

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

FORM 8-K

Current Report Pursuant to Section 13 or 15(d) of  
the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **November 5, 2019**

**CHF Solutions, Inc.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State or Other Jurisdiction of Incorporation or  
Organization)

**001-35312**  
(Commission File Number)

**No. 68-0533453**  
(I.R.S. Employer Identification No.)

**12988 Valley View Road, Eden Prairie, MN 55344**  
(Address of Principal Executive Offices) (Zip Code)

**(952) 345-4200**  
(Registrant's Telephone Number, Including Area Code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	CHFS	Nasdaq Capital Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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

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**Item 2.02 Results of Operations and Financial Condition.**

On November 5, 2019, CHF Solutions, Inc. issued a press release reporting its financial results for the quarter ended September 30, 2019. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information included in this Current Report on Form 8-K (including Exhibit 99.1) is furnished pursuant to Item 2.02 and shall not be deemed to be “filed” for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits**

<b>Exhibit No.</b>	<b>Description</b>
<a href="#"><u>99.1</u></a>	Press Release, dated November 5, 2019, reporting the financial results of CHF Solutions, Inc. for the quarter ended September 30, 2019

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## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 5, 2019

**CHF SOLUTIONS, INC.**

By: /s/ CLAUDIA DRAYTON

Name: Claudia Drayton

Title: Chief Financial Officer

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**CHF Solutions, Inc. Announces Third Quarter Financial Results and Provides Company Update**

Eden Prairie, Minn., November 5, 2019 (GLOBE NEWSWIRE) -- CHF Solutions, Inc. (Nasdaq: CHFS), a medical device company focused on developing, manufacturing and commercializing a clinically proven solution for diuretic-resistant patients suffering from fluid overload, announced today its results for the third quarter ended September 30, 2019, which included the following highlights:

- Submitted 510(k) application for pediatric label modification on September 30, 2019. Expect regulatory clearance early Q1 2020.
- Announced publication of a multi-center, retrospective clinical study titled “Kidney Support in Children Using an Ultrafiltration Device” in the *Clinical Journal of the American Society of Nephrology*, highlighting the use of Aquadex FlexFlow® system in pediatric patients, showing positive survival outcomes across all pediatric populations.
- Hosted an investor call with principal investigators of pediatric study, Stuart Goldstein, MD (Cincinnati Children’s Hospital Center), David Askenazi, MD (Children’s of Alabama), and Shina Menon, MD (Seattle Children’s Hospital).
- Announced that Abington Hospital of the Jefferson Health System has initiated a retrospective 344 patient study to evaluate the use of Aquadex FlexFlow in fluid overloaded patients.
- Opened 4 new accounts in large hospital systems in Texas and Tennessee, and 2 pediatric accounts in Pennsylvania and Delaware. In Q4 expect to continue to open new hospital systems in Ohio, Georgia, Tennessee, and New York, and 5 pediatric accounts.
- Announced sales force realignment to increase focus on cardiac surgery and eventually pediatrics. Revenue for third quarter ended September 30, 2019 was \$1.3 million, a decrease of 8 percent from Q3 2018. Gross margin percentages increased to 57 percent from 33 percent for the same period a year ago.
- Ended the quarter with \$3.6 million in cash and no debt. Subsequent to quarter end, announced financing transactions totaling approximately \$1.7 million in net proceeds, for total pro forma cash balance of approximately \$5.3 million.

“We continue to execute on our strategy of finding new clinical applications for our therapy including new applications in critical care and eventually pediatrics” said John Erb, chairman and CEO of CHF Solutions. “We will continue to develop and refine our strategic focus toward driving revenue, which is the key metric our employees, shareholders and potential investors use to measure performance.”

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## CHF SOLUTIONS, INC. AND SUBSIDIARIES

*Condensed Consolidated Statements of Operations and Comprehensive Loss*  
(Unaudited and in thousands, except per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
<b>Net sales</b>	\$ 1,252	\$ 1,363	\$ 4,144	\$ 3,499
<b>Costs and expenses:</b>				
Cost of goods sold	540	915	1,987	2,686
Selling, general and administrative	4,107	3,713	12,098	11,489
Research and development	1,112	985	3,719	2,107
Total costs and expenses	5,759	5,613	17,804	16,282
Loss from operations	(4,507)	(4,250)	(13,660)	(12,783)
Other income (loss), net	(1)	10	(1)	10
Loss before income taxes	(4,508)	(4,240)	(13,661)	(12,773)
Income tax expense	(1)	(1)	(5)	(3)
<b>Net loss</b>	<b>\$ (4,509)</b>	<b>\$ (4,241)</b>	<b>\$ (13,666)</b>	<b>\$ (12,776)</b>
<b>Basic and diluted loss per share</b>	<b>\$ (1.70)</b>	<b>\$ (8.50)</b>	<b>\$ (9.49)</b>	<b>\$ (34.59)</b>
Weighted average shares outstanding – basic and diluted	2,646	499	1,915	369
<b>Other comprehensive loss:</b>				
Foreign currency translation adjustments	\$ 1	\$ (1)	\$ (4)	\$ (2)
<b>Total comprehensive loss</b>	<b>\$ (4,508)</b>	<b>\$ (4,242)</b>	<b>\$ (13,670)</b>	<b>\$ (12,778)</b>

