

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 1, 2022**

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 March 1, 2022, Nuwellis, Inc. (the “Company”) issued a press release reporting its financial results for the twelve months ended December 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 March 1, 2022, reporting the financial results of Nuwellis, Inc. for the twelve months ended December 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: March 1, 2022

NUWELLIS, INC.

By: /s/ Nestor Jaramillo

Name: Nestor Jaramillo

Title: President and Chief Executive Officer



Nuwellis, Inc. Announces Fourth Quarter and Full Year 2021 Financial Results

Minneapolis, MN, March 1, 2022 (GLOBE NEWSWIRE) -- Nuwellis, Inc. (Nasdaq: NUWE) announced today its results for the fourth quarter and full year ended December 31, 2021, which included the following highlights:

- Generated \$1.6 million in total revenue for the fourth quarter 2021, 19.6% below the prior-year period and a 20% increase above the comparable pre-pandemic period in 2019.
- Generated \$7.9 million in total revenue for the fiscal year 2021, representing 6.5% growth compared to the prior-year period and a 44% increase above the comparable pre-pandemic period in 2019
- Announced the commencement of the REVERSE-HF randomized controlled multi-center trial designed to validate Aquadex therapy as a first-line treatment option for re-hospitalized heart failure patients
- Received a Category III CPT Code effective January 1, 2022 specifically for the use of therapeutic ultrafiltration, thereby increasing reimbursement to professionals and facilities, an important step in advancing Aquadex to standard of care
- Ended 2021 with approximately \$24.2 million in cash and no debt

“We are encouraged by our progress executing our strategy throughout 2021. Our organization and its employees continued to show adaptability and resilience amid changing market conditions and customer requirements, and we ultimately succeeded in helping more patients benefit from our therapy during the year.” said Nestor Jaramillo, CEO of Nuwellis. “We anticipate that when this most recent Omicron variant wave dissipates, we will see accelerating sales growth by continuing to position ourselves as the primary provider of ultrafiltration therapy for treating patients suffering from fluid overload that are refractory to diuretics.”

Fourth Quarter 2021 Financial Results

Revenue for the fourth quarter of 2021 was \$1.6 million, compared to \$2.0 million the prior year period. The decrease was primarily due to lower U.S. product sales, which was affected by order timing, hospital budgetary constraints, and a reduction in elective procedures due to COVID headwinds. When comparing fourth quarter of 2021 to the pre-pandemic fourth quarter of 2019, U.S. product revenue increased 20%.

In the fourth quarter of 2021, Pediatrics posted positive sequential growth due to increased patient census in numerous accounts following an uncharacteristically low third quarter. Heart Failure was also modestly up sequentially, while Critical Care was down due to a combination of fewer new accounts, order timing and reduced utilization.

Gross margin was 54.4% for the fourth quarter 2021, compared to 56.1% in the prior-year period based on volume and an unfavorable product and geographic mix. In contrast, volume and favorable mix increased full-year gross margin to 56.7%, a 2.2% increase compared to prior year.

Selling, general and administrative (“SG&A”) expenses for the fourth quarter of 2021 were \$4.1 million, representing a decline of 7% compared to the prior year period and 12% below third quarter of 2021 levels. Vigilant cost management amid the uncertain market environment led to our lowest quarterly SG&A spend in more than two years. For full year 2021, SG&A expenses were \$19.0 million, a 9% increase from prior year due to sales and marketing investments plus non-recurring management transition and administrative costs earlier in the year.

The net loss for the fourth quarter of 2021 was \$4.4 million, compared to a net loss of \$3.1 million in the prior year period. The primary difference in net loss compared to the prior year period is due to a one-time foreign currency translation gain of \$1.2 million dollars resulting from the dissolution of an inactive Australian subsidiary.

Cash and cash equivalents were approximately \$24.2 million as of December 31, 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>. Alternatively, you may access the live conference call by dialing (877) 303-9826 (U.S.) or (224) 357-2194 (international) and using conference ID: 9353528. An audio archive of the webcast will be available following the call at <http://ir.nuwellis.com>.

About Nuwellis

Nuwellis, Inc. (Nasdaq: NUWE) is a medical device company dedicated to transforming 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, MN, with a wholly-owned subsidiary in Ireland.

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 2022 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 risks 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.

