeds the lesser of $120,000 or 1% of the average of the Company's total assets at year-end for the last two completed fiscal years; and a related person has a direct or indirect material interest. A "related person" is a director, executive officer, nominee for director or a more than 5% stockholder, and any immediate family member of the foregoing.

To identify related person transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. We maintain a written policy for the review, approval or ratification of related person transactions, and our Audit Committee reviews all related person transactions identified by us. The Committee approves or ratifies only those related person transactions that are determined by it to be, under all of the circumstances, in the best interests of the Company and its stockholders.

Scott Erb, who served as our Senior Manager of Operations and Director of Marketing during 2017, is the son of John Erb, our Chief Executive Officer, President and Chairman of the Board. Scott Erb was paid $78,974 in 2017 as an employee of the Company. Following Scott Erb's departure from the Company, the Company paid $15,010 in 2017 to Infinitum Analytics, LLC, of which Scott Erb is Owner/Principal, for consulting services.

In January 2019, we entered into a consulting agreement with Steven Brandt, one of our non-employee directors, pursuant to which Mr. Brandt provided services, on an interim basis, until May 31, 2019, to support our commercial strategy under the direction of our Chief Executive Officer. Mr. Brandt was paid a fee of $19,000 per month, for a total of $76,000 for his services. Mr. Brandt also received $2,453 for reimbursement of expenses.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information regarding the beneficial ownership (as defined in Rule 13d-3 of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) of our common stock as of December 4, 2019 by (i) each of the directors and named executive officers, (ii) all of the directors and executive officers as a group, and (iii) to our knowledge, beneficial owners of more than 5% of our common stock. As of December 4, 2019, there were 4,674,068 shares of our common stock outstanding. Unless otherwise indicated and subject to applicable community property laws, each owner has sole voting and investment powers with respect to the securities listed below.

Name of Beneficial Owner	Number of Shares	Right to Acquire[1]	Total	Aggregate Percent of Class[2]
John L. Erb	11,617	48,005[3]	59,622	1.26%
Steve Brandt	5	4,374	4,379	*
Maria Rosa Costanzo, M.D.		438	438	*
Matthew E. Likens[4]	5	3,758	3,743	*
Jon W. Salveson	3	5,319	5,322	*
Gregory D. Waller	2	5,788	5,790	*
Warren S. Watson	3	5,319	5,322	*
Claudia Drayton	2	7,081	7,083	*
Nestor Jaramillo, Jr.	—	—	—	—
All directors and executive officers as a group (8 persons)	11,637	80,062	91,699	1.93%
Bigger Capital Fund, L.P.[5] 175 W. Carver Street Huntington, New York 11743	83,154	661,041	774,195	9.99%
Anson Funds Management LP[6] 5950 Berkshire Lane, Suite 210 Dallas, Texas 75225	51,000	1,102,106	1,153,106	9.99%
Altium Capital Management, L.P.[7] 551 Fifth Avenue, Floor 19 New York, New York 10176	25,000	832,142	857,142	9.99%

* Less than one percent.

(1) Except as otherwise described below, amounts reflect the number of shares that such holder could acquire through (i) the exercise of outstanding stock options, (ii) the vesting/settlement of outstanding RSUs, (iii) the exercise of outstanding warrants to purchase common stock and (iv) the conversion of outstanding Series F convertible preferred stock, in each case within 60 days after December 4, 2019.

(2) Based on 4,674,068 shares outstanding as of December 4, 2019.

(3) Consists of (i) 23,609 shares issuable upon the exercise of outstanding stock options, (ii) 20,996 shares issuable upon the exercise of outstanding warrants to purchase common stock and (iv) 3,400 shares issuable upon conversion of outstanding shares of Series F Convertible Preferred Stock (assuming all 100 shares of Series F Convertible Preferred Stock held by Mr. Erb are converted at once and rounded up to the nearest whole share).

(4) Mr. Likens resigned as a director on September 24, 2019.

(5) Based on the Schedule 13G/A filed by Bigger Capital Fund, LP, Bigger Capital Fund GP, LLC, District 2 Capital Fund LP, District 2 Capital LP, District 2 GP LLC, District 2 Holdings LLC and Michael Bigger with the SEC on November 27, 2019. Consists of 83,154 shares of common stock beneficially owned by Bigger Capital Fund, LP. The number of shares under "Right to Acquire" consists of (i) 561,041 shares of common stock issuable upon the exercise of outstanding warrants to purchase common stock beneficially owned by Bigger Capital Fund, LP and (ii) 100,000 shares of common stock issuable upon the exercise of outstanding warrants to purchase common stock beneficially owned by District 2 Capital Fund LP. Bigger Capital Fund GP, LLC is the general partner of, and may be deemed to beneficially own the securities owned by, Bigger Capital Fund, LP. Each of (i) District 2 Capital LP, as the investment manager of District 2 Capital Fund LP, (ii) District 2 GP LLC, as the general partner of District 2 Capital Fund LP, and (iii) District 2 Holdings LLC, as the managing member of District 2 GP LLC, may be deemed to beneficially own securities owned by District 2 Capital Fund LP. Mr. Bigger is the managing member of Bigger Capital Fund GP, LLC and is the managing member of District 2 Holdings LLC and may be deemed to beneficially own the securities held by Bigger Capital Fund, LP and District 2 Capital Fund LP. The percentage in this table reflects that the reporting persons may not exercise the warrants to the extent such exercise would cause the reporting persons to beneficially own a number of shares of common stock that would exceed 4.99% of our then outstanding common stock following such exercise; provided, however, that upon prior notice to us, such holder may increase its ownership, provided that in no event will the ownership exceed 9.99%.

(6) Based on the Schedule 13G filed by Anson Funds Management LP, Anson Management GP LLC, Bruce R. Winson, Anson Advisors Inc. Amin Nathoo, and Moez Kassam on March 15, 2019 relating to common stock purchased by a private fund to which Anson Funds Management LP and Anson Advisors Inc. serve as co-investment advisors. The number of shares under "Right to Acquire" consists of (i) 772,154 shares such holder could acquire upon exercise of outstanding warrants to purchase common stock and (ii) 329,952 shares such

holder could acquire upon conversion of outstanding Series G Preferred Stock. Each of the reporting persons shares voting and disposal power over the shares. The percentage in this table reflects that the reporting persons may not exercise the warrants to the extent such exercise would cause the reporting persons to beneficially own a number of shares of common stock that would exceed 4.99% of our then outstanding common stock following such exercise; provided, however, that upon prior notice to us, such holder may increase its ownership, provided that in no event will the ownership exceed 9.99%.

(7) Based on the Schedule 13G filed by Altium Capital Management, LP, Altium Growth Fund, LP, and Altium Growth GP, LLC on March 15, 2019. Altium Growth Fund, LP is the record and direct beneficial owner of the securities. Altium Capital Management, LP is the investment advisor of, and may be deemed to beneficially own securities owned by Altium Growth Fund, LP. Altium Growth GP, LLC is the general partner of, and may be deemed to beneficially own securities owned by, Altium Growth Fund, LP. The number of shares under “Right to Acquire” consists of (i) 571,428 shares such holder could acquire upon exercise of outstanding warrants to purchase common stock and (ii) 260,714 shares such holder could acquire upon conversion of outstanding Series G Preferred Stock. Each of the reporting persons shares voting and disposal power over the shares. The percentage in this table reflects that the reporting persons may not exercise the warrants to the extent such exercise would cause the reporting persons to beneficially own a number of shares of common stock that would exceed 4.99% of our then outstanding common stock following such exercise; provided, however, that upon prior notice to us, such holder may increase its ownership, provided that in no event will the ownership exceed 9.99%.

DESCRIPTION OF SECURITIES

Description of Units

We are offering up to **[ ]** Class A Units, with each Class A Unit consisting of one share of common stock and a warrant to purchase one share of our common stock (together with the shares of common stock underlying such warrants) at a public offering price of $[ ] per Class A Unit. Each warrant included in the Class A Units entitles its holder to purchase one share of Common Stock at an exercise price of $[ ].

We are also offering **[ ]** Class B Units to purchasers who prefer not to beneficially own more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering with each Class B Unit consisting of one share of Series H Preferred Stock, par value $0.0001 per share, convertible into a number of shares of common stock equal to $[ ] divided by the conversion price of $[ ] (the "Conversion Price") and warrants to purchase a number of shares of common stock equal to $[ ] divided by the Conversion Price (together with the shares of common stock underlying such warrants) at an assumed public offering price of $[ ] per Class B Unit. Each warrant included in the Class B Units entitles its holder to purchase a number of shares of Common Stock equal to 100% of the shares of Common Stock issuable upon conversion of the Series H Preferred Stock included in such units at an exercise price of $[ ] per share.

The securities of which the units are composed (the "underlying securities") are being sold in this offering only as part of the units. However, the Class A Units and Class B Units will not be certificated and the underlying securities comprising such units are immediately separable. Each underlying security purchased in this offering will be issued independent of each other underlying security and not as part of a unit. Upon issuance, each underlying security may be transferred independent of any other underlying security, subject to applicable law and transfer restrictions.

Description of Warrants Included in the Units

The material terms and provisions of the warrants being offered pursuant to this prospectus are summarized below. This summary of some provisions of the warrants is not complete. For the complete terms of the warrants, you should refer to the form of warrant filed as an exhibit to the registration statement of which this prospectus is a part.

Pursuant to a warrant agency agreement between us and American Stock Transfer & Trust Company LLC, as warrant agent, the warrants will be issued in book-entry form and shall initially be represented only by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

Each Class A Unit includes a warrant to purchase one share of our common stock at an exercise price of $[ ] per share at any time for up to five years after the date of the closing of this offering. Each Class B Unit issued in this offering includes a warrant to purchase a number of shares of common stock equal to $[ ] divided by the Conversion Price at any time for up to five years after the date of the closing of this offering. The warrants issued in this offering will be governed by the terms of a global warrant held in book-entry form. The holder of a warrant will not be deemed a holder of our underlying common stock until the warrant is exercised, except as set forth in the warrants.

