

**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): **May 11, 2021**

Nuwellis, 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	NUWE	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 May 11, 2021, Nuwellis, Inc. (the “Company”) issued a press release reporting its financial results for the three months ended March 31, 2021. 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 May 11, 2021, reporting the financial results of Nuwellis, Inc. for the three months ended March 31, 2021.

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: May 11, 2021

NUWELLIS, INC.

By: /s/ Nestor Jaramillo

Name: Nestor Jaramillo

Title: President, Chief Executive Officer,
and Interim Chief Financial Officer



Nuwellis, Inc. Announces 18 Percent Increase in Revenue for First Quarter 2021 Over Previous Year and Provides Company Update

Eden Prairie, MN: May 11, 2021: (GLOBE NEWSWIRE) Nuwellis, Inc. (Nasdaq: NUWE) (previously CHF Solutions, Inc.) announced today its results for the first quarter ended March 31, 2021, which included the following highlights:

- Completed corporate rebranding from CHF Solutions, Inc. to Nuwellis, Inc. on April 27, 2021
- Revenue for the first quarter ended March 31, 2021, was \$1.9 million, an increase of 18 percent compared to the prior year period
- Increased Aquadex therapy utilization amongst strategic Critical Care accounts; highest levels seen in the past five quarters
- Enrolled first pediatric patient into clinical registry in April 2021
- Received strong endorsements for Category III CPT code application from two major medical societies
- Ended the quarter with \$27.9 million in cash and no debt

“Following our most recent \$20.9 million capital raise with net proceeds of \$18.9 million on March 19, 2021, Nuwellis is in a strong position to execute against our long-term strategic growth plan,” said Nestor Jaramillo, CEO of Nuwellis. “While COVID-19 headwinds persisted during the quarter, we continue to see strong growth in capital equipment sales and utilization among Critical Care and Pediatric accounts. Lastly, we completed our corporate rebranding to Nuwellis, Inc. in late April 2021. When we expanded the therapeutic focus areas we serve to include pediatrics, critical care and heart failure, we realized our name was no longer a true representation of what we do. As a provider of innovative medical technology, we have an obligation and duty to help improve outcomes for as many patients as possible.”

First Quarter 2021 Financial Results

Revenue for the first quarter of 2021 was \$1.9 million, an increase of 18% compared to \$1.6 million in the prior year period. Revenue growth in the first quarter of 2021 was primarily driven by increased capital equipment sales and strong utilization within Critical Care. The Company also continued to see increasing utilization among established pediatric accounts during the quarter.

Gross margin was 50.4% for the first quarter 2021, compared to 51.2% in the prior year period. The decline in gross margins was primarily due to strong sales of capital equipment. When compared to the prior year period, first quarter 2021 revenue mix was more heavily weighted towards capital equipment sales in the Critical Care and Pediatric segments. Quarterly gross margins are dependent on revenue mix, but to the extent that the install base of Aquadex systems grows, the Company expects that gross margins will increase with higher levels of consumable utilization.

Selling, general and administrative (“SG&A”) expenses for the first quarter of 2021 were \$5.2 million, an increase of 15% compared to the prior year period. The increase in SG&A was primarily due to the timing of non-recurring administrative expenses and continued investment in sales and marketing activities. Research and development (“R&D”) expenses in the first quarter of 2021 were \$0.9 million, an increase of 10% compared to the prior year period. The increase in R&D expenses was driven primarily by clinical expenditures related to the pediatric registry.

The net loss for the first quarter of 2021 was \$5.2 million, compared to a net loss of \$4.6 million in the prior year period.

Cash and cash equivalents were \$27.9 million with no debt as of March 31, 2021. During the first quarter of 2021, the Company used \$5.4 million of cash in operations. The Company also completed a \$20.9 million capital raise with net proceeds of \$18.9 million on March 19, 2021.

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.nuwellis.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: 2282685. An audio archive of the webcast will be available following the call at <http://ir.nuwellis.com/events>.

About Nuwellis

Nuwellis, Inc. (Nasdaq:NUWE), formally CHF Solutions, 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. Nuwellis is headquartered in Minneapolis, Minn., with a wholly-owned subsidiary in Ireland. The Company has been listed on the Nasdaq Capital Market since February 2012, previously branded as CHF Solutions (Nasdaq:CHFS).