**CHF SOLUTIONS, INC. AND SUBSIDIARIES**  
**Condensed Consolidated Balance Sheets**  
(In thousands, except share and share amounts)

	September 30, 2019	December 31, 2018
	(unaudited)	
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 3,634	\$ 5,480
Accounts receivable	528	786
Inventory	1,612	1,658
Other current assets	277	203
<b>Total current assets</b>	<b>6,051</b>	<b>8,127</b>
Property, plant and equipment, net	1,025	536
Operating lease right-of-use asset, net	487	—
Other assets	21	113
<b>TOTAL ASSETS</b>	<b>\$ 7,584</b>	<b>\$ 8,776</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 1,427	\$ 1,133
Accrued compensation	1,242	1,498
Current portion of operating lease liability	181	—
Other current liabilities	87	209
<b>Total current liabilities</b>	<b>2,937</b>	<b>2,840</b>
Operating lease liability	309	—
<b>Total liabilities</b>	<b>3,246</b>	<b>2,840</b>
Commitments and contingencies	—	—
<b>Stockholders' equity</b>		
Series A junior participating preferred stock as of September 30, 2019 and December 31, 2018, par value \$0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Series F convertible preferred stock as of September 30, 2019 and December 31, 2018, par value \$0.0001 per share; authorized 535 and 535 shares, respectively, issued and outstanding 535 and 535, respectively	—	—
Series G convertible preferred stock as of September 30, 2019 and December 31, 2018, par value \$0.0001 per share; authorized 0 and 0 shares, respectively, issued and outstanding 0 and 0, respectively	—	—
Preferred stock as of September 30, 2019 and December 31, 2018, par value \$0.0001 per share; authorized 39,969,465 and 39,969,465 shares, respectively, none outstanding	—	—
Common stock as of September 30, 2019 and December 31, 2018, par value \$0.0001 per share; authorized 100,000,000 shares, issued and outstanding 2,879,162 and 513,445, respectively	—	—
Additional paid-in capital	216,173	204,101
Accumulated other comprehensive income:		
Foreign currency translation adjustment	1,219	1,223
Accumulated deficit	(213,054)	(199,388)
<b>Total stockholders' equity</b>	<b>4,338</b>	<b>5,936</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 7,584</b>	<b>\$ 8,776</b>

**CHF SOLUTIONS, INC. AND SUBSIDIARIES**  
**Condensed Consolidated Statements of Stockholders' Equity**  
(Unaudited, In thousands, except share amounts)

	Outstanding Shares of Common Stock	Common Stock	Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Equity
<b>Balance December 31, 2017</b>	271,357	\$ —	\$ 197,367	\$ 1,227	\$ (182,356)	\$ 16,238
Net loss	—	—	—	—	(4,354)	(4,354)
Foreign currency translation adjustment	—	—	—	1	—	1
Stock-based compensation, net	3	—	501	—	—	501
Conversion of preferred stock into common stock	32,365	—	—	—	—	—
<b>Balance March 31, 2018</b>	<b>303,725</b>	<b>\$ —</b>	<b>\$ 197,868</b>	<b>\$ 1,228</b>	<b>\$ (186,710)</b>	<b>\$ 12,386</b>
Net loss	—	—	—	—	(4,181)	(4,181)
Foreign currency translation adjustment	—	—	—	(2)	—	(2)
Stock-based compensation and stock awards, net	3	—	606	—	—	606
Conversion of preferred stock into common stock	18,127	—	—	—	—	—
<b>Balance June 30, 2018</b>	<b>321,855</b>	<b>\$ —</b>	<b>\$ 198,474</b>	<b>\$ 1,226</b>	<b>\$ (190,891)</b>	<b>\$ 8,809</b>
Net loss	—	—	—	—	(4,241)	(4,241)
Foreign currency translation adjustment	—	—	—	(1)	—	(1)
Stock-based compensation and stock awards, net	3	—	437	—	—	437
Issuance of common stock, net	181,941	—	4,649	—	—	4,649
Conversion of preferred stock into common stock	1,516	—	—	—	—	—
<b>Balance September 30, 2018</b>	<b>505,315</b>	<b>\$ —</b>	<b>\$ 203,560</b>	<b>\$ 1,225</b>	<b>\$ (195,132)</b>	<b>\$ 9,653</b>
	Outstanding Shares of Common Stock	Common Stock	Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Equity
<b>Balance December 31, 2018</b>	513,445	\$ —	\$ 204,101	\$ 1,223	\$ (199,388)	\$ 5,936
Net loss	—	—	—	—	(4,727)	(4,727)
Foreign currency translation adjustment	—	—	—	(2)	—	(2)
Stock-based compensation, net	3	—	362	—	—	362
Issuance of common and preferred stock, net	455,178	—	10,959	—	—	10,959
Conversion of preferred stock into common stock	1,100,394	—	—	—	—	—
<b>Balance March 31, 2019</b>	<b>2,069,020</b>	<b>\$ —</b>	<b>\$ 215,422</b>	<b>\$ 1,221</b>	<b>\$ (204,115)</b>	<b>\$ 12,528</b>
Net loss	—	—	—	—	(4,430)	(4,430)
Foreign currency translation adjustment	—	—	—	(3)	—	(3)
Stock-based compensation, net	—	—	339	—	—	339
Conversion of preferred stock into common stock	259,300	—	—	—	—	—
<b>Balance June 30, 2019</b>	<b>2,328,320</b>	<b>\$ —</b>	<b>\$ 215,761</b>	<b>\$ 1,218</b>	<b>\$ (208,545)</b>	<b>\$ 8,434</b>
Net loss	—	—	—	—	(4,509)	(4,509)
Foreign currency translation adjustment	—	—	—	1	—	1
Stock-based compensation, net	—	—	412	—	—	412
Conversion of preferred stock into common stock	550,842	—	—	—	—	—
<b>Balance September 30, 2019</b>	<b>2,879,162</b>	<b>\$ —</b>	<b>\$ 216,173</b>	<b>\$ 1,219</b>	<b>\$ (213,054)</b>	<b>\$ 4,338</b>

