Filed pursuant to Rule 424(b)3
Registration No. 333-235658

PROSPECTUS

CHF SOLUTIONS, INC.

1,794,906 Shares of Common Stock issuable upon exercise of Warrants

This prospectus relates to the resale, from time to time, of (i) an aggregate of 575,830 shares of our common stock, par value $0.0001 per share (the "Common Stock") issuable upon exercise of common stock purchase warrants issued on October 25, 2019 (the "October Warrants") and (ii) an aggregate of 1,219,076 shares of our Common Stock issuable upon exercise of common stock purchase warrants issued on November 6, 2019 ("November Warrants" together with the October Warrants, the "Warrants") by Bigger Capital Fund, LP ("Bigger Capital"), District 2 Capital Fund LP ("District 2") and Hudson Bay Master Fund Ltd ("Hudson Bay," and together with Bigger Capital and District 2, we collectively refer to the "Selling Stockholders").

We are not selling any securities under this prospectus and we will not receive proceeds from the sale of Common Stock by the Selling Stockholders. However, we may receive proceeds from the cash exercise of the Warrants, which, if exercised in cash at the current applicable exercise price with respect to all of the 1,794,906 shares of Common Stock, would result in gross proceeds of $2,023,925. We sold the October Warrants to Bigger Capital and Hudson Bay under a purchase agreement (the "October Purchase Agreement") dated October 23, 2019 for gross proceeds of approximately $660,000 on October 25, 2019. For a more detailed description of the October Warrants, see the section "Sale of Securities to Selling Stockholders". Furthermore, we sold the November Warrants to the Selling Stockholders under a purchase agreement, dated November 4, 2019 ("November Purchase Agreement"). For a more detailed description of the November Warrants, see the section "Sale of Securities to Selling Stockholders".

We will pay the expenses of registering the shares of Common Stock offered by this prospectus, but all selling and other expenses incurred by each Selling Stockholder will be paid by such Selling Stockholder. The Selling Stockholders may sell the shares of our Common Stock offered by this prospectus from time to time on terms to be determined at the time of sale through ordinary brokerage transactions or through any other means described in this prospectus under "Plan of Distribution." The prices at which the Selling Stockholders may sell shares will be determined by the prevailing market price for shares of our Common Stock or in negotiated transactions.

Our Common Stock trades on The Nasdaq Capital Market under the ticker symbol "CHFS". On December 18, 2019, the last reported sale price per share of our Common Stock was $0.724 per share. See "Description of Capital Stock – Common Stock – Listing."

Investing in our Common Stock involves a high degree of risk. Before making any investment in our Common Stock, you should read and carefully consider the risks described in this prospectus under the section of this prospectus entitled "Risk Factors" on page 5 of this prospectus.

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 date of this prospectus is December 27, 2019.

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You should rely only on the information contained in this prospectus or any prospectus supplement or amendment thereto. We have not authorized anyone to provide you with different information.

ABOUT THIS PROSPECTUS

This prospectus relates to the resale by the Selling Stockholders of up to 1,794,906 shares of our Common Stock issuable upon exercise of the October Warrants and November Warrants, in each case as described below under "Sale of Securities to Selling Stockholders" and "Description of Capital Stock." We are not selling any shares of Common Stock under this prospectus and will not receive any proceeds from the sale of shares of Common Stock by the Selling Stockholders.

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 by the Selling Stockholders. 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, November 4, 2019, December 6, 2019 and December 20, 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].

The Aquadex FlexFlow system consists of:

- A console, a piece of capital equipment containing electromechanical pumps and an LCD screen;

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[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.

- 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 United States Food and Drug Administration (“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.

The Offering

Securities offered by the Selling Stockholders	1,794,906 shares of our Common Stock
Common stock outstanding	4,674,068 (as of December 18, 2019)
Common stock to be outstanding after this offering, assuming full conversion or exercise of all Warrants	6,468,974 shares
Use of proceeds	We will not receive any proceeds from the sale by the Selling Stockholders of the shares of Common Stock being offered by this prospectus.
NASDAQ Symbol	"CHFS".
Risk Factors	Investing in our securities involves a high degree of risk. You should carefully review and consider the section of this prospectus entitled "Risk Factors" on page 5 of this prospectus for a discussion of factors to consider before deciding to invest in shares of our Common Stock.

