#### 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): August 6, 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 <u>Section 12(b)</u> 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  $\Box$ 

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 August 6, 2019, CHF Solutions, Inc. issued a press release reporting its financial results for the quarter ended June 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

#### Exhibit No. Description

99.1 Press Release, dated August 6, 2019, reporting the financial results of CHF Solutions, Inc. for the quarter ended June 30, 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: August 6, 2019

#### CHF SOLUTIONS, INC.

By:	/s/ Claudia Drayton
Name:	Claudia Drayton
Title:	Chief Financial Officer

#### CHF Solutions, Inc. Announces 53 Percent Increase in Revenues for Second Quarter 2019 Over Previous Year and 38 Percent Increase from Q1 2019

Eden Prairie, Minn., August 6, 2019 (GLOBE NEWSWIRE) -- CHF Solutions, Inc. (Nasdaq: CHFS), a medical device company focused on developing, manufacturing and commercializing a clinically proven alternative to diuretics for the treatment of fluid overload, announced today its results for the second quarter ended June 30, 2019, which included the following highlights:

- Revenue for second quarter ended June 30, 2019 was \$1.7 million, an increase of 53 percent compared to the same period of the prior year, and 38% sequentially from Q1 2019. Gross margin percentages increased to 50 percent from 21 percent during the same period a year ago, after transition to in-house manufactured inventory.
- Opened 7 new hospitals and hospital systems. In Q3 expect to open more than 10 new accounts including several new hospital systems.
- Increased field education specialists from 5 to 14 to support new account launches and rapid growth.
- Continued progress towards obtaining regulatory clearance for an expanded label in pediatrics. Pre-submission meeting with the FDA held in May 2019; submission expected in Q3 2019 and clearance in Q4 2019.
- Working with a large hospital system in New York on a 700 patient retrospective study to evaluate the clinical impact of utilizing the Aquadex FlexFlow® system on post-surgery patients, and with a large hospital in Philadelphia on a 344 patient retrospective study to evaluate the impact of ultrafiltration on fluid removal, renal outcomes, and readmission rates.

"We continue to deliver impressive double-digit increase in our revenue, and we believe we are well-poised to continue to grow in the quarters to come," 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."

#### FINANCIALS

#### CHF SOLUTIONS, INC. AND SUBSIDIARIES

#### Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited and in thousands, except per share amounts)

	Three months ended June 30,				Six months ended June 30,			
		2019		2018	2019		2018	
Net sales	\$	1,677	\$	1,099	\$ 2,892	\$	2,136	
Costs and expenses:								
Cost of goods sold		835		870	1,447		1,771	
Selling, general and administrative		3,973		3,765	7,991		7,776	
Research and development		1,297		643	 2,607		1,122	
Total costs and expenses		6,105		5,278	12,045		10,669	
Loss from operations		(4,428)		(4,179)	 (9,153)		(8,533)	
Loss before income taxes		(4,428)		(4,179)	(9,153)		(8,533)	
Income tax expense		(2)		(2)	 (4)		(2)	
Net loss	\$	(4,430)	\$	(4,181)	\$ (9,157)	\$	(8,535)	
Basic and diluted loss per share	\$	(1.93)	\$	(13.03)	\$ (8.82)	\$	(28.03)	
Weighted average shares outstanding – basic and diluted		2,295		321	1,550		304	
Other comprehensive loss:								
Foreign currency translation adjustments	\$	(3)	\$	(2)	\$ (5)	\$	(1)	
Total comprehensive loss	\$	(4,433)	\$	(4,183)	\$ (9,162)	\$	(8,536)	