Subject to limited exceptions, a holder of warrants will not have the right to exercise any portion of its warrants if the holder (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of common stock in excess of 4.99% (or, upon election by a holder prior to the issuance of any warrants, 9.99%) of the shares of our common stock then outstanding after giving effect to such exercise (the "Beneficial Ownership Limitation"); provided, however, that upon notice to the Company, the holder may increase or decrease the Beneficial Ownership Limitation, provided that in no event shall the Beneficial Ownership Limitation exceed 9.99% and any increase in the Beneficial Ownership Limitation will not be effective until 61 days following notice of such increase from the holder to us.

The exercise price and the number of shares issuable upon exercise of the warrants is subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock. The warrant holders must pay the exercise price in cash upon exercise of the warrants, unless such warrant holders are utilizing the cashless exercise provision of the warrants, which is only available in certain circumstances such as if the underlying shares are not registered with the SEC pursuant to an effective registration statement. We intend to use commercially reasonable efforts to have the registration statement of which this prospectus forms a part, effective when the warrants are exercised.

In addition, in the event we consummate a merger or consolidation with or into another person or other reorganization event in which our common shares are converted or exchanged for securities, cash or other property, or we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets or we or another person acquire 50% or more of our outstanding shares of common stock, then following such event, the holders of the warrants will be entitled to receive upon exercise of the warrants the same kind and amount of securities, cash or property which the holders would have received had they exercised the warrants immediately prior to such fundamental transaction. Any successor to us or surviving entity shall assume the obligations under the warrants. Further, as more fully described in the warrants, in the event of certain fundamental transactions, the holders of the warrants will be entitled to receive consideration in an amount equal to the Black-Scholes value of the warrants as of the date of consummation of such transaction.

Upon the holder's exercise of a warrant, we will issue the shares of common stock issuable upon exercise of the warrant within the earlier of three trading days following our receipt of a notice of exercise or the standard settlement period for the market on which the common stock is then listed, provided that payment of the exercise price has been made (unless exercised via the "cashless" exercise provision).

Prior to the exercise of any warrants to purchase common stock, holders of the warrants will not have any of the rights of holders of the common stock purchasable upon exercise, including the right to vote, except as set forth therein.

Warrant holders may exercise warrants only if the issuance of the shares of common stock upon exercise of the warrants is covered by an effective registration statement, or an exemption from registration is available under the Securities Act and the securities laws of the state in which the holder resides. We intend to use commercially reasonable efforts to have the registration statement of which this prospectus forms a part effective when the warrants are exercised. The warrant holders must pay the exercise price in cash upon exercise of the warrants unless there is not an effective registration statement or, if required, there is not an effective state law registration or exemption covering the issuance of the shares underlying the warrants (in which case, the warrants may only be exercised via a "cashless" exercise provision).

The warrants are callable by us in certain circumstances. Subject to certain exceptions, in the event that the warrants are outstanding, following the date that is 180 days after the closing date, (i) the volume weighted average price of our common stock for each of 30 consecutive trading days (the "Measurement Period"), which Measurement Period commences after the date that is 180 days after the closing date, exceeds 300% of the initial exercise price (subject to adjustment for forward and reverse stock splits, recapitalizations, stock dividends and similar transactions), (ii) the average daily trading volume for such Measurement Period exceeds $500,000 per trading day and (iii) the holder is not in possession of any information that constitutes or might constitute, material non-public information which was provided by the Company, and subject to the Beneficial Ownership Limitation, then we may, within one trading day of the end of such Measurement Period, upon notice (a "Call Notice"), call for cancellation of all or any portion of the warrants for which a notice of exercise has not yet been delivered (a "Call") for consideration equal to $0.0001 per share. Any portion of a warrant subject to such Call Notice for which a notice of exercise shall not have been received by the Call Date (as hereinafter defined) will be canceled at 6:30 p.m. (New York City time) on the tenth trading day after the date the Call Notice is received by the Holder (such date and time, the "Call Date"). Our right to call the warrants shall be exercised ratably among the holders based on the outstanding warrants.

We do not intend to apply for listing of the warrants on any securities exchange or other trading system.

Description of Capital Stock

Our authorized capital stock consists of 100,000,000 shares of common stock, par value $0.0001 per share, and 40,000,000 shares of preferred stock, par value $0.0001 per share, 30,000 of which are designated as Series A Junior Participating Preferred Stock and 535 of which are designated Series F Convertible Preferred Stock (the "Series F Preferred Stock") as of December 4, 2019. Once shares of Series F Preferred Stock are converted, redeemed or reacquired by us, such shares shall resume the status of authorized but unissued shares of undesignated preferred stock.

As of December 4, 2019, we had (i) 4,674,068 outstanding shares of common stock, (ii) 535 outstanding shares of Series F Preferred Stock, which, at the currently applicable conversion price, would convert into 538,210 shares of common stock, subject to future adjustment, (iii) outstanding options to acquire 409,468 shares of our common

stock, and (iv) outstanding warrants to purchase 6,948,466 shares of our common stock. 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. All share and per share amounts presented herein have been retroactively adjusted to reflect the reverse stock split.

The following description summarizes the most important terms of our capital stock. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description you should refer to our certificate of incorporation, bylaws and certificate of designation of preferences, rights and limitations of Series F Preferred Stock, copies of which have been incorporated by reference as exhibits to the registration statement of which this prospectus forms a part, and to the applicable provisions of the Delaware General Corporation Law.

Common Stock

Dividends

Holders of our common stock are entitled to receive dividends when and as declared by our board of directors out of funds legally available.

Voting

Holders of our common stock are entitled to one vote for each share on each matter properly submitted to our stockholders for their vote; provided however, that except as otherwise required by law, holders of our common stock will not be entitled to vote on any amendment to our certificate of incorporation (including any certificate of designation filed with respect to any series of preferred stock) that relates solely to the terms of a series of outstanding preferred stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon by law or pursuant to our certificate of incorporation (including any certificate of designation filed with respect to any series of preferred stock).

Subject to the voting restrictions described above, holders of our common stock may adopt, amend or repeal our bylaws and/or alter certain provisions of our certificate of incorporation with the affirmative vote of the holders of at least 66⅔% of the voting power of all of the then-outstanding shares of our capital stock entitled to vote generally in the election of directors, voting together as a single class, in addition to any vote of the holders of a class or series of our stock required by law or our certificate of incorporation. Those provisions of our certificate of incorporation that may be altered only by the super-majority vote described above relate to:

- the number of directors on our board of directors, the classification of our board of directors and the terms of the members of our board of directors;
- the limitations on removal of any of our directors described below under "—Anti-Takeover Effects of Certain Provisions of Our Certificate of Incorporation and Bylaws and Delaware Law;"
- the ability of our directors to fill any vacancy on our board of directors by the affirmative vote of a majority of the directors then in office under certain circumstances;
- the ability of our board of directors to adopt, amend or repeal our bylaws and the super-majority vote of our stockholders required to adopt, amend or repeal our bylaws described above;
- the limitation on action of our stockholders by written action described below under "—Anti-Takeover Effects of Certain Provisions of Our Certificate of Incorporation and Bylaws and Delaware Law;"
- the choice of forum provision described below under "—Choice of Forum;"
- the limitations on director liability and indemnification described below under the heading "—Limitation on Liability of Directors and Indemnification;" and
- the super-majority voting requirement to amend our certificate of incorporation described above.

Conversion, Redemption and Preemptive Rights

Holders of our common stock do not have any conversion, redemption or preemptive rights pursuant to our organizational documents.

Liquidation, Dissolution and Winding-up

In the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in any assets remaining after the satisfaction in full of the prior rights of creditors and the aggregate of any liquidation preference pursuant to the terms of any certificate of designation filed with respect to any series of preferred stock, including our outstanding Series F Preferred Stock and the Series H Preferred Stock being offered hereby.

Listing

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

Preferred Stock

We may issue any class of preferred stock in any series. Our board of directors has the authority to establish and designate series, and to fix the number of shares included in each such series and to determine or alter for each such series, such voting powers, designation, preferences, and relative participating, optional, or other rights and such qualifications, limitations or restrictions thereof. Our board of directors is not restricted in repurchasing or redeeming such stock while there is any arrearage in the payment of dividends or sinking fund installments. Our board of directors is authorized to increase or decrease the number of shares of any series subsequent to the issuance of shares of that series, but not below the number of shares of such series then outstanding. The number of authorized shares of preferred stock may be increased or decreased, but not below the number of shares thereof then outstanding, by the affirmative vote of the holders of a majority of the common stock, without a vote of the holders of the preferred stock, or of any series thereof, unless a vote of any such holders is required pursuant to the terms of any certificate of designation filed with respect to any series of preferred stock.

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

Outstanding Series F Convertible Preferred Stock. Our Board designated 18,000 shares of preferred stock as Series F convertible preferred stock, $0.0001 par value. As of December 4, 2019, there were 535 shares of Series F Preferred Stock outstanding with a conversion price of $0.9942.

Liquidation. Upon any dissolution, liquidation or winding up, whether voluntary or involuntary, holders of Series F Preferred Stock will be entitled to receive distributions out of our assets, whether capital or surplus, of an amount equal to $0.0001 per share of Series F Preferred Stock before any distributions shall be made on the common stock or any series of preferred stock ranked junior to the Series F Preferred Stock.