Except as otherwise indicated, all information in this prospectus is based on 4,674,068 shares of Common Stock outstanding as of December 18, 2019 and excludes the shares of Common Stock being offered by this prospectus and issuable upon exercise of the Warrants 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);
- 185,110 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 $0.74, the closing price of our common stock on December 18, 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

Investing in our securities involves a high degree of risk. Before deciding to invest in our securities, you should consider carefully the risks and uncertainties described under Item 1A. "Risk Factors" in our Annual Report on Form 10-K, filed with the SEC on February 21, 2019 and our subsequent Quarterly Reports on Form 10-Q , which are incorporated by reference in this prospectus, together with all of the other information contained in this prospectus and documents incorporated by reference herein. If any of the matters discussed in the risk factors were to occur, our business, financial condition, results of operations, cash flows or prospects could be materially adversely affected, the market price of our common stock could decline and you could lose all or part of your investment in our securities. Additional risks and uncertainties not presently known or which we consider immaterial as of the date hereof may also have an adverse effect on our business. Except for the addition of the following risk factors there have been no other material changes to the Risk Factors described under Item 1A. "Risk Factors" in our Annual Report on Form 10-K, filed with the SEC on February 21, 2019 and our subsequent Quarterly Reports on Form 10-Q for the fiscal year.

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.

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.

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.

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.

SALE OF SECURITIES TO SELLING STOCKHOLDERS

General

On October 23, 2019, we entered into the October Purchase Agreement with Bigger Capital and Hudson Bay under which we agreed to issue and sell warrants to purchase an aggregate of 575,830 shares of Common Stock, pursuant to an exemption from the registration requirements of the Securities Act provided in Section 4(a)(2) thereof and/or Rule 506 of Regulation D promulgated thereunder. We received gross proceeds of $660,000 at the closing on October 25, 2019, before deducting fees owed to the placement agent and other fees applicable to the offering. The October Purchase Agreement contains customary representations, warranties and agreements by the Company, customary conditions to closing, indemnification obligations of the Company, other obligations of the parties and termination provisions.

On November 4, 2019, we entered into the November Purchase Agreement with Bigger Capital, District 2 and Hudson Bay under which we agreed to issue and sell warrants to purchase an aggregate of 1,219,076 shares of Common Stock, pursuant to an exemption from the registration requirements of the Securities Act provided in Section 4(a)(2) thereof and/or Rule 506 of Regulation D promulgated thereunder. We received gross proceeds of $1.36 million at the closing on November 6, 2019, before deducting fees owed to the placement agent and other fees applicable to the offering. The November Purchase Agreement contains customary representations, warranties and agreements by the Company, customary conditions to closing, indemnification obligations of the Company, other obligations of the parties and termination provisions. The November Purchase Agreement also provided for the issuance of pre-funded warrants, which do not expire until exercised in full ("Pre-Funded Warrants"). These Pre-Funded Warrants were issued in lieu of additional shares to the extent an applicable investor's total purchase commitment exceeded the Beneficial Ownership Limitation (defined as a warrant holder not having the right to exercise any portion of its warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or, at the election of a holder prior to the date of issuance, 9.99%) of the number of shares of Common Stock outstanding immediately after giving effect to such exercise). Additionally, the November Purchase Agreement provides that the Company will use its best efforts to reduce the exercise price of each of the previously issued and outstanding warrants to purchase common stock of the Company issued in April 2017, November 2017, July 2018 and March 2019, as applicable, held by a purchaser of those shares to the then-current market price of the Common Stock at the time of such reduction.

Placement Agent

In connection with each of the October Purchase Agreements and November Purchase Agreement, we separately entered into a placement agent engagement letter with Ladenburg Thalmann & Co. Inc. (the "Placement Agent") pursuant to which we agreed to pay the Placement Agent an aggregate cash placement fee equal to 8% of the aggregate purchase price raised in the transactions consummated in each of October and November. Subject to certain conditions, we also have agreed to reimburse certain out-of-pocket expenses of the Placement Agent, including but not limited to legal fees. The engagement letter contains customary representations, warranties and agreements by us and customary conditions to closing. We have further agreed to indemnify the Placement Agent against certain liabilities arising out of or in connection with the transactions.

