

**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 2, 2021**

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 2, 2021, CHF Solutions, Inc. (the “Company”) issued a press release reporting its financial results for the period ended December 31, 2020. 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 2, 2021, reporting the financial results of CHF Solutions, Inc. for the period ended December 31, 2020.

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 2, 2021

CHF SOLUTIONS, INC.

By: /s/ CLAUDIA DRAYTON

Name: Claudia Drayton

Title: Chief Financial Officer

CHF Solutions, Inc. Announces 49.5 Percent Increase in Revenue for Fourth Quarter 2020 and Provides Company Update

Eden Prairie, MN: March 2, 2021: (GLOBE NEWSWIRE) CHF Solutions, Inc. (Nasdaq: CHFS) announced today its results for the fourth quarter ended December 31, 2020.

Recent Highlights

- Revenue for the fourth quarter of 2020 was \$2 million, an increase of 49.5% compared to the prior year period
- Gross margin was 56.1% for the fourth quarter 2020, up from 50.8% in the corresponding period in 2019 and up from 46.1% in the third quarter of 2020
- Critical Care revenue benefited in the quarter from increased utilization from hospitals treating COVID-19 patients with the Aquadex System.
- Continued to see strong momentum in pediatric accounts, adding 5 new locations including Children's Hospitals in Philadelphia, Houston, and the San Francisco Bay Area
- Presented a 355 consecutive patient retrospective study at the Annual Scientific Meeting of Heart Failure Society of America, which showed substantial mean fluid removal with no negative changes in renal function and reduced rehospitalization rates in patients treated with Aquadex therapy
- Successfully submitted CPT code application for ultrafiltration using Aquadex SmartFlow, which will provide access to heart failure patients in the outpatient setting
- Cash and cash equivalents totaled \$14.4 million with no debt as of December 31, 2020

“CHF Solutions built on its momentum over the last few quarters, having delivered solid fourth quarter results, most notably within critical care and pediatric accounts,” said Nestor Jaramillo, CEO of CHF Solutions. “We anticipate that when healthcare systems return to some level of the new normal, we are strongly positioned to see accelerating sales growth as a leading and primary provider of ultrafiltration therapy to cardiologists, nephrologists, hospitalists, intensivists, cardiac surgeons, and pediatricians who treat fluid overload.”

Fourth Quarter 2020 Financial Results

Revenue for the fourth quarter was \$2.0 million, an increase of 49.5% compared to \$1.4 million in the prior year period. For the fifth straight quarter, the Company achieved sequential revenue growth, with revenues in the fourth quarter having increased 7.4% sequentially compared to the third quarter of 2020. Revenue growth in the quarter was driven by increased utilization among established pediatric accounts, the addition of five new pediatric accounts, and strong performance in critical care accounts. As COVID-19 cases accelerated in the back half of the quarter, the Company saw an increase in the number of hospitals treating COVID-19 patients with the Aquadex SmartFlow. CHF Solutions ended the year with a total of 14 centers using the Aquadex SmartFlow to treat COVID-19 patients, up from three earlier in the pandemic.

Gross margin was 56.1% for the fourth quarter 2020, up from 50.8% in the corresponding period in 2019 and up from 46.1% in the third quarter of 2020. Gross margins for the quarter were favorably impacted by increased consumables volume and improved manufacturing efficiencies.

Operating expenses for the fourth quarter of 2020 were \$5.4 million, an increase of 5.7% as compared to the prior year period. The increase in operating expenses was primarily due to fully staffed sales territories and increased R&D expenses, up 10% as compared to the prior year period in 2019.

The Company recognized a gain of \$1.2 million in the fourth quarter of 2020 related to the dissolution of a foreign subsidiary in Australia. The gain relates to the realization of cumulative foreign exchange adjustments previously recorded on the balance sheet. Net loss for the fourth quarter of 2020 was \$3.1 million, as compared to a loss of \$4.4 million in the prior year period in 2019.

The Company used \$3.4 million of cash in the fourth quarter of 2020 to finance operations. Cash and cash equivalents were \$14.4 million with no debt as of December 31, 2020.

Webcast and Conference Call Information

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: 5495878. 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 headquartered in Minneapolis, Minn., 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 delivers clinically proven therapy using a simple, flexible and smart method of removing excess fluid from patients suffering from hypervolemia (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 kg or more whose fluid overload is unresponsive to medical management, including diuretics. All treatments must be administered by a health care provider, within an outpatient or inpatient clinical setting, under physician prescription, both 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 value that the company brings to its customers. 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 impact of the COVID-19 pandemic, 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.