Dividends. Holders of the Series F Preferred Stock are entitled to receive dividends equal (on an "as converted to common stock" basis) to and in the same form as dividends actually paid on shares of our common stock when, as and if such dividends are paid on shares of our common stock. No other dividends will be paid on shares of Series F Preferred Stock.

Conversion. Each share of Series F Preferred Stock is convertible, at any time and from time to time at the option of the holder thereof, into that number of shares of common stock determined by dividing $1,000 by the conversion price of $0.9942 (subject to adjustment described below). This right to convert is limited by the beneficial ownership limitation described below.

Forced Conversion. Subject to certain ownership limitations as described below and certain equity conditions being met, until such time that during any 20 of 30 consecutive trading days, the volume weighted average price of our common stock exceeds 300% of the conversion price and the daily dollar trading volume during such period exceeds $200,000 per trading day, we have the right to force the conversion of the Series F Preferred Stock into common stock.

Beneficial Ownership Limitation. A holder shall have no right to convert any portion of Series F Preferred Stock, to the extent that, after giving effect to such conversion, such holder, together with such holder's affiliates, and any persons acting as a group together with such holder or any such affiliate, would beneficially own in excess of 4.99%

of the number of shares of common stock outstanding immediately after giving effect to the issuance of shares of common stock upon such conversion (subject to the right of the holder to increase such beneficial ownership limitation upon not less than 61 days prior notice provided that such limitation can never exceed 9.99% and such 61 day period cannot be waived). Beneficial ownership of the holder and its affiliates will be determined in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder. Holders of Series F Preferred Stock who are subject to such beneficial ownership limitation are and will remain responsible for ensuring their own compliance with Regulation 13D-G promulgated under the Securities Exchange Act of 1934, as amended, consistent with their individual facts and circumstances. In addition, pursuant to Rule 13d-3(d)(1) (i) promulgated under the Securities Exchange Act of 1934, as amended, any person who acquires Series F Preferred Stock with the purpose or effect of changing or influencing the control of our company, or in connection with or as a participant in any transaction having such purpose or effect, immediately upon such acquisition will be deemed to be the beneficial owner of the underlying common stock.

Optional Redemption. Subject to the terms of the certificate of designation, the Company holds an option to redeem some or all the Series F Preferred Stock six months after its issuance date at a 200% premium to the stated value of the Series F Preferred Stock subject to the redemption, upon 30 days prior written notice to the holder of the Series F Preferred Stock. The Series F Preferred Stock would be redeemed by the Company for cash.

Conversion Price Adjustment

Subsequent Equity Sales. The Series F Preferred Stock 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, including in this offering. If during any 20 of 30 consecutive trading days the volume weighted average price of our 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 anti-dilution protection in the Series F Preferred Stock will expire and cease to apply.

Stock Dividends and Stock Splits. If we pay a stock dividend or otherwise make a distribution payable in shares of common stock on shares of common stock or any other common stock equivalents, subdivide or combine outstanding common stock, or reclassify common stock, the conversion price will be adjusted by multiplying the then conversion price by a fraction, the numerator of which shall be the number of shares of common stock outstanding immediately before such event, and the denominator of which shall be the number of shares outstanding immediately after such event.

Fundamental Transaction. If we effect a fundamental transaction in which we are the surviving entity, then upon any subsequent conversion of Series F Preferred Stock, the holder thereof shall have the right to receive, for each share of common stock that would have been issuable upon such conversion immediately prior to the occurrence of such fundamental transaction, the number of shares of our common stock and any additional consideration receivable as a result of such fundamental transaction by a holder of the number of shares of common stock into which Series F Preferred Stock is convertible immediately prior to such fundamental transaction. If we effect a fundamental transaction in which we are not the surviving entity or a reverse merger in which we are the surviving entity, then the surviving entity shall purchase the outstanding Series F Preferred Stock by paying and issuing, in the event that such consideration given to common stockholders is non-cash consideration, as the case may be, to such holder (or canceling such holder's outstanding Series F Preferred Stock and converting it into the right to receive) an amount equal to the greater of (i) the cash consideration plus the non-cash consideration (in the form issuable to the holders of common stock) per share of the common stock in the fundamental transaction multiplied by the number of conversion shares underlying the shares of Series F Preferred Stock held by the holder on the date of the consummation of the fundamental transaction or (ii) 130% of the stated value of the Series F Preferred Stock then outstanding on the date immediately prior to the consummation of the fundamental transaction. Such amount shall be paid in the same form and mix (be it securities, cash or property, or any combination of the foregoing) as the consideration received by the common stock in such fundamental transaction. A fundamental transaction means: (i) our merger or consolidation with or into another entity, (ii) any sale or other disposition of all or substantially all of our assets in one transaction or a series of related transactions, (iii) any tender offer or exchange offer allowing holders of our common stock to tender or exchange their shares for cash, property or securities, and has been accepted by the holders of 50% or more of the outstanding common stock (iv) any reclassification of our common stock or any compulsory share exchange by which common stock is effectively converted into or exchanged for other securities, cash or property, or (v) consummation of a stock or share purchase agreement or other business combination with another person whereby such other person acquires more than 50% of the outstanding shares of common stock.

Voting Rights, etc. Except as otherwise provided in the Series F Preferred Stock certificate of designation or required by law, the Series F Preferred Stock has no voting rights. However, as long as any shares of Series F Preferred Stock are outstanding, we may not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series F Preferred Stock, alter or change adversely the powers, preferences or rights given to the Series F Preferred Stock, amend its certificate of designation, amend our certificate of incorporation or other charter documents in any manner that adversely affects any rights of the holders, increase the number of authorized shares of Series F Preferred Stock, or enter into any agreement with respect to any of the foregoing. The Series F Preferred Stock certificate of designation provides that if any party commences an action or proceeding to enforce any provisions of the certificate of designation, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its attorneys' fees and other costs and expenses incurred in the investigation, preparation and prosecution of such action or proceeding. This provision may, under certain circumstances, be inconsistent with federal securities laws and Delaware general corporation law.

Fractional Shares. No fractional shares of common stock will be issued upon conversion of Series F Preferred Stock. Rather, we shall, at our election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the conversion price or round up to the next whole share.

The Series F Preferred Stock was issued in book-entry form under a preferred stock agent agreement between American Stock Transfer & Trust as preferred stock agent, and us, and shall initially be represented by one or more book-entry certificates deposited with The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC. There is no established public trading market for the Series F Preferred Stock, and the Series F Preferred Stock is not listed on The Nasdaq Capital Market, any other national securities exchange or any other nationally recognized trading system.

Series H Convertible Preferred Stock Being Offered Pursuant to this Prospectus. Our Board has designated [___] shares of preferred stock as Series H convertible preferred stock, $0.0001 par value ("Series H Preferred Stock"), none of which are issued and outstanding prior to this offering. Although there is no current intent to do so, our Board may, without stockholder approval, issue shares of an additional class or series of preferred stock with voting and conversion rights which could adversely affect the voting power of the holders of the common stock or the convertible preferred stock, except as prohibited by the certificate of designation of preferences, rights and limitations of Series H Preferred Stock.

The following is a summary of the material terms of our Series H Preferred Stock. For more information, please refer to the certificate of designation of preferences, rights and limitations of Series H Preferred Stock to be filed as an exhibit to the registration statement of which this prospectus is a part.

Liquidation. Upon any dissolution, liquidation or winding up, whether voluntary or involuntary, holders of Series H Preferred Stock will be entitled to receive distributions out of our assets, whether capital or surplus, of an amount equal to $0.0001 per share of Series H Preferred Stock before any distributions shall be made on the common stock or any series of preferred stock ranked junior to the Series H Preferred Stock, but after distributions shall be made on any outstanding Series F Preferred Stock and any of our existing or future indebtedness.

Dividends. Holders of the Series H Preferred Stock will be entitled to receive dividends equal (on an "as converted to common stock" basis) to and in the same form as dividends actually paid on shares of our common stock when, as and if such dividends are paid on shares of our common stock. No other dividends will be paid on shares of Series H Preferred Stock.

Conversion. Each share of Series H Preferred Stock is convertible, at any time and from time to time at the option of the holder thereof, into that number of shares of common stock determined by dividing $[ ] by the conversion price of $[__] (subject to adjustment described below). This right to convert is limited by the beneficial ownership limitation described below.

Forced Conversion. Subject to certain ownership limitations as described below and certain equity conditions being met, until such time that during any 20 of 30 consecutive trading days, the volume weighted average price of our common stock exceeds 300% of the conversion price and the daily dollar trading volume during such period exceeds $200,000 per trading day, we shall have the right to force the conversion of the Series H Preferred Stock into common stock.

Beneficial Ownership Limitation. A holder shall have no right to convert any portion of Series H Preferred Stock, to the extent that, after giving effect to such conversion, such holder, together with such holder's affiliates, and

any persons acting as a group together with such holder or any such affiliate, would beneficially own in excess of 4.99% (or, upon the election by a holder prior to the issuance of any shares of Series H Preferred Stock, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to the issuance of shares of common stock upon such conversion (subject to the right of the holder to increase such beneficial ownership limitation upon not less than 61 days prior notice provided that such limitation can never exceed 9.99% and such 61 day period cannot be waived). Beneficial ownership of the holder and its affiliates will be determined in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder. Holders of Series H Preferred Stock who are subject to such beneficial ownership limitation are and will remain responsible for ensuring their own compliance with Regulation 13D-G promulgated under the Securities Exchange Act of 1934, as amended, consistent with their individual facts and circumstances. In addition, pursuant to Rule 13d-3(d)(1)(i) promulgated under the Securities Exchange Act of 1934, as amended, any person who acquires Series H Preferred Stock with the purpose or effect of changing or influencing the control of our company, or in connection with or as a participant in any transaction having such purpose or effect, immediately upon such acquisition will be deemed to be the beneficial owner of the underlying common stock.