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 new market opportunities and anticipated growth in 2021 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 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. Nuwellis 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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FINANCIALS
NUWELLIS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited, in thousands, except per share amounts)

	Three months ended	
	March 31,	
	2021	2020
Net sales	\$ 1,918	\$ 1,630
Cost of goods sold	952	796
Gross margin	<u>966</u>	<u>834</u>
Operating expenses:		
Selling, general and administrative	5,237	4,537
Research and development	947	864
Total operating expenses	<u>6,184</u>	<u>5,401</u>
Loss from operations	(5,218)	(4,567)
Other income (expense), net	(1)	1
Loss before income taxes	(5,219)	(4,566)
Income tax expense	(2)	(2)
Net loss	<u>\$ (5,221)</u>	<u>\$ (4,568)</u>
Basic and diluted loss per share	<u>\$ (1.25)</u>	<u>\$ (11.54)</u>
Weighted average shares outstanding – basic and diluted	4,212	548
Other comprehensive loss:		
Foreign currency translation adjustments	\$ (3)	\$ (3)
Total comprehensive loss	<u>\$ (5,224)</u>	<u>\$ (4,571)</u>

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

	March 31, 2021 <u>(unaudited)</u>	December 31, 2020 <u></u>
ASSETS		
Current assets		
Cash and cash equivalents	\$ 27,893	\$ 14,437
Accounts receivable	919	905
Inventory	2,957	2,957
Other current assets	369	237
Total current assets	32,138	18,536
Property, plant and equipment, net	1,219	1,200
Operating lease right-of-use asset	206	255
Other assets	—	21
TOTAL ASSETS	\$ 33,563	\$ 20,012
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,613	\$ 1,097
Accrued compensation	1,245	2,192
Current portion of operating lease liability	212	206
Current portion of finance lease liability	24	24
Other current liabilities	69	66
Total current liabilities	3,163	3,585
Operating lease liability	—	55
Finance lease liability	48	54
Total liabilities	3,211	3,694
Commitments and contingencies	—	—
Stockholders' equity		
Series A junior participating preferred stock as of March 31, 2021 and December 31, 2020, par value \$0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Series F convertible preferred stock as of March 31, 2021 and December 31, 2020, par value \$0.0001 per share; authorized 127 shares, issued and outstanding 127 shares	—	—
Preferred stock as of March 31, 2021 and December 31, 2020, par value \$0.0001 per share; authorized 39,969,873 shares, none outstanding	—	—
Common stock as of March 31, 2021 and December 31, 2020, par value \$0.0001 per share; authorized 100,000,000 shares, issued and outstanding 6,531,942 and 2,736,060, respectively	—	—
Additional paid-in capital	268,921	249,663
Accumulated other comprehensive loss:		
Foreign currency translation adjustment	(10)	(7)
Accumulated deficit	(238,559)	(233,338)
Total stockholders' equity	30,352	16,318
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 33,563	\$ 20,012

NUWELLIS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
(unaudited, in thousands)

	Three months ended	
	March 31,	
	2021	2020
Operating Activities:		
Net loss	\$ (5,221)	\$ (4,568)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	126	65
Stock-based compensation expense, net	355	380
Loss on disposal of property and equipment	—	46
Changes in operating assets and liabilities:		
Accounts receivable	(14)	72
Inventory	(89)	(398)
Other current assets	(132)	20
Other assets and liabilities	24	67
Accounts payable and accrued expenses	(431)	(1,179)
Net cash used in operating activities	(5,382)	(5,495)
Investing Activities:		
Purchases of property and equipment	(56)	(17)
Net cash used in investing activities	(56)	(17)
Financing Activities:		
Proceeds from public stock offerings, net	18,902	9,616
Proceeds from warrant exercises	1	289
Payments on finance lease liability	(6)	—
Net cash provided by financing activities	18,897	9,905
Effect of exchange rate changes on cash	(3)	(3)
Net increase in cash and cash equivalents	13,456	4,390
Cash and cash equivalents - beginning of period	14,437	1,279
Cash and cash equivalents - end of period	\$ 27,893	\$ 5,669
Supplemental cash flow information		
Inventory transferred to property, plant and equipment	\$ 89	\$ —

CONTACTS:

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