

**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 13, 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 August 13, 2024, Nuwellis, Inc. (the “Company”) issued a press release reporting its financial results for the three and six months ended June 30, 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 August 13, 2024, reporting the financial results of Nuwellis, Inc. for the three and six months ended June 30, 2024.
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: August 13, 2024

NUWELLIS, INC.

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

Nuwellis, Inc. Announces Second Quarter 2024 Financial Results

Minneapolis, MN, August 13, 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 second quarter ended June 30, 2024.

Highlights:

- Revenue of \$2.2 million, a 6% increase over the second quarter of 2023.
- Critical Care revenue growth of 28% compared to the prior year quarter; Heart Failure consumables utilization growth of 35% over the prior-year quarter.
- Gross margin of 67.2%, compared to 55.3% in the prior-year quarter.
- Total operating cost reduction of 38% compared to the prior-year quarter.
- Expanded Aquadex® to pediatric patients at one of the largest hospital networks in Florida.
- Announced purchase agreement with a 50-hospital network in Texas for Aquadex Ultrafiltration Therapy.

“Our second quarter 2024 results continue to demonstrate market traction for our Aquadex ultrafiltration therapy, with revenue growth driven by steady increases in consumables utilization, particularly in Critical Care and Heart Failure, supported by our growing body of clinical evidence that highlights the benefits of Aquadex for patients experiencing fluid overload who have not responded to traditional diuretic treatments. Of note, our higher margin consumables business continues to fuel manufacturing efficiencies, resulting in strong gross margin gains compared to the year ago period,” said Nestor Jaramillo, President and CEO of Nuwellis. “Bolstering our positive momentum in 2024, we are also excited to now expand our Pediatric product offerings with QUELIMMUNE™, providing our growing Pediatric network with a new therapy for acute kidney injury (AKI) and sepsis. This novel therapy comes to Nuwellis from our exclusive license and distribution agreement with SeaStar Medical Holding Corporation (Nasdaq: ICU).”

Second Quarter 2024 Financial Results

Revenue for the second quarter of 2024 was \$2.2 million, a 6% increase compared to the prior-year quarter. The year-over-year increase is attributable to a 30% increase in heart failure and critical care consumables utilization. Pediatrics had a 25% decline in utilization due to patient census.

Gross margin was 67.2% for the second quarter of 2024, compared to 55.3% in the prior-year quarter. The increase was primarily due to higher manufacturing volumes of consumables in the current year period and lower fixed overhead manufacturing expenses.

Selling, general and administrative expenses (SG&A) for the second quarter of 2024 decreased to \$3.2 million, compared to \$4.7 million in the prior-year quarter. The decrease in SG&A expense was primarily realized through efficiency initiatives enacted in the second half of 2023.

Second quarter research and development (R&D) expenses were \$558 thousand, compared to \$1.5 million in the prior-year quarter. The decrease in R&D expense was primarily due to reduced consulting fees and compensation-related expenses.

Total operating expenses for the second quarter of 2024 were \$3.8 million, a 38% decrease compared to \$6.2 million in the prior-year quarter as we continue to realize savings from operating efficiency initiatives enacted in the second half of 2023.

Operating loss for the second quarter of 2024 decreased to \$2.3 million compared to an operating loss of \$5.0 million in the prior-year quarter.

Net loss attributable to common shareholders for the second quarter of 2024 was \$7.7 million, or a loss of \$18.85 per basic and diluted common share, compared to a net loss attributable to common shareholders of \$4.8 million, or a loss of \$127.65 per basic and diluted common share in the prior-year quarter.

As of June 30, 2024, the Company had no debt, cash and cash equivalents of approximately \$1.0 million, and approximately 516 thousand common shares outstanding. On July 25, Nuwellis closed a registered direct offering and concurrent private placement with gross proceeds of \$2.0 million before deducting placement agent fees and other offering expenses.