The October Warrants

Each October Warrant is exercisable beginning on April 27, 2020 (the "October Warrant Initial Exercise Date") at an exercise price of $1.41 per share, subject to adjustment as provided therein, and terminates five (5) years after the October Warrant Initial Exercise Date. A holder of October Warrants will not have the right to exercise any portion of its October Warrants if the holder, together with its affiliates, would beneficially own over 4.99%; provided, however, that upon prior notice to us, the holder may increase its ownership, provided that in no event will the ownership exceed 9.99%. The exercise price and number of the shares of our Common Stock issuable upon exercising the October Warrants will be subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described therein.

The November Warrants

Each November Warrant is exercisable beginning on November 6, 2019 (the "November Warrant Initial Exercise Date") at an exercise price of $0.9942 per share, subject to adjustment as provided therein, and terminates five (5) years after the November Warrant Initial Exercise Date. A holder of November Warrants will

not have the right to exercise any portion of its November Warrants if the holder, together with its affiliates, would beneficially own over 4.99%; provided, however, that upon prior notice to us, the holder may increase its ownership, provided that in no event will the ownership exceed 9.99%. The exercise price and number of the shares of our Common Stock issuable upon exercising the November Warrants will be subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described therein.

USE OF PROCEEDS

We are not selling any securities under this prospectus and will not receive any proceeds from the sale of shares of Common Stock offered by this prospectus by the Selling Stockholders. However, we may receive proceeds from the cash exercise of the Warrants, which, if exercised in cash at the current exercise price with respect to all 1,794,906 shares of Common Stock, would result in gross proceeds of approximately $2,023,925 to us.

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 18, 2019, the last reported sale price of our common stock on The Nasdaq Capital Market was $0.74.

As of December 18, 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 18, 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.

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 fourth quarter of 2019, 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[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 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.

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

[7] Selewski Dt, el 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.

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[9] 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.[10] 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.[11] 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.[12] Approximately 40% of heart failure patients have poor diuretic response.[13] This poor response is possibly due to noncompliance or high intake of salt, poor drug absorption, insufficient kidney

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

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

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

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

[13] 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.

response to drug, and reduced diuretic secretion.[14] 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.[15]

Nearly one-half of hospitalized patients with heart failure are discharged with residual fluid excess after receiving conventional diuretic therapies.[16] 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.[17] There is an association of chronic loop diuretic therapy and greater resource utilization at hospitals.[18] 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.[19] 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.[20]

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.[21] 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);[22]

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

[15] 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.

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

[17] 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.

[18] 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.

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

[20] 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.

[21] 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.

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

- Following ultrafiltration, neurohormonal activation is reset toward a more physiological condition and diuretic efficacy is restored;[23]
- Provides highly automated operation with only one setting required to begin;
- Utilizes a single-use, disposable auto-loading blood filter circuit that facilitates easy set-up;
- The console guides medical practitioner through the setup and operational process; and
- Decreased hospital readmissions and duration resulting in cost savings at 90 days.[24]25 /sup>

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,[26] 180,000 valve procedures[27], and 3,000 ventricular assist device (VAD) implants[28]29 /sup>

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

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

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

[25] 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.

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

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

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

[29] 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.

length of stay, and higher rates of discharge to a location other than home.[30] 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.[31] It is estimated that 13.5% of post cardiac surgery patients are readmitted due to fluid overload within 30 days of discharge, which equates to an estimated 70,000 fluid overload-related readmissions for CABG, valve, and VAD procedures per year in the United States.[32] 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.[33] 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.[34] 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.[35] In addition, approximately 68% of patients are discharged with sub-optimal results.[36] 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.[37] 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.[38] [39]

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

[31] 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.

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

[33] 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).

[34] 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).

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

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

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

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

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.[40] As the population ages, healthcare expenditures are expected to increase substantially.[41] Therefore, therapies aimed at treating congestion and fluid overload are essential from a patient care and health economic perspective.

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[42] and approximately 18,000 receiving cardiac surgery, ECMO therapy, and solid organ transplantation.[43] [44]45 /sup> 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.[46]

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

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[39] 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.

