

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): **March 3, 2020**

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
Common Stock, par value \$0.0001 per share

Trading Symbol(s)
CHFS

Name of each exchange on which registered
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.

Item 2.02 Results of Operations and Financial Condition.

On March 3, 2020, CHF Solutions, Inc. issued a press release reporting its financial results for the quarter and year ended December 31, 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

Exhibit No. Description

[99.1](#) Press Release, dated March 3, 2020, reporting the financial results of CHF Solutions, Inc. for the quarter and year ended December 31, 2019

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: March 3, 2020

CHF SOLUTIONS, INC.

By: /s/ CLAUDIA DRAYTON

Name: Claudia Drayton

Title: Chief Financial Officer

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

Eden Prairie, MN: March 3, 2020: (GLOBE NEWSWIRE) CHF Solutions, Inc. (Nasdaq: CHFS) announced today its results for the fourth quarter and year ended December 31, 2019, which included the following highlights:

- Received 510(k) clearance in the U.S. and CE Mark in the EU for adult and pediatric patients who weigh 20 kg or more and for the next generation Aquadex console, which will be sold as Aquadex SmartFlow™.
- Announced expansion of commercial presence in Europe with distribution arrangement for Germany, Austria and Switzerland.
- Announced presentation of clinical data from an investigator-initiated analysis at the American Society of Kidney Week highlighting the efficacy and simplicity of use of Aquadex FlexFlow in treating patients in critical care settings such as cardiogenic shock, anasarca, ATN with fluid overload, ESRD with bridge ultrafiltration between hemodialysis treatment, and post-operative fluid overload.
- Completed sales force realignment to increase focus on cardiac surgery and eventually pediatrics. Revenue for fourth quarter ended December 31, 2019 was \$1.4 million, a decrease of 8.8 percent from Q4 2018. For the year 2019, revenue totaled \$5.5 million, a 10 percent increase from 2018.
- Ended the year with \$1.3 million in cash and no debt. Subsequent to quarter end, announced the closing of an underwritten public offering for net proceeds of approximately \$8.6 million, for total pro forma cash balance of \$9.9 million.

“I look back at 2019 as a very successful year for the company,” said John Erb, chairman and CEO of CHF Solutions. “We made important strides in our commercialization efforts, including focusing on new market opportunities and driving important product improvements which we believe will deliver additional growth in 2020 and beyond.”

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 <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: 7489468. An audio archive of the webcast will be available following the call 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 innovation. The company is focused on developing, manufacturing, and commercializing the Aquadex SmartFlow 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 the Aquadex SmartFlow System

The Aquadex SmartFlow system is a clinically proven therapy that provide a safe, effective, and predictable method of removing excess fluid from patients suffering from fluid overload. The Aquadex SmartFlow system is indicated for temporary (up to 8 hours) or extended (longer than 8 hours in patients who require hospitalization) use in adult and pediatric patients weighing 20 kilograms or more whose fluid overload is unresponsive to medical management, including diuretics. All treatments must be administered by a healthcare provider, within an outpatient or inpatient clinical setting, 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 new market opportunities and anticipated growth in 2020 and beyond. 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.

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CHF SOLUTIONS, INC. AND SUBSIDIARIES
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except per share amounts)

	Three months ended December 31		Year ended December 31,	
	2019	2018	2019	2018
Net sales	\$ 1,367	\$ 1,499	\$ 5,511	\$ 4,998
Costs and Expenses:				
Cost of goods sold	673	984	2,660	3,670
Selling, general and administrative	4,187	3,822	16,285	15,311
Research and development	953	946	4,672	3,053
Total costs and expenses	<u>5,813</u>	<u>5,752</u>	<u>23,617</u>	<u>22,034</u>
Loss from operations	(4,446)	(4,253)	(18,106)	(17,036)
Other income, net	1	—	—	10
Loss before income taxes	(4,445)	(4,253)	(18,106)	(17,026)
Income tax expense	(3)	(3)	(8)	(6)
Net loss	<u>\$ (4,448)</u>	<u>\$ (4,256)</u>	<u>\$ (18,114)</u>	<u>\$ (17,032)</u>
Basic and diluted loss per share	<u>\$ (1.12)</u>	<u>\$ (8.37)</u>	<u>\$ (9.30)</u>	<u>\$ (42.14)</u>
Weighted average shares outstanding – basic and diluted	3,988	509	2,433	404
Other comprehensive loss:				
Foreign currency translation adjustment	\$ (5)	\$ (2)	\$ (9)	\$ (4)
Total comprehensive loss	<u>\$ (4,453)</u>	<u>\$ (4,258)</u>	<u>\$ (18,123)</u>	<u>\$ (17,036)</u>

CHF SOLUTIONS, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31, 2019	December 31, 2018
ASSETS		
Current assets		
Cash and cash equivalents	\$ 1,279	\$ 5,480
Accounts receivable	799	786
Inventories	1,797	1,658
Other current assets	161	203
Total current assets	4,036	8,127
Property, plant and equipment, net	991	536
Operating lease right-of-use asset, net	442	—
Other assets	133	113
TOTAL ASSETS	\$ 5,602	\$ 8,776
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,488	\$ 1,133
Accrued compensation	1,592	1,498
Current portion of operating lease liability	186	—
Other current liabilities	85	209
Total current liabilities	3,351	2,840
Operating lease liability	261	—
Total liabilities	3,612	2,840
Commitments and contingencies		
Stockholders' equity		
Series A junior participating preferred stock as of December 31, 2019 and December 31, 2018, par value \$0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Series F convertible preferred stock as of both December 31, 2019 and December 31, 2018, par value \$0.0001 per share; authorized 535 shares, issued and outstanding 535 shares	—	—
Preferred stock as of both December 31, 2019 and December 31, 2018, par value \$0.0001 per share; authorized 39,969,465 shares, none outstanding	—	—
Common stock as of December 31, 2019 and December 31, 2018, par value \$0.0001 per share; authorized 100,000,000 shares, issued and outstanding 4,674,068 and 513,445, respectively	—	—
Additional paid-in capital	218,278	204,101
Accumulated other comprehensive income:		
Foreign currency translation adjustment	1,214	1,223
Accumulated deficit	(217,502)	(199,388)
Total stockholders' equity	1,990	5,936
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 5,602	\$ 8,776

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

	For the years ended December 31,	
	2019	2018
Operating Activities		
Net loss	\$ (18,114)	\$ (17,032)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	239	232
Stock-based compensation expense	1,512	2,087
Changes in operating assets and liabilities:		
Accounts receivable	(13)	(241)
Inventories	(343)	(70)
Other current assets	42	(67)
Other assets and liabilities	18	(14)
Accounts payable and accrued expenses	292	545
Net cash used in operations	(16,367)	(14,560)
Investing activities:		
Purchase of property and equipment	(490)	(198)
Net cash used in investing activities	(490)	(198)
Financing activities:		
Net proceeds from public stock offerings, net	12,665	4,647
Net cash provided by financing activities	12,665	4,647
Effect of exchange rate changes on cash	(9)	(4)
Net decrease in cash and cash equivalents	(4,201)	(10,115)
Cash and cash equivalents—beginning of year	5,480	15,595
Cash and cash equivalents—end of year	\$ 1,279	\$ 5,480
Supplemental schedule of non-cash activities		
Financing fees incurred for subsequent equity financing included in other assets and accounts payable	\$ 111	\$ 78
Inventory transferred to property, plant and equipment	\$ 204	\$ —
Supplemental cash flow information		
Cash paid for income taxes	\$ 4	\$ 2

CONTACTS:

INVESTORS:

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