Conversion Price Adjustment

Stock Dividends and Stock Splits. If we pay a stock dividend or otherwise make a distribution payable in shares of common stock on shares of common stock or any other common stock equivalents, subdivide or combine outstanding common stock, or reclassify common stock, the conversion price will be adjusted by multiplying the then conversion price by a fraction, the numerator of which shall be the number of shares of common stock outstanding immediately before such event, and the denominator of which shall be the number of shares outstanding immediately after such event.

Fundamental Transaction. If we effect a fundamental transaction in which we are the surviving entity, then upon any subsequent conversion of Series H Preferred Stock, the holder thereof shall have the right to receive, for each share of common stock that would have been issuable upon such conversion immediately prior to the occurrence of such fundamental transaction, the number of shares of our common stock and any additional consideration receivable as a result of such fundamental transaction by a holder of the number of shares of common stock into which Series H Preferred Stock is convertible immediately prior to such fundamental transaction. A fundamental transaction means: (i) our merger or consolidation with or into another entity, (ii) any sale or other disposition of all or substantially all of our assets in one transaction or a series of related transactions, (iii) any tender offer or exchange offer allowing holders of our common stock to tender or exchange their shares for cash, property or securities, and has been accepted by the holders of 50% or more of the outstanding common stock (iv) any reclassification of our common stock or any compulsory share exchange by which common stock is effectively converted into or exchanged for other securities, cash or property, or (v) consummation of a stock or share purchase agreement or other business combination with another person whereby such other person acquires more than 50% of the outstanding shares of common stock.

Voting Rights, etc. Except as otherwise provided in the Series H Preferred Stock certificate of designation or required by law, the Series H Preferred Stock has no voting rights. However, as long as any shares of Series H Preferred Stock are outstanding, we may not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series H Preferred Stock, alter or change adversely the powers, preferences or rights given to the Series H Preferred Stock, amend its certificate of designation, amend our certificate of incorporation or other charter documents in any manner that adversely affects any rights of the holders, increase the number of authorized shares of Series H Preferred Stock, or enter into any agreement with respect to any of the foregoing. The Series H Preferred Stock certificate of designation provides that if any party commences an action or proceeding to enforce any provisions of the certificate of designation, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its attorneys' fees and other costs and expenses incurred in the investigation, preparation and prosecution of such action or proceeding. This provision may, under certain circumstances, be inconsistent with federal securities laws and Delaware general corporation law.

Fractional Shares. No fractional shares of common stock will be issued upon conversion of Series H Preferred Stock. Rather, we shall, at our election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the conversion price or round up to the next whole share.

The Series H Preferred Stock will be issued in book-entry form under a preferred stock agent agreement between American Stock Transfer & Trust as preferred stock agent, and us, and shall initially be represented by one or more

book-entry certificates deposited with The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC. There is no established public trading market for the Series H Preferred Stock and we do not expect a market to develop. We do not plan on applying to list the Series H Preferred Stock on The Nasdaq Capital Market, any other national securities exchange or any other nationally recognized trading system.

Description of Outstanding Warrants

As of December 4, 2019, there were warrants outstanding to purchase a total of 6,948,466 shares of our common stock, which expire between 2019 and 2025. Each of these warrants entitles the holder to purchase one share of common stock at prices ranging from $0.9942 to $43,848 per common share, with a weighted average exercise price of $7.06 per share. Certain of these warrants have a net exercise provision under which its holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of our common stock at the time of exercise of the warrant after deduction of the aggregate exercise price. Each of these warrants also contains provisions for the adjustment of the exercise price and the aggregate number of shares issuable upon the exercise of the warrant in the event of dividends, share splits, reorganizations and reclassifications and consolidations. Certain of these warrants provide that, subject to limited exceptions, a holder will not have the right to exercise any portion of its warrants if the holder, together with its affiliates, would beneficially own over 4.99% of our then outstanding common stock following such exercise; provided, however, that upon prior notice to us, the warrant holder may increase its ownership, provided that in no event will the ownership exceed 9.99%.

Anti-Takeover Effects of Certain Provisions of Our Certificate of Incorporation and Bylaws and

Delaware Law Certificate of Incorporation and Bylaws

Certain provisions of our certificate of incorporation and bylaws may be considered to have an anti-takeover effect, such as those provisions:

- providing for our board of directors to be divided into three classes with staggered three-year terms, with only one class of directors being elected at each annual meeting of our stockholders and the other classes continuing for the remainder of their respective three-year terms;
- authorizing our board of directors to issue from time to time any series of preferred stock and fix the voting powers, designation, powers, preferences and rights of the shares of such series of preferred stock;
- prohibiting stockholders from acting by written consent in lieu of a meeting;
- requiring advance notice of stockholder intention to put forth director nominees or bring up other business at a stockholders' meeting;
- prohibiting stockholders from calling a special meeting of stockholders;
- requiring a 66⅔% super-majority stockholder approval in order for stockholders to alter, amend or repeal certain provisions of our certificate of incorporation;
- requiring a 66⅔% super-majority stockholder approval in order for stockholders to adopt, amend or repeal our bylaws;
- providing that, subject to the rights of the holders of any series of preferred stock to elect additional directors under specified circumstances, neither the board of directors nor any individual director may be removed without cause;
- creating the possibility that our board of directors could prevent a coercive takeover of our Company due to the significant amount of authorized, but unissued shares of our common stock and preferred stock;
- providing that, subject to the rights of the holders of any series of preferred stock, the number of directors shall be fixed from time to time exclusively by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- providing that any vacancies on our board of directors under certain circumstances will be filled only by a majority of our board of directors then in office, even if less than a quorum, and not by the stockholders.

Delaware Law

We are also subject to Section 203 of the DGCL, which generally prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder, unless:

- prior to that date, our board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of our voting stock outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned by (i) persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to that date, the business combination is approved by our board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66⅔% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 of the DGCL defines an interested stockholder as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by any of these entities or persons.

The above-summarized provisions of our certificate of incorporation and bylaws and the above-summarized provisions of the DGCL could make it more difficult to acquire us by means of a tender offer, a proxy contest or otherwise, or to remove incumbent officers and directors. These provisions are expected to discourage certain types of coercive takeover practices and takeover bids that our board of directors may consider inadequate and to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging takeover or acquisition proposals because, among other things, negotiation of these proposals could result in an improvement of their terms.

Choice of Forum

Our Fourth Amended and Restated Certificate of Incorporation, as amended, 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 exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law; or any action asserting a claim against us that is governed by the internal affairs doctrine. These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. Our Fourth Amended and Restated Certificate of Incorporation, as amended, will further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, subject to applicable law. Any person or entity purchasing or otherwise acquiring any interest in our securities shall be deemed to have notice of and consented to these provisions. Our exclusive forum provision will not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations.

The provisions of the Delaware General Corporation Law, our Fourth Amended and Restated Certificate of Incorporation, as amended, and our Second Amended and Restated Bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Limitation on Liability of Directors and Indemnification

Our certificate of incorporation limits the liability of our directors to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for any:

- breach of their duty of loyalty to us or our stockholders;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares as provided in Section 174 of the DGCL; or
- transaction from which the directors derived an improper personal benefit.

These limitations of liability do not apply to liabilities arising under federal securities laws and do not affect the availability of equitable remedies such as injunctive relief or rescission.

Our bylaws provide that we will indemnify and advance expenses to our directors and officers to the fullest extent permitted by law or, if applicable, pursuant to indemnification agreements. They further provide that we may choose to indemnify our other employees or agents from time to time. Subject to certain exceptions and procedures, our bylaws also require us to advance to any person who was or is a party, or is threatened to be made a party, to any proceeding by reason of the person's service as one of our directors or officers all expenses incurred by the person in connection with such proceeding.

Section 145(g) of the DGCL and our bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to us, regardless of whether our bylaws permit indemnification. We maintain a directors' and officers' liability insurance policy.

We entered into indemnification agreements with each of our directors and executive officers that provide, in general, that we will indemnify them to the fullest extent permitted by law in connection with their service to us or on our behalf and, subject to certain exceptions and procedures, that we will advance to them all expenses that they incur in connection with any proceeding to which they are, or are threatened to be made, a party.

At present, there is no pending litigation or proceeding involving any of our directors or officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

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

Registration Rights

Outstanding Warrants. We intend to register for resale the shares of common stock underlying certain replacement warrants issued to investors under a letter agreement dated February 15, 2017 that was entered into between us and such affiliates to encourage such affiliates to exercise their then-outstanding warrants for cash on or before March 31, 2017. See our Current Reports on Form 8-K filed with the SEC on February 16, 2017 and March 29, 2017 for additional information about the letter agreement and replacement warrants.

In addition, we agreed to register for resale the shares of common stock underlying certain warrants issued in a private placement transactions to investors pursuant to a securities purchase agreement, each dated October 23, 2019 and November 4, 2019. See our Current Reports on Form 8-K filed with the SEC on October 23, 2019 and November 4, 2019 for additional information about the private placement transaction and these warrants.

Aquadex Acquisition. On August 5, 2016, upon closing of the acquisition of the Aquadex Business, we entered into a registration rights agreement with Baxter, pursuant to which Baxter or its affiliates has the right to request that we file a registration statement with the SEC to register all or part of the 1,666 shares of common stock that Baxter received in connection with the acquisition. Upon receipt of any such request, we have agreed to use reasonable best efforts to prepare and file a registration statement as expeditiously as possible but in any event within 30 days of such request, to cause the registration statement to become effective in accordance with Baxter's intended method of distribution, and to pay the expenses incurred in connection with any such registration.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company LLC.