## CHF SOLUTIONS, INC. AND SUBSIDIARIES Condensed Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	J	June 30, 2019	Dec	ember 31, 2018
ASSETS	<b>(</b> u	naudited)		
Current assets				
Cash and cash equivalents	\$	7,402	\$	5,480
Accounts receivable		932		786
Inventory		1,690		1,658
Other current assets		278		203
Total current assets		10,302		8,127
Property, plant and equipment, net		574		536
Operating lease right-of-use asset		531		
Other assets		21		113
TOTAL ASSETS	\$	11,428	\$	8,776
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities				
Accounts payable	\$	1,178	\$	1,133
Accrued compensation	Ψ	1,186	Ψ	1,498
Current portion of operating lease liability		1,100		1,450
Other current liabilities		97		209
Total current liabilities		2,637		2,840
		<b>2,03</b> 7 357		2,040
Operating lease liability		<b>2,994</b>		2,840
Total liabilities		2,994		2,840
Commitments and contingencies		—		
Stockholders' equity				
Series A junior participating preferred stock as of June 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 June 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 June 30, 2019 and December 31, 2018, par value \$0.0001 per share;				
authorized 550,842 and 0 shares, respectively, issued and outstanding 550,842 and 0, respectively				
Preferred stock as of June 30, 2019 and December 31, 2018, par value \$0.0001 per share; authorized 39,418,623 and				
39,969,465 shares, none outstanding		—		—
Common stock as of June 30, 2019 and December 31, 2018, par value \$0.0001 per share; authorized 100,000,000				
shares, issued and outstanding 2,328,320 and 513,445, respectively		—		_
Additional paid-in capital		215,761		204,101
Accumulated other comprehensive income:				
Foreign currency translation adjustment		1,218		1,223
Accumulated deficit		(208,545)		(199,388)
Total stockholders' equity		8,434		5,936
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$	11,428	\$	8,776

# 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			tockholders' Equity
Balance December 31, 2017	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 and stock awards, net	3		_		501		_		_		501
Conversion of preferred stock into common stock	32,365		_		_		_		_		_
Balance March 31, 2018	303,725	\$	_	\$	197,868	\$	1,228	\$	(186,710)	\$	12,386
Net loss									(4,181)		(4,181)
Foreign currency translation adjustment	—						(2)		_		(2)
Stock-based compensation, net	3				606				—		606
Conversion of preferred stock into common stock	18,127		_		_		_		_		_
Balance June 30, 2018	321,855	\$	_	\$	198,474	\$	1,226	\$	(190,891)	\$	8,809

	Outstanding Shares of Common Common Stock Stock		Additional Paid in Capital		Accumulated Other Comprehensive Income		A	ccumulated Deficit	Stockholders' Equity		
Balance December 31, 2018	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										
Balance March 31, 2019	2,069,020	\$		\$	215,422	\$	1,221	\$	(204,115)	\$	12,528
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				—						—
Balance June 30, 2019	2,328,320	\$		\$	215,761	\$	1,218	\$	(208,545)	\$	8,434

#### CHF SOLUTIONS, INC. AND SUBSIDIARIES Condensed Consolidated Statements of Cash Flows

(Unaudited and in thousands)

	Six months ended June 30,			
	2019	2018		
Operating Activities:				
Net loss	\$ (9,157)	\$ (8,535)		
Adjustments to reconcile net loss to cash flows used in operating activities:				
Depreciation and amortization	120	115		
Stock-based compensation expense, net	701	1,107		
Changes in operating assets and liabilities:				
Accounts receivable	(146)	(107)		
Inventory	(32)	(727)		
Other current assets	(75)	(48)		
Other assets and liabilities	(18)	—		
Accounts payable and accrued expenses	 (267)	(283)		
Net cash used in operating activities	(8,874)	(8,478)		
Investing Activities:				
Purchases of property and equipment	(158)	(121)		
Net cash used in investing activities	(158)	(121)		
Financing Activities:				
Net proceeds from public stock offering, net	10,959	_		
Net cash provided by financing activities	10,959			
Effect of exchange rate changes on cash	(5)	(1)		
Net increase (decrease) in cash and cash equivalents	1,922	(8,600)		
Cash and cash equivalents - beginning of period	5,480	15,595		
Cash and cash equivalents - end of period	\$ 7,402	\$ 6,995		

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 <u>http://ir.chf-solutions.com</u> or access the webcast directly at <u>http://ir.chf-solutions.com/events</u>. Alternatively, you may access the live conference call by dialing (877) 303-9826 (U.S.) or (224) 357-2194 (international) and using conference ID: 6292209 An audio archive of the webcast will be available following the call on the Investor page at <u>http://ir.chf-solutions.com/events</u>.

#### **About CHF Solutions**

CHF Solutions, Inc. (NASDAQ:CHFS) is a medical device company focused on developing, manufacturing and commercializing the Aquadex FlexFlow system for aquapheresis therapy. The Aquadex FlexFlow system is a clinically proven therapy that provides a safe, effective and predictable method of removing excess sodium and 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 extended (longer than 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization. All treatments must be administered by a healthcare provider, under physician prescription, both of whom having received training in extracorporeal therapies. The company's vision is to change the lives of fluid overloaded patients through science, collaboration, and innovative medical technology. 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.

#### **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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