

**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 10, 2022**

**Nuwellis, Inc.**

(Exact Name of Registrant as Specified in its Charter)

<b>Delaware</b> (State or Other Jurisdiction of Incorporation or Organization)	<b>001-35312</b> (Commission File Number)	<b>No. 68-0533453</b> (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) NUWE	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 May 10, 2022, Nuwellis, Inc. (the “Company”) issued a press release reporting its financial results for the three months ended March 31, 2022. 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**

<a href="#">99.1</a>	Press Release, dated May 10, 2022, reporting the financial results of Nuwellis, Inc. for the three months ended March 31, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

---

**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 10, 2022

**NUWELLIS, INC.**

By: /s/ Nestor Jaramillo  
Name: Nestor Jaramillo  
Title: President and Chief Executive Officer

---

**Nuwellis, Inc. Announces First Quarter 2022 Financial Results**

Minneapolis, MN, May 10, 2022 (GLOBE NEWSWIRE) -- Nuwellis, Inc. (Nasdaq: NUWE) announced today its results for the first quarter ended March 31, 2022, which included the following highlights:

- Generated \$1.9 million in total revenue for the first quarter 2022, up 17% sequentially from the fourth quarter of 2021
- 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
- On track to enroll first patients in REVERSE-HF, a randomized controlled multi-center clinical trial designed to validate clinical outcomes and the economic value of Aquadex therapy
- First quarter 2022 cash flow from operations improved \$0.6 million compared to the prior-year period

“I am very pleased with the resilient performance in the quarter” said Nestor Jaramillo, CEO of Nuwellis. “Going forward, we expect to continue benefiting from the successful execution of our strategy and rollout of our new sales management system.”

**First Quarter 2022 Financial Results**

Total revenue for the first quarter of 2022 was \$1.9 million, an increase of 17% compared to the fourth quarter of 2021 and even with the prior-year period. Growth in the quarter was fueled by higher sales of consumables. Capital equipment sales increased sequentially but were below the prior year, while total monthly year-on-year sales comparisons improved as the business advanced through the quarter.

Gross margin was 57.2% for the first quarter 2022, compared to 50.4% in the prior-year period, with the increase driven primarily by favorable product sales mix and reduced inventory revaluation expense.

Selling, general and administrative expenses for the first quarter of 2022 were \$4.4 million, representing a 16% reduction compared to the prior-year period. This reduction resulted from continued cost vigilance and certain non-recurring administrative costs in the prior-year period.

First-quarter research and development expenses were \$1.1 million dollars, compared to \$0.9 million dollars in the first quarter of 2021. This increase reflects investment in our dedicated pediatric device.

The net loss for the first quarter of 2022 was \$4.5 million, compared to a net loss of \$5.2 million in the prior-year period. This resulted in \$0.6 million lower net cash used in operating activities.

Cash and cash equivalents were approximately \$19.3 million as of March 31, 2022.

---

**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: 6092276. 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 SUBSIDIARY**  
Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)  
(In thousands, except per share amounts)

	<b>Three months ended</b>	
	<b>March 31,</b>	
	<b>2022</b>	<b>2021</b>
<b>Net sales</b>	\$ 1,926	\$ 1,918
Cost of goods sold	824	952
Gross profit	<u>1,102</u>	<u>966</u>
<b>Operating expenses:</b>		
Selling, general and administrative	4,412	5,237
Research and development	1,106	947
Total operating expenses	<u>5,518</u>	<u>6,184</u>
Loss from operations	(4,416)	(5,218)
Other income (expense), net	(55)	(1)
Loss before income taxes	(4,471)	(5,219)
Income tax expense	(2)	(2)
<b>Net loss</b>	<u>\$ (4,473)</u>	<u>\$ (5,221)</u>
<b>Basic and diluted loss per share</b>	<u>\$ (0.42)</u>	<u>\$ (1.62)</u>
Weighted average shares outstanding – basic and diluted	10,538	3,242
<b>Other comprehensive loss:</b>		
Unrealized foreign currency translation adjustments	\$ (2)	\$ (3)
<b>Total comprehensive loss</b>	<u>\$ (4,475)</u>	<u>\$ (5,224)</u>