Listing

Our common stock trades on The Nasdaq Capital Market under the symbol “CHFS.” See “Prospectus Summary—Recent Developments” in this prospectus for important information about the listing of our common stock on The Nasdaq Capital Market.

UNDERWRITING

We are offering the units described in this prospectus through the underwriters named below. Ladenburg Thalmann & Co. Inc. is acting as book-running manager of the offering. Subject to the terms and conditions of the underwriting agreement, the underwriters have agreed to purchase the number of our securities set forth opposite its name below.

Underwriters	Class A Units	Class B Units
Ladenburg Thalmann & Co. Inc.	[__]	[__]
Total	[__]	[__]

A copy of the underwriting agreement will be filed as an exhibit to the registration statement of which this prospectus is part.

We have been advised by the underwriters that they propose to offer the Units directly to the public at the public offering price set forth on the cover page of this prospectus. The underwriters may sell Class A Units or Class B Units separately to purchasers or may sell a combination of Class A Units and Class B Units to purchasers in any proportion. Any securities sold by the underwriters to securities dealers will be sold at the public offering price less a selling concession not in excess of $[.] per share and $[ ] per warrant.

The underwriting agreement provides that the underwriters' obligation to purchase the securities we are offering is subject to conditions contained in the underwriting agreement.

No action has been taken by us or the underwriters that would permit a public offering of the Units, or the shares of common stock, shares of preferred stock and warrants included in the Units in any jurisdiction outside the United States where action for that purpose is required. None of our securities included in this offering may be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sales of any of the securities offering hereby be distributed or published in any jurisdiction except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons who receive this prospectus are advised to inform themselves about and to observe any restrictions relating to this offering of securities and the distribution of this prospectus. This prospectus is neither an offer to sell nor a solicitation of any offer to buy the securities in any jurisdiction where that would not be permitted or legal.

The underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

Underwriting Discount and Expenses

The following table summarizes the underwriting discount and commission to be paid to the underwriters by us.

	Per Class A Unit[1]	Per Class B Unit[1]	Total	Total with Full Exercise of Overallotment
Public offering price				
Underwriting discount to be paid to the underwriters by us (8.0%)[2][3]				
Proceeds to us (before expenses)				

(1) The public offering price and underwriting discount corresponds to (x) in respect of the Class A Units (i) a public offering price per share of common stock of $[ ] and (ii) a public offering price per warrant of $[ ] and (y) in respect of the Class B Units (i) a public offering price per share of Series H Preferred Stock of $[ ] and (ii) a public offering price per warrant of $[ ].

(2) We have also agreed to reimburse the accountable expenses of the representative, including legal fees, in this offering, up to a maximum of $85,000.

(3) We have granted a 45 day option to the representative to purchase up to [ ] additional shares of common stock (up to 15% of the shares of common stock plus the number of shares of common stock issuable upon conversion of shares of Series H Preferred Stock) and/or additional warrants exercisable for up to an additional [ ] shares of common stock (up to 15% of the warrants sold in this offering) at the assumed public offering price per share of common stock and the assumed public offering price per warrant set forth above less the underwriting discounts and commissions solely to cover over-allotments, if any.

We estimate the total expenses payable by us for this offering to be approximately $[ ], which amount includes (i) the underwriting discount of $[ ] and (ii) reimbursement of the accountable expenses of the underwriters, including the legal fees of the representative and (iii) other estimated company expenses of approximately $[ ] which includes legal accounting printing costs and various fees associated with the registration and listing of our shares.

The securities we are offering are being offered by the underwriters subject to certain conditions specified in the underwriting agreement.

Over-allotment Option

We have granted to the underwriters an option exercisable not later than 45 days after the date of this prospectus to purchase up to a number of additional shares of common stock and/or warrants equal to 15% of the number of shares of common stock sold in the primary offering (including the number of shares of common stock issuable upon conversion of shares of Series H Preferred Stock but excluding any shares of common stock underlying the warrants issued in this offering and any shares of common stock issued upon any exercise of the underwriters' over-allotment option) and/or 15% of the warrants sold in the primary offering at the public offering price per share of common stock and the public offering price per warrant set forth on the cover page hereto less the underwriting discounts and commissions. The underwriters may exercise the option solely to cover overallotments, if any, made in connection with this offering. If any additional shares of common stock and/or warrants are purchased, the underwriters will offer these shares of common stock and/or warrants on the same terms as those on which the other securities are being offered.

Other Relationships

Upon completion of this offering, we have granted the representative a right of first refusal to act as lead bookrunner or lead placement agent in connection with any subsequent public or private offering of equity securities or other capital markets financing by us. This right of first refusal extends for 12 months from the closing date of this offering. The terms of any such engagement of the representative will be determined by separate agreement. The representative and its respective affiliates have in the past and may in the future engage in investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. The representative has received, or may in the future receive, customary fees and commissions for these transactions.

Determination of Offering Price

Our common stock is currently traded on The Nasdaq Capital Market under the symbol "CHFS." See "Prospectus Summary—Recent Developments" for important information about the listing of our common stock on The Nasdaq Capital Market. On December 4, 2019, the closing price of our common stock was $0.89 per share. We do not intend to apply for listing of the Series H Preferred Stock or the warrants on any securities exchange or other trading system.

The public offering price of the securities offered by this prospectus will be determined by negotiation between us and the underwriters among the factors considered in determining the public offering price of the shares were;

- our history and our prospects;
- the industry in which we operate;
- our past and present operating results;
- the previous experience of our executive officers; and
- the general condition of the securities markets at the time of this offering, including discussions between the underwriters and prospective investors.

The offering price stated on the cover page of this prospectus should not be considered an indication of the actual value of the securities sold in this offering. That price is subject to change as a result of market conditions and other factors and we cannot assure you that the securities sold in this offering can be resold at or above the public offering price.

Lock-up Agreements

Our officers, directors and each of their respective affiliates and associated partners have agreed with the underwriters to be subject to a lock-up period of 90 days following the date of this prospectus. This means that, during the applicable lock-up period, such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock. Certain limited transfers are permitted during the lock-up period if the transferee agrees to these lock-up restrictions. We have also agreed, in the underwriting agreement, to similar lock-up restrictions on the issuance and sale of our securities for 90 days following the closing of this offering, although we will be permitted to issue stock options or stock awards to directors, officers and employees under our existing plans. The representative may, in their sole discretion and without notice, waive the terms of any of these lock-up agreements.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company LLC.

Stabilization, Short Positions and Penalty Bids

The underwriters may engage in syndicate covering transactions stabilizing transactions and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of our common stock;

- Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. Such a naked short position would be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect investors who purchase in the offering.
- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specific maximum.
- Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These syndicate covering transactions, stabilizing transactions, and penalty bids may have the effect of raising or maintaining the market prices of our securities or preventing or retarding a decline in the market prices of our securities. As a result the price of our common stock may be higher than the price that might otherwise exist in the open market. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on the Nasdaq Capital Market, in the over-the-counter market or on any other trading market and, if commenced, may be discontinued at any time.

In connection with this offering, the underwriters also may engage in passive market making transactions in our common stock in accordance with Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of the distribution. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for that security. However, if all independent bids are lowered below the passive market maker’s bid that bid must then be lowered when specific purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

Neither we, nor the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the prices of our securities. In addition, neither we nor the underwriters make any representation that the underwriters will engage in these transactions or that any transactions, once commenced will not be discontinued without notice.

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including certain liabilities arising under the Securities Act or to contribute to payments that the underwriters may be required to make for these liabilities.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following is a general discussion of material U.S. federal income considerations relating to the purchase, ownership and disposition of our common stock, Series H Preferred Stock or warrants. This discussion is based on current provisions of the Internal Revenue Codeon payment t, existing and proposed U.S. Treasury Regulations promulgated or proposed thereunder and current administrative and judicial interpretations thereof, all as in effect as of the date of this prospectus and all of which are subject to change or to differing interpretation, possibly with retroactive effect. We have not sought and will not seek any rulings from the Internal Revenue Service (the "IRS") regarding the matters discussed below. There can be no assurance that the IRS or a court will not take a contrary position.

This discussion is limited to U.S. holders and non-U.S. holders who hold our common stock, Series H Preferred Stock or warrants as capital assets within the meaning of Section 1221 of the Internal Revenue Code (generally, as property held for investment). This discussion does not address all aspects of U.S. federal income taxation, such as the U.S. alternative minimum income tax and the additional tax on net investment income, nor does it address any aspect of state, local or non-U.S. taxes, or U.S. federal taxes other than income taxes, such as federal estate taxes. This discussion does not consider any specific facts or circumstances that may apply to a holder and does not address the special tax considerations that may be applicable to particular holders, such as:

- insurance companies;
- tax-exempt organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;
- pension plans;
- controlled foreign corporations;
- passive foreign investment companies;
- corporations that accumulate earnings to avoid U.S. federal income tax;
- certain U.S. expatriates;
- U.S. persons that have a "functional currency" other than the U.S. dollar;
- persons that acquire our common stock as compensation for services;
- owners that hold our common stock, Series H Preferred Stock or warrants as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;
- entities that are treated as disregarded entities for U.S. federal income tax purposes (regardless of their places of organization or formation) and their investors; and
- partnerships or other entities treated as partnerships for U.S. federal income tax purposes and their investors.

If any entity taxable as a partnership for U.S. federal income tax purposes holds our common stock, Series H Preferred Stock or warrants, the U.S. federal income tax treatment of a partner in the partnership generally will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. An investor in a partnership or entity treated as disregarded for U.S. federal income tax purposes should consult his, her or its own tax advisor regarding the applicable tax consequences relating to the purchase, ownership and disposition of our common stock, Series H Preferred Stock or warrants.