**CHF SOLUTIONS, INC. AND SUBSIDIARIES**  
**Condensed Consolidated Statements of Cash Flows**  
(Unaudited and in thousands)

Nine months ended  
September 30,  
2019                      2018

<b>Operating Activities:</b>		
Net loss	\$ (13,666)	\$ (12,776)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	179	174
Stock-based compensation expense, net	1,113	1,544
Changes in operating assets and liabilities:		
Accounts receivable	258	(242)
Inventory	(158)	(360)
Other current assets	(74)	(104)
Other assets and liabilities	(27)	—
Accounts payable and accrued expenses	38	(79)
<b>Net cash used in operating activities</b>	<b>(12,337)</b>	<b>(11,843)</b>
<b>Investing Activities:</b>		
Purchases of property, plant and equipment	(464)	(177)
<b>Net cash used in investing activities</b>	<b>(464)</b>	<b>(177)</b>
<b>Financing Activities:</b>		
Net proceeds from public stock offering, net	10,959	4,649
<b>Net cash provided by financing activities</b>	<b>10,959</b>	<b>4,649</b>
Effect of exchange rate changes on cash	(4)	(2)
Net decrease in cash and cash equivalents	(1,846)	(7,373)
Cash and cash equivalents - beginning of period	5,480	15,595
<b>Cash and cash equivalents - end of period</b>	<b>\$ 3,634</b>	<b>\$ 8,222</b>
<b>Supplemental schedule of non-cash activities:</b>		
Inventory transferred to property, plant and equipment	\$ 204	\$ —

The Company will host a conference call and webcast at 9:00 AM ET today to discuss its financial results and provide an update on the Company's performance.

To access the live webcast, please visit the Investors page of the CHF Solutions website at <http://ir.chf-solutions.com> or access the webcast directly at <http://ir.chf-solutions.com/events>. Alternatively, you may access the live conference call by dialing (877) 303-9826 (U.S.) or (224) 357-2194 (international) and using conference ID: 5258206. An audio archive of the webcast will be available following the call on the Investor page at <http://ir.chf-solutions.com/events>.



## **About CHF Solutions**

CHF Solutions, Inc. (Nasdaq:CHFS) is 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. CHF Solutions is a Delaware corporation headquartered in Minneapolis, Minnesota with wholly owned subsidiaries in Australia and Ireland. The company has been listed on the Nasdaq Capital Market since February 2012.

## **About Aquadex FlexFlow® System**

The Aquadex FlexFlow system is a clinically proven therapy that provides a safe, effective, and predictable method of removing excess fluid from patients suffering from fluid overload. 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 for extended (longer than 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization. The company has 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. All treatments must be administered by a healthcare provider, under physician prescription, both of whom having received training in extracorporeal therapies.

## **Forward-Looking Statements**

Certain statements in this release are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including without limitation, statements regarding the Company's ability to grow revenue and add new accounts in future quarters and the timing of the regulatory clearance for an expanded label in pediatrics. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Many factors could cause actual future events to differ materially from the forward-looking statements in this release, including, without limitation, those risk associated with our ability to execute on our commercialization strategy, the possibility that we may be unable to raise sufficient funds necessary for our anticipated operations, our post-market clinical data collection activities, benefits of our products to patients, our expectations with respect to product development and commercialization efforts, our ability to increase market and physician acceptance of our products, potentially competitive product offerings, intellectual property protection, our ability to integrate acquired businesses, our expectations regarding anticipated synergies with and benefits from acquired businesses, and other risks and uncertainties described in our filings with the SEC. Forward-looking statements speak only as of the date when made. CHF Solutions does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

## **CONTACTS:**

### **INVESTORS:**

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