[40] 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.

[41] 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.

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

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

[44] 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.

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

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

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 by physicians to treat various conditions in pediatric patients, including heart failure, cardiac surgery[47], extracorporeal membrane oxygenation (ECMO) therapy[48], solid organ transplantation[49], 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.

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

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

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

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.

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, 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, a delay in receipt of the CE Mark could cause a shortage in product availability in the EU and the timing of the receipt of the CE Mark for the console 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.

DESCRIPTION OF CAPITAL STOCK

The following description of our Common Stock is a summary only and is qualified in its entirety by reference to our certificate of incorporation and bylaws, both of which are exhibits to the registration statement of which this prospectus is a part.

General

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 18, 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 18, 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 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:
holders of at least $66\frac{2}{3}$% of the voting power of all of the then-outstanding shares of our capital stock entitled 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.

Description of Outstanding Warrants

As of December 18, 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

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 66 2/3% super-majority stockholder approval in order for stockholders to alter, amend or repeal certain provisions of our certificate of incorporation;
- requiring a 66 2/3% 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 stockholder.
affirmative vote of at least 66$\frac{2}{3}$% of the outstanding voting stock that is not owned by the interested

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

With the closing of each of the October Purchase Agreement and the November Purchase Agreement, we agreed to prepare and file a registration statement to register for resale the shares of common stock underlying certain warrants issued in each private placement transaction. We agreed to use our commercially reasonable efforts to cause such registration to become effective within 181 days following each of October 25, 2019 and November 6, 2019. We have filed the registration statement of which this prospectus forms a part pursuant to the requirements in each of the October Purchase Agreement and November Purchase Agreement to register for resale the shares of Common Stock issuable upon conversion of the Warrants that were issued at each closing.

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.

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 18, 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 18, 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	48,987[3]	60,604	1.28%
Steve Brandt	5	4,374	4,379	*
Maria Rosa Costanzo, M.D.		438	438	*
Matthew E. Likens[4]	5	3,738	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	7,376	7,378	*
Nestor Jaramillo, Jr.	—	—	—	—
All directors and executive officers as a group (8 persons)	11,637	81,339	92,976	1.97%
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 18, 2019.

(3) Consists of (i) 24,591 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%.

PLAN OF DISTRIBUTION

Each Selling Stockholder of the securities and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the principal trading market or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or at prices then prevailing or related to the then current market price or at negotiated prices. The offering price of the shares from time to time will be determined by the Selling Stockholders and, at the time of the determination, may be higher or lower than the market price of our Common Stock. A Selling Stockholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- in transactions through broker-dealers that agree with the Selling Stockholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The Selling Stockholders may also sell securities under Rule 144 or any other exemption from registration under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the Selling Stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholders (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

In connection with the sale of the securities or interests therein, the Selling Stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The Selling Stockholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The Selling Stockholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Stockholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the securities. The Company has agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

We agreed to use our commercially reasonable efforts to keep the registration statement of which this prospectus forms a part effective until no purchaser owns any Warrants or Warrant shares issuable upon exercise of the Warrants. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the Common Stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the Common Stock by the Selling Stockholders or any other person. We will make copies of this prospectus available to the Selling Stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

We will not receive any proceeds from the sale of the shares by the Selling Stockholders.

SELLING STOCKHOLDERS

The shares of Common Stock being offered by the Selling Stockholders are those issuable to the Selling Stockholders upon exercise of the Warrants. For additional information regarding the issuances of those Warrants, see "Sale of Securities to Selling Stockholders". We are registering the shares of Common Stock in order to permit the Selling Stockholders to offer the shares for resale from time to time. Except for the ownership of shares of Common Stock, preferred stock and warrants, the Selling Stockholders have not had any material relationship with us within the past three years.

The percentage of each Selling Shareholder's ownership is based on 4,674,068 shares of common stock outstanding as of December 18, 2019. In computing the number of shares beneficially owned by a Selling Stockholder and the percentage ownership of that Selling Stockholder, shares of Common Stock underlying the Warrants held by that Selling Stockholder that are exercisable as of December 18, 2019, or exercisable within 60 days after December 18, 2019, are deemed outstanding. Such shares, however, are not deemed outstanding for the purposes of computing the percentage ownership of any other person. The percentage of beneficial ownership after this offering is based on shares outstanding on December 18, 2019 and also includes the shares of our Common Stock registered in this offering.

