

**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 7, 2024

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 7, 2024, Nuwellis, Inc. (the “Company”) issued a press release reporting its financial results for the three months ended March 31, 2024. 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 7, 2024, reporting the financial results of Nuwellis, Inc. for the three months ended March 31, 2024.

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 7, 2024

NUWELLIS, INC.

By: /s/ NESTOR JARAMILLO, JR.
Name: Nestor Jaramillo, Jr.
Title: President and Chief Executive Officer



Nuwellis, Inc. Announces First Quarter 2024 Financial Results

Minneapolis, MN, May 7, 2024 (GLOBE NEWSWIRE) -- Nuwellis, Inc. (Nasdaq: NUWE), a medical technology company focused on transforming the lives of people with fluid overload, today reported financial results for the first quarter ended March 31, 2024.

Highlights:

- Revenue of \$1.9 million, a 2% increase over the prior-year period.
- Consumables sales, representing 82% of total revenue, grew 11% year-over-year.
- Pediatric revenue growth of 40% year over year led by a 54% increase in consumable sales.
- Gross margin of 64.1%, compared to 58.4% in the prior year period.
- Received FDA clearance for an additional dual lumen extended length catheter.
- Launched Aquadex[®] ultrafiltration therapy for heart failure patients as a part of Nuwellis' pivotal REVERSE-HF clinical study at Henry Ford Health.
- Company anticipates significant expense reductions – approaching 50% – through efficiency initiatives for the rest of the calendar year.

“We are pleased to see firm utilization, led by Pediatrics and in Critical Care, driving first-quarter revenue,” said Nestor Jaramillo, President and CEO of Nuwellis. “Increased awareness of the clinical and economic benefits of the Aquadex system continues to result in healthy utilization gains demonstrating increased therapy adoption as we navigate capital sales cycles. We look forward to continued positive momentum and growth in 2024 as we provide increased access optionality and a new source of revenue with our new 12 cm catheter, advance our pilot phase with DaVita, and begin to commercialize Quelimune[™] SCD under our exclusive license and distribution agreement with SeaStar Medical (Nasdaq “ICU”).”

First Quarter 2024 Financial Results

Revenue for the first quarter of 2024 was \$1.9 million, a 2% increase compared to the prior-year period. The year-over-year increase is attributable to an 11% increase in consumable sales.

Gross margin was 64.1% for the first quarter of 2024, compared to 58.4% in the prior-year period. The increase was primarily due to higher manufacturing volumes of consumables.

Selling, general and administrative expenses for the first quarter of 2024 decreased to \$4.6 million, compared to \$5.5 million in the prior-year period. The decrease in SG&A expenses was primarily due to reduced headcount and compensation-related expense and lower corporate administrative expenses.

First quarter research and development expenses were \$1.3 million, compared to \$1.4 million in the prior-year period.

Total operating expenses for the first quarter of 2024 were \$5.9 million, a 14% decrease compared to \$6.9 million in the prior-year period. The \$1 million decrease was due to cost saving measures implemented early in the second half of 2023 and carried forward to the current period as we continue to drive operating efficiencies.

Operating loss for the first quarter of 2024 decreased to \$4.7 million compared to an operating loss of \$5.8 million in the prior-year period.

Net loss attributable to common shareholders for the first quarter of 2024 was \$3.8 million, or a loss of \$0.60 per basic and diluted common share, compared to a net loss attributable to common shareholders of \$6.5 million, or a loss of \$5.76 per basic and diluted common share in the prior-year period.

At March 31, 2024, the Company had no debt, cash and cash equivalents of approximately \$1.4 million, and approximately 6.8 million common shares outstanding. On April 30, Nuwellis closed an underwritten public offering with gross proceeds of \$2.7 million before deducting underwriting discounts and commissions related to the offering.

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 the Investors page of the Nuwellis website at <https://ir.nuwellis.com>. Alternatively, you may access the live conference call by dialing 1-833-816-1404 (U.S) or 1-412-317-0497 (international) and using the conference ID: 10188299. An audio archive of the webcast will be available following the call on the Investors page at <https://ir.nuwellis.com>.

About Nuwellis

Nuwellis, Inc. (Nasdaq: NUWE) is a medical technology company dedicated to transforming the lives of patients suffering from fluid overload through science, collaboration, and innovation. The company is focused on commercializing the Aquadex SmartFlow[®] system for ultrafiltration therapy. Nuwellis is headquartered in Minneapolis, with a wholly owned subsidiary in Ireland. For more information visit ir.nuwellis.com or visit us on [LinkedIn](#) or [X](#).

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 may be considered 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 2024 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 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 due to new information, future events or otherwise.