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

	<b>March 31, 2022</b>	<b>December 31, 2021</b>
	<b>(unaudited)</b>	
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 19,300	\$ 24,205
Accounts receivable	951	750
Inventories	3,294	2,843
Other current assets	350	328
<b>Total current assets</b>	<b>23,895</b>	<b>28,126</b>
Property, plant and equipment, net	1,153	1,188
Operating lease right-of-use asset	1,038	1,082
Other assets	21	21
<b>TOTAL ASSETS</b>	<b>\$ 26,107</b>	<b>\$ 30,417</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 1,797	\$ 1,414
Accrued compensation	1,335	1,664
Current portion of operating lease liability	181	167
Current portion of finance lease liability	24	26
Other current liabilities	55	36
<b>Total current liabilities</b>	<b>3,392</b>	<b>3,307</b>
Operating lease liability	909	956
Finance lease liability	22	28
Other long-term liability	71	179
<b>Total liabilities</b>	<b>4,394</b>	<b>4,470</b>
Commitments and contingencies		
<b>Stockholders' equity</b>		
Series A junior participating preferred stock as of March 31, 2022 and December 31, 2021, par value \$0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Series F convertible preferred stock as of both March 31, 2022 and December 31, 2021, par value \$0.0001 per share; authorized 127 shares, issued and outstanding 127 shares	—	—
Preferred stock as of both March 31, 2022 and December 31, 2021, par value \$0.0001 per share; authorized 39,969,873 shares, none outstanding	—	—
Common stock as of March 31, 2022 and December 31, 2021, par value \$0.0001 per share; authorized 100,000,000 shares, issued and outstanding 10,537,606 shares	1	1
Additional paid-in capital	279,114	278,873
Accumulated other comprehensive income:		
Foreign currency translation adjustment	(13)	(11)
Accumulated deficit	(257,389)	(252,916)
<b>Total stockholders' equity</b>	<b>21,713</b>	<b>25,947</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 26,107</b>	<b>\$ 30,417</b>

**NUWELLIS, INC. AND SUBSIDIARY**  
Condensed Consolidated Statements of Cash Flows  
(Unaudited)  
(in thousands)

	<b>Three months ended</b>	
	<b>March 31,</b>	
	<b>2022</b>	<b>2021</b>
<b>Operating Activities:</b>		
Net loss	\$ (4,473)	\$ (5,221)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	105	126
Stock-based compensation expense, net	241	355
Changes in operating assets and liabilities:		
Accounts receivable	(201)	(14)
Inventory	(451)	(89)
Other current assets	(22)	(132)
Other assets and liabilities	(80)	24
Accounts payable and accrued expenses	54	(431)
<b>Net cash used in operating activities</b>	<b>(4,827)</b>	<b>(5,382)</b>
<b>Investing Activities:</b>		
Purchases of property and equipment	(70)	(56)
<b>Net cash used in investing activities</b>	<b>(70)</b>	<b>(56)</b>
<b>Financing Activities:</b>		
Proceeds from public stock offerings, net	—	18,902
Proceeds from warrant exercises	—	1
Payments on finance lease liability	(6)	(6)
<b>Net cash provided (used in) by financing activities</b>	<b>(6)</b>	<b>18,897</b>
Effect of exchange rate changes on cash	(2)	(3)
Net increase in cash and cash equivalents	(4,905)	13,456
Cash and cash equivalents - beginning of period	24,205	14,437
<b>Cash and cash equivalents - end of period</b>	<b>\$ 19,300</b>	<b>\$ 27,893</b>
<b>Supplemental cash flow information</b>		
Inventory transferred to property, plant and equipment	\$ —	\$ 89

# # #

**INVESTOR CONTACTS:**

George Montague, CFA  
Chief Financial Officer, Nuwellis, Inc.  
[ir@nuwellis.com](mailto:ir@nuwellis.com)

Matt Bacso, CFA  
Gilmartin Group  
[Matt.Bacso@gilmartinir.com](mailto:Matt.Bacso@gilmartinir.com)