For purposes of this discussion, the term "U.S. holder" means a beneficial owner of our common stock, Series H Preferred Stock or warrants that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized in or under the laws of the United States or of any political subdivision of the United States;

- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if (i) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (ii) the trust has a valid election to be treated as a U.S. person under applicable U.S. Treasury Regulations.

A "non-U.S. holder" is a beneficial owner of our common stock, Series H Preferred Stock or warrants that is, for U.S. federal income tax purposes, an individual, corporation, estate or trust that is not a U.S. holder.

Prospective investors should consult their own tax advisors regarding the U.S. federal, state, local and non-U.S. income and other tax considerations of purchasing, holding and disposing of our common stock, Series H Preferred Stock or warrants.

U.S. Holders

Purchase of Units

For U.S. federal income tax purposes, the purchase of a Class A Unit will be treated as the purchase of two components: a component consisting of one share of our common stock and a component consisting of one warrant to purchase one share of our common stock. The purchase of a Class B Unit will be treated as the purchase of two components: a component consisting of one share of our Series H Preferred Stock and a component consisting of warrants to purchase a number of shares of our common stock equal to $[ ] divided by the Conversion Price. The purchase price for each Unit will be allocated between its components in proportion to the relative fair market value of each at the time the Unit is purchased by the holder. This allocation of the purchase price for each Unit will establish a holder's initial tax basis for U.S. federal income tax purposes in the shares and warrants that compose each Unit.

Exercise of Warrants

A U.S. holder generally will not recognize gain or loss on the exercise of a warrant and related receipt of shares of our common stock (unless cash is received in lieu of the issuance of a fractional share of our common stock). A U.S. holder's initial tax basis in the shares of our common stock received upon the exercise of a warrant will be equal to the sum of (a) such U.S. holder's tax basis in such warrant plus (b) the exercise price paid by such U.S. holder on the exercise of such warrant. A U.S. holder's holding period for the shares of our common stock received upon the exercise of a warrant will begin on the day after the date that the warrant is exercised.

In certain limited circumstances, a U.S. holder may be permitted to undertake a cashless exercise of warrants into shares of our common stock. The U.S. federal income tax treatment of a cashless exercise of warrants into shares of common stock is unclear, and the tax consequences of a cashless exercise could differ from the consequences upon the exercise of a warrant described in the preceding paragraph. U.S. holders should consult their own tax advisors regarding the U.S. federal income tax consequences of a cashless exercise of warrants.

Certain Adjustments to the Warrants or Series H Preferred Stock

An adjustment to the number of shares of our common stock that will be issued upon the exercise of a warrant or conversion of a share of Series H Preferred Stock, or an adjustment to the exercise price of a warrant, may be treated as a constructive distribution to a U.S. holder of the warrant or share depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our shareholders). Adjustments to the exercise price of warrants or conversion price of Series H Preferred Stock made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution of the interest of the holders thereof generally should not be considered to result in a constructive distribution. Any such constructive distribution would be taxable whether or not there is an actual distribution of cash or other property. See the more detailed discussion of the rules applicable to distributions made by us under the heading "Distributions on Common Stock or Series H Preferred Stock" below.

Expiration of the Warrants without Exercise

Upon the lapse or expiration of a warrant, a U.S. holder will recognize a loss in an amount equal to such U.S. holder's tax basis in the warrant. Any such loss generally will be a capital loss and will be long-term capital loss if the warrant is held for more than one year. Deductions for capital losses are subject to certain limitations.

Conversion of Series H Preferred Stock

A U.S. holder generally will not recognize gain or loss upon the conversion of a share of Series H Preferred Stock into common stock. A U.S. holder's initial tax basis in the shares of our common stock received upon the conversion of a share of Series H Preferred Stock will be equal to such U.S. holder's tax basis in the share of Series H Preferred Stock. A U.S. holder's holding period for the shares of our common stock received upon the conversion of a share of Series H Preferred Stock will include the U.S. holder's holding period in such share of Series H Preferred Stock.

Distributions on Common Stock or Series H Preferred Stock

If we pay distributions of cash or property with respect to our common stock or Series H Preferred Stock (including constructive distributions as described above under the heading "Certain Adjustments to the Warrants or Series H Preferred Stock"), those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the U.S. holder's investment, up to such holder's tax basis in its shares of our common stock or Series H Preferred Stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below under the heading "—Gain on Sale, Exchange or Other Taxable Disposition."

Gain on Sale, Exchange or Other Taxable Disposition

Upon the sale or other taxable disposition of common shares, Series H Preferred Stock or warrants, a U.S. holder generally will recognize capital gain or loss in an amount equal to the difference between (a) the amount of cash plus the fair market value of any property received and (b) such U.S. holder's tax basis in such common shares, Series H Preferred Stock or warrants sold or otherwise disposed of. Such gain or loss generally will be long-term capital gain or loss if, at the time of the sale or other disposition, the common shares, Series H Preferred Stock or warrants have been held by the U.S. holder for more than one year. Preferential tax rates may apply to long-term capital gain of a U.S. holder that is an individual, estate, or trust. Deductions for capital losses are subject to certain limitations.

Non-U.S. Holders

Distributions on Common Stock or Series H Preferred Stock

If we pay distributions of cash or property with respect to our common stock or Series H Preferred Stock (including constructive distributions as described above under the heading "Certain Adjustments to the Warrants or Series H Preferred Stock"), those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's tax basis in its shares of our common stock or Series H Preferred Stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below under the heading "—Gain on Sale, Exchange or Other Taxable Disposition." Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence. In the case of any constructive distribution, it is possible that this tax would be withheld from any amount owed to the non-U.S. holder, including, but not limited to, distributions of cash, common stock or sales proceeds subsequently paid or credited to that holder. If we are unable to determine, at the time of payment of a distribution, whether the distribution will constitute a dividend, we may nonetheless choose to withhold any U.S. federal income tax on the distribution as permitted by U.S. Treasury Regulations.

Distributions that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States are generally not subject to the 30% withholding tax if the non-U.S. holder provides a properly executed IRS Form W-8ECI stating that the distributions are not subject to withholding because they are effectively connected with the non-U.S. holder's conduct of a trade or business in the United States. If a non-U.S. holder is engaged in a trade or business in the United States and the distribution is effectively connected with the conduct of that trade or business, the distribution will generally have the consequences described above for a U.S. holder (subject to any modification provided under an applicable income tax treaty). Any U.S. effectively connected income received by a non-U.S. holder that is treated as a corporation for U.S. federal income tax purposes may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate (or such lower rate as may be specified by an applicable income tax treaty).

A non-U.S. holder who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E, as applicable, and satisfy applicable certification and other requirements. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty generally may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS. Non-U.S. holders should consult their own tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

Gain on Sale, Exchange or Other Taxable Disposition

Subject to the discussion below in "—Information Reporting and Backup Withholding" and "—Foreign Account Tax Compliance Act," a non-U.S. holder generally will not be subject to U.S. federal income tax on gain recognized on a sale, exchange or other taxable disposition of our common stock, Series H Preferred Stock or warrants unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment maintained by the non-U.S. holder in the United States; in these cases, the non-U.S. holder will be taxed on a net income basis at the regular graduated rates and in the manner applicable to a U.S. holder, and, if the non-U.S. holder is a corporation, an additional branch profits tax at a rate of 30%, or a lower rate as may be specified by an applicable income tax treaty, may also apply;
- the non-U.S. holder is an individual present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the amount by which such non-U.S. holder's capital gains allocable to U.S. sources exceed capital losses allocable to U.S. sources during the taxable year of the disposition; or
- we are or were a "U.S. real property holding corporation" during the shorter of the five-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. Generally, a corporation is a "U.S. real property holding corporation" if the fair market value of its "U.S. real property interests" (within the meaning of the Internal Revenue Code) equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. We believe that we are not currently, and we do not anticipate becoming, a "U.S. real property holding corporation" for U.S. federal income tax purposes.

Information Reporting and Backup Withholding

Distributions on, and the payment of the proceeds of a disposition of, our common stock, Series H Preferred Stock or warrants generally will be subject to information reporting if made within the United States or through certain U.S.-related financial intermediaries. Information returns are required to be filed with the IRS and copies of information returns may be made available to the tax authorities of the country in which a holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding may also apply if the holder fails to provide certification of exempt status or a correct U.S. taxpayer identification number and otherwise comply with the applicable backup withholding requirements. Generally, a holder will not be subject to backup withholding if it provides a properly completed and executed IRS Form W-9 or appropriate IRS Form W-8, as applicable. Backup withholding is not an additional tax. Amounts withheld under the backup withholding rules may be refunded or credited against the holder's U.S. federal income tax liability, if any, provided certain information is timely filed with the IRS.

Foreign Account Tax Compliance Act

Legislation commonly referred to as the Foreign Account Tax Compliance Act, or FATCA, generally imposes a U.S. federal withholding tax of 30% on dividends paid to certain non-U.S. entities (including certain intermediaries) unless such persons comply with FATCA's information reporting and withholding regime. We will not pay any additional amounts to stockholders in respect of any amounts withheld. This regime and its requirements are different from, and in addition to, the certification requirements described elsewhere in this discussion. If a payment is both subject to withholding under FATCA and subject to withholding tax discussed above, the withholding under FATCA may be credited against, and therefore reduce, such other withholding tax.

The United States has entered into, and continues to negotiate, intergovernmental agreements (each, an "IGA") with a number of other jurisdictions to facilitate the implementation of FATCA. An IGA may significantly alter the application of FATCA and its information reporting and withholding requirements with respect to any particular investor. FATCA is particularly complex and its application remains uncertain. Prospective investors should consult their own tax advisors regarding how these rules may apply in their particular circumstances.