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 1-800-267-6316 (U.S) or 1-203-518-9783 (international) and using the conference ID: NUWEQ2. 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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NUWELLIS, INC. AND SUBSIDIARY
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	June 30, 2024	December 31, 2023
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 1,023	\$ 3,800
Accounts receivable	1,292	1,951
Inventories, net	1,967	1,997
Other current assets	544	461
Total current assets	4,826	8,209
Property, plant and equipment, net	630	728
Operating lease right-of-use asset	613	713
Other assets	120	120
TOTAL ASSETS	\$ 6,189	\$ 9,770
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable and accrued liabilities	\$ 3,028	\$ 2,380
Accrued compensation	706	525
Current portion of operating lease liability	226	216
Other current liabilities	56	51
Total current liabilities	4,016	3,172
Common stock warrant liability	8,579	2,843
Operating lease liability	428	544
Total liabilities	13,023	6,559
Commitments and contingencies		
Mezzanine Equity		
Series J Convertible Preferred Stock as of June 30, 2024 and December 31, 2023, par value \$0.0001 per share; authorized 600,000 shares, issued and outstanding 88 and 11,950, respectively	2	221
Stockholders' equity (deficit)		
Series A junior participating preferred stock as of June 30, 2024 and December 31, 2023, par value \$0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Series F convertible preferred stock as of June 30, 2024 and December 31, 2023, par value \$0.0001 per share; authorized 18,000 shares, issued and outstanding 127 shares	—	—
Preferred stock as of June 30, 2024 and December 31, 2023, par value \$0.0001 per share; authorized 39,352,000 shares, none outstanding	—	—
Common stock as of June 30, 2024 and December 31, 2023, par value \$0.0001 per share; authorized 100,000,000 shares, issued and outstanding 515,744 and 162,356, respectively	—	—
Additional paid-in capital	292,887	290,647
Accumulated other comprehensive income:		
Foreign currency translation adjustment	(42)	(31)
Accumulated deficit	(299,681)	(287,626)
Total stockholders' equity (deficit)	(6,836)	2,990
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	\$ 6,189	\$ 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 June 30		Six months ended June 30	
	2024	2023	2024	2023
Net sales	\$ 2,194	\$ 2,075	\$ 4,051	\$ 3,901
Cost of goods sold	720	928	1,386	1,687
Gross profit	<u>1,474</u>	<u>1,147</u>	<u>2,665</u>	<u>2,214</u>
Operating expenses:				
Selling, general and administrative	3,236	4,664	7,842	10,154
Research and development	558	1,505	1,892	2,933
Total operating expenses	<u>3,794</u>	<u>6,169</u>	<u>9,734</u>	<u>13,087</u>
Loss from operations	(2,320)	(5,022)	(7,069)	(10,873)
Other income (expense), net	6	179	(95)	302
Financing Expense	(5,607)	—	(5,607)	—
Change in fair value of warrant liability	198	—	720	(755)
Loss before income taxes	(7,723)	(4,843)	(12,051)	(11,326)
Income tax expense	(2)	(2)	(4)	(4)
Net loss	<u>\$ (7,725)</u>	<u>\$ (4,845)</u>	<u>\$ (12,055)</u>	<u>\$ (11,330)</u>
Deemed dividend attributable to Series J Convertible Preferred Stock	—	—	541	—
Net loss attributable to common shareholders	<u>\$ (7,725)</u>	<u>\$ (4,845)</u>	<u>\$ (11,514)</u>	<u>\$ (11,330)</u>
Basic and diluted loss per share	<u>\$ (18.85)</u>	<u>\$ (127.65)</u>	<u>\$ (40.91)</u>	<u>\$ (323.15)</u>
Weighted average shares outstanding – basic and diluted	409,690	37,949	294,649	35,060
Other comprehensive loss:				
Foreign currency translation adjustments	\$ (2)	\$ 1	\$ (11)	\$ (6)
Total comprehensive loss	<u>\$ (7,727)</u>	<u>\$ (4,844)</u>	<u>\$ (12,066)</u>	<u>\$ (11,336)</u>

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

	Six months ended	
	June 30	
	2024	2023
Operating Activities:		
Net loss	\$ (12,055)	\$ (11,330)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	151	169
Stock-based compensation expense	273	378
Change in fair value of warrant liability	(720)	755
Warrant financing costs	5,607	—
Net realized gain on marketable securities	—	(65)
Changes in operating assets and liabilities:		
Accounts receivable	659	230
Inventory, net	30	(72)
Other current assets	(395)	(547)
Other assets and liabilities	5	(20)
Accounts payable and accrued expenses	829	(856)
Net cash used in operating activities	(5,616)	(11,358)
Investing Activities:		
Proceeds from sale of marketable securities	—	578
Additions to intangible assets	—	(99)
Purchases of property and equipment	(53)	(64)
Net cash provided by (used in) investing activities	(53)	415
Financing Activities:		
Issuance of common stock from offering	2,403	—
Proceeds from the exercise of Series J Convertible Preferred Warrants	500	—
Proceeds from ATM stock offerings, net	—	2,108
Net cash provided by financing activities	2,903	2,108
Effect of exchange rate changes on cash	(11)	(6)
Net decrease in cash and cash equivalents	(2,777)	(8,841)
Cash and cash equivalents - beginning of period	3,800	17,737
Cash and cash equivalents - end of period	\$ 1,023	\$ 8,896
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)	\$ —
Common stock offering costs included in prepaids	\$ 306	\$ —