NUWELLIS, INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except per share amounts)

	Three months ended December 31,		Twelve months ended December 31,	
	2021	2020	2021	2020
Net sales	\$ 1,642	\$ 2,044	\$ 7,921	\$ 7,441
Cost of goods sold	748	897	3,430	3,384
Gross profit	894	1,147	4,491	4,057
Operating expenses:				
Selling, general and administrative	4,094	4,384	19,039	17,417
Research and development	1,131	1,047	4,978	3,668
Total operating expenses	5,225	5,431	24,017	21,085
Loss from operations	(4,331)	(4,284)	(19,526)	(17,028)
Realized foreign currency translation gain from dissolution of subsidiary	-	1,202	-	1,202
Other income (expense), net	(21)	(2)	(43)	(1)
Loss before income taxes	(4,352)	(3,084)	(19,569)	(15,827)
Income tax expense	(2)	(2)	(9)	(9)
Net loss	\$ (4,354)	\$ (3,086)	\$ (19,578)	\$ (15,836)
Basic and diluted loss per share	\$ (0.41)	\$ (1.13)	\$ (2.87)	\$ (10.67)
Weighted average shares outstanding – basic and diluted	10,538	2,736	6,852	1,649
Other comprehensive loss:				
Realized foreign currency translation gain from dissolution of subsidiary	\$ -	\$ (1,202)	\$ -	\$ (1,202)
Unrealized foreign currency translation adjustments	(1)	(12)	(4)	(19)
Total comprehensive loss	\$ (4,355)	\$ (4,300)	\$ (19,582)	\$ (17,057)

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

	<u>December 31, 2021</u>	<u>December 31, 2020</u>
ASSETS		
Current assets		
Cash and cash equivalents	\$ 24,205	\$ 14,437
Accounts receivable	750	905
Inventories	2,843	2,957
Other current assets	328	237
Total current assets	<u>28,126</u>	<u>18,536</u>
Property, plant and equipment, net	1,188	1,200
Operating lease right-of-use asset, net	1,082	255
Other assets	21	21
TOTAL ASSETS	<u>\$ 30,417</u>	<u>\$ 20,012</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,414	\$ 1,097
Accrued compensation	1,664	2,192
Current portion of operating lease liability	167	206
Current portion of finance lease liability	26	24
Other current liabilities	36	66
Total current liabilities	<u>3,307</u>	<u>3,585</u>
Operating lease liability	956	55
Finance lease liability	28	54
Other long-term liability	179	—
Total liabilities	<u>4,470</u>	<u>3,694</u>
Commitments and contingencies		
Stockholders' equity		
Series A junior participating preferred stock as of December 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 December 31, 2021 and December 31, 2020, par value \$0.0001 per share; authorized 127 shares, issued and outstanding 127 shares	—	—
Preferred stock as of December 31, 2021 and December 31, 2020, par value \$0.0001 per share; authorized 39,969,873 shares, none outstanding	—	—
Common stock as of December 31, 2021 and December 31, 2020, par value \$0.0001 per share; authorized 100,000,000 shares, issued and outstanding 10,537,606 and 2,736,060, respectively	1	—
Additional paid-in capital	278,873	249,663
Accumulated other comprehensive income:		
Foreign currency translation adjustment	(11)	(7)
Accumulated deficit	(252,916)	(233,338)
Total stockholders' equity	<u>25,947</u>	<u>16,318</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 30,417</u>	<u>\$ 20,012</u>

NUWELLIS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows
(In thousands)

	For the years ended December 31,	
	2021	2020
Operating Activities		
Net loss	\$ (19,578)	\$ (15,836)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	488	376
Stock-based compensation expense, net	1,314	1,349
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	155	(106)
Inventory	(143)	(1,420)
Other current assets	(91)	(76)
Other assets and liabilities	186	112
Accounts payable and accrued expenses	(211)	191
Net cash used in operations	(17,880)	(16,572)
Investing activities:		
Purchase of property and equipment	(219)	(298)
Proceeds from the sale of property and equipment	—	31
Net cash used in investing activities	(219)	(267)
Financing activities:		
Proceeds from public stock offerings, net	27,896	25,921
Proceeds from warrant exercises	1	4,115
Payments on finance lease liability	(26)	(20)
Net cash provided by financing activities	27,871	30,016
Effect of exchange rate changes on cash	(4)	(19)
Net increase (decrease) in cash and cash equivalents	9,768	13,158
Cash and cash equivalents—beginning of year	14,437	1,279
Cash and cash equivalents—end of year	\$ 24,205	\$ 14,437
Supplemental schedule of non-cash activities		
Inventory transferred to property, plant and equipment	\$ 257	\$ 260
Equipment acquired through finance lease liability	\$ —	\$ 98
Operating right-of-use asset recorded as an operating lease liability	\$ 901	\$ —
Supplemental cash flow information		
Cash paid for income taxes	\$ 11	\$ 10

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