LEGAL MATTERS

Honigman LLP, Kalamazoo, Michigan, will issue a legal opinion as to the validity of the securities offered by this prospectus. Ellenoff Grossman & Schole LLP, New York, New York is acting as counsel for the underwriters in connection with certain legal matters in connection with this offering.

EXPERTS

The consolidated financial statements of CHF Solutions, Inc. and subsidiaries for the years ended December 31, 2018 and 2017 from the company's Annual Report on Form 10-K have been audited by Baker Tilly Virchow Krause, LLP, our independent registered public accounting firm, as stated in their report, which is incorporated herein by reference (which report expresses an unqualified opinion on the consolidated financial statements and includes an explanatory paragraph related to the substantial doubt about the company's ability to continue as a going concern as described in Note 1 to the financial statements). Such consolidated financial statements have been so incorporated in reliance upon the report of such firm given on their authority as experts in accounting and auditing.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

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

		Amount to be Paid
SEC registration fee	$	649
FINRA filing fee	$	1,250
Legal fees and expenses	$	150,000
Printing expenses	$	30,000
Accountant's fees and expenses	$	40,000
Transfer agent and registrar fees	$	7,500
Miscellaneous expenses	$	12,601
Total	$	242,000

Item 14. Indemnification of Directors and Officers.

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

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

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

- from any breach of the director's duty of loyalty to us or our stockholders;
- from acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- under Section 174 of the DGCL; and
- from any transaction from which the director derived an improper personal benefit.

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

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

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

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

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

Item 15. Recent Sales of Unregistered Securities.

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

- On July 20, 2016, the registrant entered into a securities purchase agreement with Sabby Healthcare Master Fund Ltd. and Sabby Volatility Warrant Master Fund Ltd. (collectively, Sabby) under which the registrant issued and sold, on July 26, 2016, 3,468 shares of Series B Convertible Preferred Stock at $1,000 per share directly to Sabby in a registered direct offering. In a concurrent private placement, the registrant issued warrants to purchase an aggregate of 440 shares of its common stock to Sabby. Each warrant was exercisable beginning on the six month anniversary of the date of issuance at an exercise price of $7,896 per share (as adjusted), subject to further adjustment as provided therein and for 36 months from the initial exercise date, but not thereafter. Northland Securities, Inc. acted as placement agent and the registrant issued Northland Securities, Inc. and its designees warrants to purchase an aggregate of 27 shares of common stock. The Northland warrants were exercisable beginning immediately upon the closing at an exercise price of $11,340 per share, subject to adjustment as provided there in, and for 5 years thereafter. The warrants were issued under an exemption from the registration requirements of the Securities Act provided in Section 4(a)(2) of the Securities Act and/or Regulation D.

- On August 5, 2016, the registrant entered into and consummated the transactions contemplated by an asset purchase agreement with Gambro UF Solutions, Inc. (the "Seller"), pursuant to which the registrant acquired certain assets exclusively related to the production and sale of Seller's Aquadex FlexFlow products for consideration consisting of $4.0 million paid in cash and 120 shares of the registrant's common stock. The shares of common stock were issued to Seller under an exemption from the registration requirement of the Securities Act provided in Section 4(a)(2) of the Securities Act and/or Regulation D.

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

- On October 30, 2016, the registrant entered into securities purchase agreements with Sabby under which it agreed to issue and sell 2,900 shares of Series C Convertible Preferred Stock at $1,000 per share directly to Sabby in a registered direct offering. In a concurrent private placement, the registrant agreed to issue and sell 900 shares of Series D Convertible Preferred Stock at $1,000 per share directly to Sabby and warrants to purchase an aggregate of 2,662 shares of common stock. The registered direct offering closed on November 3, 2016, and the registrant concurrently sold 700 shares of the Series D Convertible Preferred Stock and warrants to purchase 2,522 shares of common stock. The remaining 200 shares of Series D Convertible Preferred Stock and warrants to purchase 141 shares of common stock were issued and sold at a second closing on January 11, 2017. The Series D Convertible Preferred Stock had a stated value of $1,000 per share and a conversion price of $1,428 (as adjusted) subject to further adjustment and may be converted to shares of common stock at any time following the receipt of stockholder approval of such issuance upon conversion. Each warrant became exercisable beginning on the day that is the later of the date stockholder approval of the issuance of common stock underlying such warrants is obtained or the six month anniversary of the date of issuance at an exercise price of $1,512 per share (as adjusted), subject to further adjustment as provided therein, and terminate five years thereafter. Northland Securities, Inc. acted as placement agent and the registrant issued Northland Securities, Inc. and its designees warrants to purchase an aggregate of 160 shares of common stock, with an exercise price of $1,786.40 per share. Subject to limited exceptions, a holder of Series D Convertible Preferred Stock or warrants will not have the right to convert or exercise if the holder, together with its affiliates, would beneficially own over 4.99% of the number of shares of the registrant's common stock outstanding immediately after giving effect to such exercise; provided, however, that upon not less than 61 days' prior notice, the holder may increase the limitation, provided that in no event will the limitation exceed 9.99%. The Series D Convertible Preferred Stock and the warrants were issued pursuant to an exemption from the registration requirement of the Securities Act provided in Section 4(a)(2) of the Securities Act and/or Regulation D.

- On February 15, 2017, the registrant entered into a letter agreement with Sabby, to incent the cash exercise of the warrants held by Sabby on or before March 31, 2017 (the "Exercise Period"). In exchange for any such exercise, the registrant agreed to provide Sabby replacement warrants (the "Replacement Warrants") to purchase the same number of shares of common stock as were issued upon exercise of the exercised warrants, with an exercise price equal to the consolidated closing bid price of the registrant's common stock on the date of issuance. The agreement also (i) amends the definition of "Beneficial Ownership" in the existing warrants to mean, solely for purposes of any exercises of warrants that occur during the Exercise Period, "9.99%" and (ii) amends the Initial Exercise Date of the existing warrants issued on November 3, 2016 and January 11, 2017 so that such warrants are exercisable on or after the receipt of stockholder approval. Since such stockholder approval was received on January 9, 2017, such warrants were immediately exercisable as of the date of the agreement. The Replacement Warrants will be in the same form as the exercised warrants except the exercise price will not be subject to reduction for subsequent equity issuances and (ii) the Replacement Warrants will not allow Sabby to demand that the registrant purchase the Replacement Warrants in the event of a fundamental transaction involving the registrant. Concurrent with the signing of the agreement, Sabby exercised warrants to purchase 373 shares of common stock for cash proceeds of approximately $564,000, and the registrant issued Replacement Warrants to purchase 373 shares of common stock at an exercise price of $1,397.20 per share. From March 10, 2017 to March 28, 2017, Sabby exercised warrants to purchase 2,727 shares of common stock for cash proceeds of approximately $1.4 million, and the registrant issued Replacement Warrants to purchase 2,727 shares of

common stock with exercise prices equal to the closing consolidated bid price of its common stock available on the date of issuance (ranging from $484.40 to $1,055.60 per share). The Replacement Warrants were issued pursuant to an exemption from the registration requirement of the Securities Act provided in Section 4(a)(2) of the Securities Act and/or Regulation D.

- On, November 15, 2018, the registrant entered into a letter agreement with Maxim Group LLC ("Maxim"), under which Maxim would provide general financial advisory and investment banking services to the registrant on a non-exclusive basis. In exchange for such services, the registrant agreed to issue to Maxim, 7,143 shares of its common stock. The shares were issued pursuant to an exemption from the registration requirement of the Securities Act provided in Section 4(a)(2) of the Securities Act and/or Regulation D.
- On May 30, 2019, the registrant granted a market-based warrant to a consultant in exchange for investor relations services. The warrant represents the right to acquire up to 100,000 shares of the registrant's common stock at an exercise price $3.18 per share, the closing stock price of the registrant's common shares on May 30, 2019. The warrant is subject to a vesting schedule based on the registrant achieving certain market stock prices within a specified period of time. The warrant expires on May 30, 2024. This issuance was made pursuant to the exemption from registration contained in Section 4(a)(2) of the Securities Act.
- On October 25, 2019, the registrant closed on a registered direct offering of its common stock and in a concurrent private placement, the registrant agreed to issue to the investors in the registered direct offering unregistered warrants to purchase up to 575,830 shares of the registrant's common stock at an exercise price of $1.41 per share, which will be exercisable six months from the date of issuance, and will expire five years from the initial exercise date. This issuance was made pursuant to the exemption from registration contained in Section 4(a)(2) of the Securities Act.
- On November 6, 2019, the registrant closed on a registered direct offering of its common stock, or common equivalents, and in a concurrent private placement, the registrant agreed to issue to the investors in the registered direct offering unregistered warrants to purchase up to 1,219,076 shares of the registrant's common stock at an exercise price of $0.9942 per share, which will be exercisable upon the date of issuance, and will expire five years from the initial exercise date. This issuance was made pursuant to the exemption from registration contained in Section 4(a)(2) of the Securities Act.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits

See the Exhibit Index attached to this Registration Statement, which is incorporated by reference herein.

(b) Financial Statement Schedules

No financial statement schedules are provided because the information called for is not required or is shown in the financial statements or the notes thereto.

Item 17. Undertakings.

