

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 10, 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	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 10, 2020, CHF Solutions, Inc. (the “Company”) issued a press release reporting its financial results for the period ended September 30, 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 November 10, 2020, reporting the financial results of CHF Solutions, Inc. for the period ended September 30, 2020

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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 10, 2020

**CHF SOLUTIONS, INC.**

By: /s/ CLAUDIA DRAYTON

Name: Claudia Drayton

Title: Chief Financial Officer

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**CHF Solutions, Inc. Announces 52 Percent Increase in Revenue for Third Quarter 2020 and Provides Company Update**

Eden Prairie, MN: November 10, 2020: (GLOBE NEWSWIRE) CHF Solutions, Inc. (Nasdaq: CHFS) announced today its results for the third quarter ended September 30, 2020.

**Recent Highlights**

- Revenue for the third quarter of 2020 was \$1.9 million, an increase of 52% compared to the prior year period
- Increased Aquadex™ therapy utilization in existing pediatric hospital accounts; opened 6 new pediatric hospital accounts
- Partnered with Acute Kidney Injury Critical Care Research Foundation and Watermark Research Partners to initiate a pediatric registry to collect real-world evidence for the use of Aquadex SmartFlow™
- Announced the Aquadex product line was added to the Federal Supply Schedule, expanding access to all federal agencies and eliminating months of fulfillment process time
- Hosted two webinars during the quarter, led by:
  - o Dr. David Askenazi, M.D. MSPH on treatment of fluid overload on pediatric patients and clinical benefits of Aquadex therapy
  - o Dr. John Jefferies, M.D. on the use of precision medicine for the treatment of fluid overload in heart failure patients utilizing the Aquadex SmartFlow system
- A 355-patient retrospective study was presented 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
- On November 3, 2020, received notification from Nasdaq that the company had regained compliance with NASDAQ's minimum bid price requirement, after effecting a 1-for-30 reverse stock split to remain in compliance
- Cash and cash equivalents totaled \$17.9 million with no debt as of September 30, 2020

“CHF Solutions achieved very solid performance in the third quarter, most notably within pediatric accounts,” said John Erb, chairman and CEO of CHF Solutions. “The pediatric opportunity is growing, as more children’s hospitals acquire our Aquadex SmartFlow product and complete training. In the third quarter, we had twelve children’s hospitals purchase product, reinforcing our strategic focus in this area.”

**Third Quarter 2020 Financial Results**

Revenue for the third quarter was \$1.9 million, an increase of 52% compared to \$1.3 million in the prior year period. Revenue growth in the quarter was driven by increased utilization among established pediatric accounts, and the addition of six new pediatric accounts.

The Company offered incentives to existing customers to upgrade consoles to Aquadex SmartFlow which impacted third quarter gross margins. The Company believes these upgrades will improve the customer experience with the therapy and increase utilization. Additionally, the Company experienced a higher mix of international distributor revenue which normally carries a lower sales price than in the U.S. Gross margin was 46.1% in the third quarter, compared to 56.9% in the prior year period.

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Operating expenses for the third quarter of 2020 were \$5.1 million, a decrease of 1.6% compared to the prior year period. The slight decrease in operating expenses was primarily due reduced product development costs compared to the prior year period.

Net loss from operations for the third quarter of 2020 was \$4.3 million, compared to a loss of \$4.5 million in the prior year period.

Cash and cash equivalents were \$17.9 million with no debt as of September 30, 2020. During the quarter, the Company announced the closing of a public offering for net proceeds of \$13 million. The Company also received \$1.8 million in cash proceeds from the exercise of warrants in the third quarter of 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: 6097367. 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.

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## CHF SOLUTIONS, INC. AND SUBSIDIARIES