CONTACTS

INVESTORS:

Vivian Cervantes

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PART I—FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS
NUWELLIS, INC. AND SUBSIDIARY
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	March 31, 2024	December 31, 2023
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 1,400	\$ 3,800
Accounts receivable	1,226	1,951
Inventories, net	2,131	1,997
Other current assets	440	461
Total current assets	5,197	8,209
Property, plant and equipment, net	681	728
Operating lease right-of-use asset	664	713
Other assets	120	120
TOTAL ASSETS	\$ 6,662	\$ 9,770
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 3,332	\$ 2,380
Accrued compensation	725	525
Current portion of operating lease liability	221	216
Other current liabilities	45	51
Total current liabilities	4,323	3,172
Common stock warrant liability	964	2,843
Operating lease liability	488	544
Total liabilities	5,775	6,559
Commitments and contingencies		
Mezzanine Equity		
Series J Convertible Preferred Stock as of March 31, 2024 and December 31, 2023, par value \$0.0001 per share; authorized 600,000 shares, issued and outstanding 82 and 11,950, respectively	2	221
Stockholders' equity		
Series A junior participating preferred stock as of March 31, 2024 and December 31, 2023, par value \$0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Series F convertible preferred stock as of March 31, 2024 and December 31, 2023, par value \$0.0001 per share; authorized 18,000 shares, issued and outstanding 127 shares	—	—
Preferred stock as of March 31, 2024 and December 31, 2023, par value \$0.0001 per share; authorized 39,352,000 shares, none outstanding	—	—
Common stock as of March 31, 2024 and December 31, 2023, par value \$0.0001 per share; authorized 100,000,000 shares, issued and outstanding 6,801,443 and 5,682,461, respectively	1	1
Additional paid-in capital	292,880	290,646
Accumulated other comprehensive income:		
Foreign currency translation adjustment	(40)	(31)
Accumulated deficit	(291,956)	(287,626)
Total stockholders' equity	885	2,990
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY	\$ 6,662	\$ 9,770

NUWELLIS, INC. AND SUBSIDIARY
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except per share amounts and weighted average shares outstanding)

	Three months ended	
	March 31	
	2024	2023
Net sales	\$ 1,857	\$ 1,826
Cost of goods sold	666	759
Gross profit	<u>1,191</u>	<u>1,067</u>
Operating expenses:		
Selling, general and administrative	4,606	5,490
Research and development	1,334	1,428
Total operating expenses	<u>5,940</u>	<u>6,918</u>
Loss from operations	(4,749)	(5,851)
Other income (expense), net	(101)	123
Change in fair value of warrant liability	522	(755)
Loss before income taxes	<u>(4,328)</u>	<u>(6,483)</u>
Income tax expense	(2)	(2)
Net loss	<u>(4,330)</u>	<u>(6,485)</u>
Deemed dividend attributable to Series J Convertible Preferred Stock	541	—
Net loss attributable to common shareholders	<u>\$ (3,789)</u>	<u>\$ (6,485)</u>
Basic and diluted loss per share	<u>\$ (0.60)</u>	<u>\$ (5.76)</u>
Weighted average shares outstanding – basic and diluted	6,286,298	1,125,993
Other comprehensive loss:		
Net loss	\$ (4,330)	\$ (6,485)
Unrealized gain on marketable securities	—	6
Foreign currency translation adjustments	(9)	(7)
Total comprehensive loss	<u>\$ (4,339)</u>	<u>\$ (6,486)</u>

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

	Three months ended March 31	
	2024	2023
Operating Activities:		
Net loss	\$ (4,330)	\$ (6,485)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	76	86
Stock-based compensation expense	158	181
Change in fair value of warrant liability	(522)	755
Changes in operating assets and liabilities:		
Accounts receivable	725	105
Inventory, net	(134)	(81)
Other current assets	21	(81)
Other assets and liabilities	(6)	(16)
Accounts payable and accrued expenses	1,150	(570)
Net cash used in operating activities	(2,862)	(6,106)
Investing Activities:		
Additions to intangible assets	—	(85)
Purchases of property and equipment	(29)	(13)
Net cash used in investing activities	(29)	(98)
Financing Activities:		
Issuance costs related to 2022 common stock offering	—	(11)
Proceeds from the exercise of Series J Convertible Preferred Warrants	500	—
Net cash provided by (used in) financing activities	500	(11)
Effect of exchange rate changes on cash	(9)	(7)
Net decrease in cash and cash equivalents	(2,400)	(6,222)
Cash and cash equivalents - beginning of period	3,800	17,737
Cash and cash equivalents - end of period	\$ 1,400	\$ 11,515
Supplemental cash flow information		
Issuance of Series J Preferred Stock for exercise of Warrants	\$ 1,857	\$ —
Issuance of Common Stock for conversion of Series J Preferred Stock	\$ 1,535	\$ —
Deemed dividend on Series J Preferred Stock	\$ 541	\$ —