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

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

The undersigned registrant hereby undertakes that, for the purposes of determining liability to any purchaser, if the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into

the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

The undersigned registrant hereby undertakes that, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

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

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

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing			
1.1*	Form of Underwriting Agreement						
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		
3.9	Form of Certificate of Designation of Preferences, Rights and Limitations of Series G Convertible Preferred Stock	S-1/A	333-229102	February 25, 2019	3.9		
3.10*	Form of Certificate of Designation of Preferences, Rights and Limitations of Series H Convertible Preferred Stock						
4.1	Warrant to Purchase Stock, dated February 18, 2015, issued to Silicon Valley Bank	8-K	001-35312	February 19, 2015	4.1		
4.2	Warrant to Purchase Stock, dated February 18, 2015, issued to Life Science Loans, LLC	8-K	001-35312	February 19, 2015	4.2		
4.3	Form of common stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated July 20, 2016, among the Company and the purchasers signatory thereto	8-K	001-35312	July 22, 2016	4.2		

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing			
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 common stock Purchase Warrant issued pursuant to the Underwriting Agreement between the Company and Ladenburg Thalmann & Co. Inc., dated November 22, 2017	S-1/A	333-221010	November 17, 2017	4.9		
4.10	Form of Series 1 and Series 2 common stock Purchase Warrants issued pursuant to the Underwriting Agreement between the Company and Ladenburg Thalmann & Co. Inc., dated March 8, 2019	S-1/A	333-229102	February 25, 2019	4.10		
4.11	Common Stock Purchase Warrant, dated May 30, 2019, between CHF Solutions, Inc. and Redington, Inc.	10-Q	001-35312	August 6, 2019	4.1		
4.12	Form of common stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated October 23, 2019, among the Company and the purchasers signatory thereto	8-K	001-35312	October 23, 2019	4.1		
4.13	Form of common stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated November 4, 2019, among the Company and the purchasers signatory thereto	8-K	001-35312	November 4, 2019	4.1		
4.14	Form of common stock Pre-Funded Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated November 4, 2019, among the Company and the purchasers signatory thereto	8-K	001-35312	November 4, 2019	4.2		

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing			
4.15*	Form of Warrant to purchase shares of common stock						
5.1*	Opinion of Honigman LLP						
10.1	Securities Purchase Agreement, dated July 20, 2016 among the Company and the purchasers signatory thereto	8-K	001-35312	July 22, 2016	10.1		
10.2	Patent License Agreement between Sunshine Heart, Inc. and Gambro UF Solutions, Inc. dated August 5, 2016	8-K	001-35312	August 8, 2016	10.1		
10.3	Loan and Security Agreement between Sunshine Heart, Inc. and Silicon Valley Bank dated August 5, 2016	8-K	001-35312	August 8, 2016	10.2		
10.4	Amended and Restated 2002 Stock Plan†	10	001-35312	December 16, 2011	10.2		
10.5	Form of Notice of Stock Option Grant and Option Agreement for Amended and Restated 2002 Stock Plan†	10	001-35312	September 30, 2011	10.3		
10.6	Second Amended and Restated 2011 Equity Incentive Plan, as amended†	14A	001-35312	July 27, 2012	App. A		
10.7	Form of Stock Option Grant Notice and Option Agreement for 2011 Equity Incentive Plan†	10	001-35312	September 30, 2011	10.5		
10.8	Form of Stock Option Grant Notice and Option Agreement (Senior Management) for 2011 Equity Incentive Plan†	10	001-35312	September 30, 2011	10.6		
10.9	Form of Stock Option Grant Notice and Option Agreement (Director) for 2011 Equity Incentive Plan†	8-K	001-35312	September 18, 2012	10.1		
10.10	Form of Stock Grant Notice and Award Agreement for 2011 Equity Incentive Plan†	8-K	001-35312	September 10, 2013	10.1		
10.11	Form of Restricted Stock Unit Grant Notice and Agreement for 2011 Equity Incentive Plan†	8-K	001-35312	September 10, 2013	10.2		
10.12	2013 Non-Employee Directors' Equity Incentive Plan†	14A	001-35312	April 5, 2013	App. A		
10.13	Form of Stock Option Grant Notice and Option Agreement for 2013 Non-Employee Directors' Equity Incentive Plan†	10-K	001-35312	May 29, 2013	10.2		
10.14	Form of Restricted Stock Unit Award Grant Notice and Agreement for 2013 Non-Employee Directors' Equity Incentive Plan†	10-K	001-35312	March 20, 2015	10.11		

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing			
10.15	New-Hire Equity Incentive Plan†	10-Q	001-35312	August 8, 2013	10.1		
10.16	First Amendment to New-Hire Equity Incentive Plan†	10-Q	001-35312	November 12, 2013	10.1		
10.17	Second Amendment to New-Hire Equity Incentive Plan†	S-8	333-202904	March 20, 2015	99.12		
10.18	Third Amendment to New-Hire Equity Incentive Plan†	S-8	333-210215	March 15, 2016	99.13		
10.19	Fourth Amendment to New-Hire Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.4		
10.20	Fifth Amendment to New-Hire Equity Incentive Plan†	8-K	001-35312	January 18, 2018	10.1		
10.21	Form of Stock Option Grant Notice and Option Agreement for New-Hire Equity Incentive Plan†	10-Q	001-35312	November 12, 2013	10.2		
10.22	2017 Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.1		
10.23	Form of Stock Option Grant Notice and Option Agreement for 2017 Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.2		
10.24	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement for 2017 Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.3		
10.25	Form of Indemnity Agreement for the Company's executive officers and directors†	10	001-35312	September 30, 2011	10.1		
10.26	Form of Change in Control Agreement for the Company's executive officers†	10-K	001-35312	March 20, 2015	10.16		
10.27	Non-Employee Director Compensation Policy†	10-Q	001-35312	August 8, 2013	10.2		
10.28	Lease Agreement dated October 21, 2011 by and between the Company and Silver Prairie Crossroads, LLC	10	001-35312	December 16, 2011	10.18		
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			Exhibit Number	Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing			
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 between the Company 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		
10.44	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		
10.45	Consulting Agreement, dated as of January 28, 2019, between CHF Solutions, Inc. and Steve Brandt†	10-K	001-35312	February 21, 2019	10.44		
10.46	Underwriting Agreement, dated as of March 8, 2019, by and between CHF Solutions, Inc. and Ladenburg Thalmann & Co. Inc.	8-K	001-35312	March 13, 2019	1.1		

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing			
10.47	Warrant Agency Agreement between the Company and American Stock Transfer & Trust Company, LLC dated March 12, 2019	8-K	001-35312	March 13, 2019	4.2		
10.48	Form of Employee Proprietary Information, Inventions Assignment and Non-Competition Agreement for the Company's employees, including executive officers†	10-Q	001-35312	May 9, 2019	10.3		
10.49	Offer Letter, by and between CHF Solutions, Inc. and Claudia Drayton, dated December 9, 2014†	10-Q	001-35312	May 9, 2019	10.4		
10.50	Offer Letter, by and between CHF Solutions, Inc. and Nestor Jaramillo, dated May 7, 2019†	10-Q	001-35312	May 9, 2019	10.5		
10.51	Sixth Amendment to New-Hire Equity Incentive Plan†	10-Q	001-35312	August 8, 2019	10.2		
10.52	Placement Agency Agreement, dated as of October 23, 2019, by and between CHF Solutions, Inc. and Ladenburg Thalmann & Co. Inc.	8-K	001-35312	October 23, 2019	1.1		
10.53	Securities Purchase Agreement, dated as of October 23, 2019, by and among CHF Solutions, Inc. and the purchasers identfied therein	8-K	001-35312	October 23, 2019	10.1		
10.54	Placement Agency Agreement, dated as of November 4, 2019, by and between CHF Solutions, Inc. and Ladenburg Thalmann & Co. Inc.	8-K	001-35312	November 4, 2019	1.1		
10.55	Securities Purchase Agreement, dated as of November 4, 2019, by and among CHF Solutions, Inc. and the purchasers identified therein	8-K	001-35312	November 4, 2019	10.1		
10.56	Non-Employee Director Compensation Policy†	10-Q	001-35312	November 8, 2019	10.1		
10.57	Seventh Amendment to New-Hire Equity Incentive Plan†	8-K	001-35312	December 6, 2019	10.1		
15.1	Letter regarding unaudited interim financial information	S-1/A	333-221010	November 6, 2017	15.1		
21	List of Subsidiaries	10-K	001-35312	March 22, 2018	21		
23.1	Consent of Baker Tilly Virchow Krause, LLP					X	
23.2	Consent of Honigman LLP					Included in Exhibit 5.1	
24.1	Power of Attorney (included on signature page)	S-1	333-235385	December 6, 2019	24.1		

† Indicates management compensatory plan, contract or arrangement.

* To be filed by amendment or by a report filed under the Securities Exchange Act of 1934, as amended, and incorporated by reference herein.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Eden Prairie, State of Minnesota, on this 20th day of December 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 Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ John L. Erb John L. Erb	Principal Executive Officer and Chairman of the Board	December 20, 2019
/s/ Claudia Drayton Claudia Drayton	Principal Financial Officer and Principal Accounting Officer	December 20, 2019
* Steve Brandt	Director	December 20, 2019
* Maria Rosa Costanzo	Director	December 20, 2019
* Jon W. Salveson	Director	December 20, 2019
* Gregory Waller	Director	December 20, 2019
* Warren Watson	Director	December 20, 2019

*By: /s/ John L. Erb
John L. Erb
Attorney-in-fact

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in this Amendment No. 1 to the Registration Statement on Form S-1/A (No. 333-235385) of CHF Solutions, Inc. and subsidiaries of our report dated February 21, 2019, relating to the consolidated financial statements of CHF Solutions, Inc. and subsidiaries (the "Company"), (which report expresses an unqualified opinion on the consolidated financial statements for the year ended December 31, 2018 and includes an explanatory paragraph relating to the substantial doubt about the Company's ability to continue as a going concern as described in Note 1 to the consolidated financial statements) appearing in the Annual Report on Form 10-K of CHF Solutions, Inc. and subsidiaries for the year ended December 31, 2018, and to the reference to us under the heading "Experts" in the Prospectus, which is part of this Registration Statement.

/s/ Baker Tilly Virchow Krause, LLP

Minneapolis, Minnesota

December 20, 2019