## Condensed Consolidated Statements of Operations and Comprehensive Loss

*(Unaudited)*

(In thousands, except per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
<b>Net sales</b>	\$ 1,904	\$ 1,252	\$ 5,397	\$ 4,144
<b>Costs and expenses:</b>				
Cost of goods sold	1,026	540	2,486	1,987
Selling, general and administrative	4,264	4,107	13,034	12,098
Research and development	871	1,112	2,620	3,719
Total costs and expenses	6,161	5,759	18,140	17,804
Loss from operations	(4,257)	(4,507)	(12,743)	(13,660)
Other income (loss), net	—	(1)	—	(1)
Loss before income taxes	(4,257)	(4,508)	(12,743)	(13,661)
Income tax expense	(3)	(1)	(7)	(5)
<b>Net loss</b>	<b>\$ (4,260)</b>	<b>\$ (4,509)</b>	<b>\$ (12,750)</b>	<b>\$ (13,666)</b>
<b>Basic and diluted loss per share</b>	<b>\$ (2.08)</b>	<b>\$ (51.12)</b>	<b>\$ (11.27)</b>	<b>\$ (284.70)</b>
Weighted average shares outstanding – basic and diluted	2,049	88	1,287	64
<b>Other comprehensive loss:</b>				
Foreign currency translation adjustments	\$ (7)	\$ 1	\$ (12)	\$ (4)
<b>Total comprehensive loss</b>	<b>\$ (4,267)</b>	<b>\$ (4,508)</b>	<b>\$ (12,762)</b>	<b>\$ (13,670)</b>

**CHF Solutions, INC. AND SUBSIDIARIES**

**Condensed Consolidated Balance Sheets**  
(In thousands, except share and per share amounts)

	September 30, 2020 <u>(unaudited)</u>	December 31, 2019
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 17,947	\$ 1,279
Accounts receivable	1,048	799
Inventory	2,921	1,797
Other current assets	235	161
<b>Total current assets</b>	<b>22,151</b>	<b>4,036</b>
Property, plant and equipment, net	1,244	991
Operating lease right-of-use asset	303	442
Other assets	21	133
<b>TOTAL ASSETS</b>	<b>\$ 23,719</b>	<b>\$ 5,602</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 929	\$ 1,488
Accrued compensation	2,012	1,592
Current portion of operating lease liability	201	186
Current portion of finance lease liability	24	—
Other current liabilities	57	85
<b>Total current liabilities</b>	<b>3,223</b>	<b>3,351</b>
Operating lease liability	108	261
Finance lease liability	60	—
<b>Total liabilities</b>	<b>3,391</b>	<b>3,612</b>
Commitments and contingencies		
<b>Stockholders' equity</b>		
Series A junior participating preferred stock as of September 30, 2020 and December 31, 2019, par value \$0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Series F convertible preferred stock as of September 30, 2020 and December 31, 2019, par value \$0.0001 per share; authorized 127 and 535 shares, respectively, issued and outstanding 127 and 535, respectively	—	—
Preferred stock as of September 30, 2020 and December 31, 2019, par value \$0.0001 per share; authorized 39,969,873 and 39,969,465 shares, none outstanding	—	—
Common stock as of September 30, 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	249,378	218,278
Accumulated other comprehensive income:		
Foreign currency translation adjustment	1,202	1,214
Accumulated deficit	(230,252)	(217,502)
<b>Total stockholders' equity</b>	<b>20,328</b>	<b>1,990</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 23,719</b>	<b>\$ 5,602</b>

**CHF SOLUTIONS, INC. AND SUBSIDIARIES**

**Condensed Consolidated Statements of Cash Flows**

(Unaudited)  
(in thousands)

	Nine months ended September 30,	
	2020	2019
<b>Operating Activities:</b>		
Net loss	\$ (12,750)	\$ (13,666)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	253	179
Stock-based compensation expense, net	1,036	1,113
Loss on disposal of property and equipment	46	—
Changes in operating assets and liabilities:		
Accounts receivable	(249)	258
Inventory	(1,371)	(158)
Other current assets	(74)	(74)
Other assets	112	(27)
Accounts payable and accrued expenses	(166)	38
<b>Net cash used in operating activities</b>	<b>(13,163)</b>	<b>(12,337)</b>
<b>Investing Activities:</b>		
Purchases of property and equipment	(207)	(464)
<b>Net cash used in investing activities</b>	<b>(207)</b>	<b>(464)</b>
<b>Financing Activities:</b>		
Proceeds from public stock offerings, net	25,949	10,959
Proceeds from warrant exercises	4,115	—
Payments on finance lease liability	(14)	—
<b>Net cash provided by financing activities</b>	<b>30,050</b>	<b>10,959</b>
Effect of exchange rate changes on cash	(12)	(4)
Net increase in cash and cash equivalents	16,668	(1,846)
Cash and cash equivalents - beginning of period	1,279	5,480
<b>Cash and cash equivalents - end of period</b>	<b>\$ 17,947</b>	<b>\$ 3,634</b>
<b>Supplemental cash flow information</b>		
Cash paid for income taxes	\$ —	\$ —
Inventory transferred to property, plant and equipment	\$ 247	\$ 204
Equipment acquired through finance lease liability	\$ 98	\$ —

**CONTACTS:**

**INVESTORS:**

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