The registration of the shares of Common Stock issuable to the Selling Stockholders upon exercise of the Warrants does not mean that the Selling Stockholders will sell or otherwise dispose of all or any of those securities. The Selling Stockholders may sell or otherwise dispose of all, a portion or none of such shares from time to time. We do not know the number of shares, if any, that will be offered for sale or other disposition by any of the Selling Stockholders under this prospectus. Furthermore, the Selling Stockholders may have sold, transferred or disposed of the shares of Common Stock covered hereby in transactions exempt from the registration requirements of the Securities Act since the date on which we filed this prospectus.

To our knowledge and except as noted below, none of the Selling Stockholders has, or within the past three years has had, any position, office or other material relationship with us or any of our predecessors or affiliates. None of the Selling Stockholders is a broker-dealer or an affiliate of a broker-dealer, except as noted below. The Selling Stockholders may sell all, some or none of the shares of Common Stock subject to this prospectus. See "Plan of Distribution."

	Beneficial Ownership Before This Offering			Beneficial Ownership After This Offering	
Selling Stockholder[1]	Number of Shares Owned	Percentage of Outstanding Shares[2]	Shares Offered Hereby	Number of Shares Owned	Percentage of Outstanding Shares
Bigger Capital Fund, LP[3]	844,195	18%	848,956	183,154	4%
District 2 Capital Fund LP[4]	200,000	4%	100,000	100,000	2%
Hudson Bay Master Fund Ltd[5]	1,403,985	30%	845,950	845,950	12%
Total:	2,235,643	52%	1,794,906	1,029,104	18%

* Represents beneficial ownership of less than one percent (1%) of the outstanding shares of our common stock.

(1) This table and the information in the notes below are based upon information supplied by the Selling Stockholders and are based on shares of common stock outstanding as of December 18, 2019. Only those shares issuable upon exercise of the Warrants are being registered for resale pursuant to this registration statement, and not any other securities held by the Selling Stockholders. Beneficial ownership is determined in accordance with Rule 13d-3 under the Securities Act, and includes any shares as to which the Selling Stockholder has sole or shared voting power or investment power, and also any shares which the Selling Stockholder has the right to acquire within 60 days of the date hereof, whether through the exercise or conversion of any stock option, convertible security, warrant or other right. The indication herein that shares are beneficially owned is not an admission on the part of the Selling Stockholder that he, she or it is a direct or indirect beneficial owner of those shares.

(2) All convertible securities of the Company held by the Selling Stockholders are subject to beneficial ownership limitations such that the shares of warrants may not be converted or exercised, respectively, if it would result in the holder exceeding the beneficial ownership limitation. The beneficial ownership limitation is either 4.99% or 9.99% for each Selling Stockholder.

(3) 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 "Number of Shares Owned" consists of (i) 661,041 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. Excludes 287,915 warrants to purchase common stock purchased pursuant to the Company's private placement of shares on October 25, 2019, which are not exercisable within 60 days

of the date hereof. 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%.

(4) Represents 100,000 shares of common stock purchased in the Company's registered direct offering on November 6, 2019 and 100,000 warrants to purchase common stock purchased pursuant to the Company's private placement of shares on November 6, 2019.

(5) Represents (i) 287,915 and 345,498 shares of common stock purchased in registered direct offerings of the Company on October 25, 2019 and November 6, 2019, respectively, (ii) 558,035 warrants to purchase common stock purchased pursuant to the Company's private placement of shares on November 6, 2019, and (iii) 212,537 pre-funded warrants to purchase common stock purchased pursuant to the Company's private placement of shares on November 6, 2019. Excludes 287,915 warrants to purchase common stock purchased pursuant to the Company's private placement of shares on October 25, 2019, which are not exercisable within 60 days of the date hereof.

LEGAL MATTERS

The validity of the securities offered by this prospectus will be passed upon for us by Honigman LLP, Kalamazoo, Michigan.

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.