Financials

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

	Three months ended December 31,		Twelve months ended December 31,	
	2020	2019	2020	2019
Net sales	\$ 2,044	\$ 1,367	\$ 7,441	\$ 5,511
Costs and expenses:				
Cost of goods sold	897	673	3,384	2,660
Selling, general and administrative	4,384	4,187	17,417	16,285
Research and development	1,047	953	3,668	4,672
Total costs and expenses	<u>6,328</u>	<u>5,813</u>	<u>24,469</u>	<u>23,617</u>
Loss from operations	<u>(4,284)</u>	<u>(4,446)</u>	<u>(17,028)</u>	<u>(18,106)</u>
Realized foreign currency translation gain from dissolution of subsidiary	1,202	-	1,202	-
Other income (expense), net	(2)	1	(1)	-
Loss before income taxes	(3,084)	(4,445)	(15,827)	(18,106)
Income tax expense	(2)	(3)	(9)	(8)
Net loss	<u>\$ (3,086)</u>	<u>\$ (4,448)</u>	<u>\$ (15,836)</u>	<u>\$ (18,114)</u>
Basic and diluted loss per share	<u>\$ (1.13)</u>	<u>\$ (33.46)</u>	<u>\$ (10.67)</u>	<u>\$ (278.90)</u>
Weighted average shares outstanding – basic and diluted	2,736	133	1,649	81
Other comprehensive loss:				
Realized foreign currency translation gain from dissolution of subsidiary	\$ (1,202)	\$ -	\$ (1,202)	\$ -
Unrealized foreign currency translation adjustments	\$ (12)	\$ (5)	\$ (19)	\$ (9)
Total comprehensive loss	<u>\$ (4,300)</u>	<u>\$ (4,453)</u>	<u>\$ (17,057)</u>	<u>\$ (18,123)</u>

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

	<u>December 31,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
ASSETS		
Current assets		
Cash and cash equivalents	\$ 14,437	\$ 1,279
Accounts receivable	905	799
Inventories	2,957	1,797
Other current assets	237	161
Total current assets	<u>18,536</u>	<u>4,036</u>
Property, plant and equipment, net	1,200	991
Operating lease right-of-use asset, net	255	442
Other assets	21	133
TOTAL ASSETS	<u>\$ 20,012</u>	<u>\$ 5,602</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,097	\$ 1,488
Accrued compensation	2,192	1,592
Current portion of operating lease liability	206	186
Current portion of finance lease liability	24	-
Other current liabilities	66	85
Total current liabilities	<u>3,585</u>	<u>3,351</u>
Operating lease liability	55	261
Finance lease liability	54	-
Total liabilities	<u>3,694</u>	<u>3,612</u>
Commitments and contingencies		
Stockholders' equity		
Series A junior participating preferred stock as of December 31, 2020 and December 31, 2019, par value \$0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Series F convertible preferred stock as of December 31, 2020 and December 31, 2019, par value \$0.0001 per share; authorized 127 and 535 shares, respectively, issued and outstanding 127 and 535 shares, respectively	—	—
Preferred stock as of December 31, 2020 and December 31, 2019, par value \$0.0001 per share; authorized 39,969,873 and 39,969,465 shares, respectively, none outstanding	—	—
Common stock as of December 31, 2020 and December 31, 2019, par value \$0.0001 per share; authorized 100,000,000 shares, issued and outstanding 2,736,060 and 155,802, respectively	—	—
Additional paid-in capital	249,663	218,278
Accumulated other comprehensive income:		
Foreign currency translation adjustment	(7)	1,214
Accumulated deficit	(233,338)	(217,502)
Total stockholders' equity	<u>16,318</u>	<u>1,990</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 20,012</u>	<u>\$ 5,602</u>

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

	For the years ended December 31,	
	2020	2019
Operating Activities		
Net loss	\$ (15,836)	\$ (18,114)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	376	239
Stock-based compensation expense	1,349	1,512
Loss on disposal of property and equipment	40	—
Realized foreign currency translation gain from dissolution of subsidiary	(1,202)	—
Changes in operating assets and liabilities:		
Accounts receivable	(106)	(13)
Inventories	(1,420)	(343)
Other current assets	(76)	42
Other assets and liabilities	112	18
Accounts payable and accrued compensation	191	292
Net cash used in operations	(16,572)	(16,367)
Investing activities:		
Purchase of property and equipment	(298)	(490)
Proceeds from the sale of property and equipment	31	—
Net cash used in investing activities	(267)	(490)
Financing activities:		
Proceeds from public stock offerings, net	25,921	12,665
Proceeds from warrant exercises	4,115	—
Payments on finance lease liability	(20)	—
Net cash provided by financing activities	30,016	12,665
Effect of exchange rate changes on cash	(19)	(9)
Net increase (decrease) in cash and cash equivalents	13,158	(4,201)
Cash and cash equivalents—beginning of year	1,279	5,480
Cash and cash equivalents—end of year	\$ 14,437	\$ 1,279
Supplemental schedule of non-cash activities		
Financing fees incurred for subsequent equity financing included in other assets and accounts payable	\$ —	\$ 111
Inventory transferred to property, plant and equipment	\$ 260	\$ 204
Equipment acquired through finance lease liability	\$ 98	\$ —
Supplemental cash flow information		
Cash paid for income taxes	\$ 10	\$ 4

CONTACTS:

INVESTORS:

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