

**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): November 11, 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 November 11, 2024, Nuwellis, Inc. (the “Company”) issued a press release reporting its financial results for the three and nine months ended September 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**

<a href="#">99.1</a>	Press Release, dated November 11, 2024, reporting the financial results of Nuwellis, Inc. for the three and nine months ended September 30, 2024.
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**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: November 11, 2024

**NUWELLIS, INC.**

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

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**Nuwellis, Inc. Announces Third Quarter 2024 Financial Results and Recent Highlights**

Minneapolis, MN, November 11, 2024 (GLOBE NEWSWIRE) -- Nuwellis, Inc. (Nasdaq: NUWE), a medical device company focused on transforming the lives of people with fluid overload, today reported financial results for the third quarter ended September 30, 2024.

**Recent Highlights:**

- Received a 297% CMS reimbursement increase to \$1,639 for Aquadex facility fee, effective January 1, 2025.
- Revenue of \$2.4 million.
- Pediatrics revenue growth of 28% compared to the prior year quarter.
- Gross margin of 70%, compared to 57.3% in the prior-year quarter.
- Total operating cost reduction of 30% compared to the prior-year quarter.
- New study published in Current Problems in Cardiology highlighted statistically significant reduction in Heart Failure readmissions at 60 days when using Aquadex.
- Added three new pediatric accounts and two new adult accounts.
- Received \$5.1 million in gross proceeds through the November exercise of outstanding warrants.

“We commend the hard work and dedication of the Nuwellis team, fueling steady market adoption of our Aquadex ultrafiltration therapy, with revenue in the third quarter 2024 led by console sales and new account wins in our Pediatric customer category, which posted 28% annual growth,” said Nestor Jaramillo, President and CEO of Nuwellis. “We continue to see momentum with new accounts steadily opening on increasing awareness of the efficacy and supporting clinical evidence for Aquadex ultrafiltration therapy in the adult and pediatric customer categories. We believe these newly published clinical results will have a positive impact in growing our business and supporting Aquadex in becoming the standard of care for fluid removal when diuretics are ineffective.” Following the closing of the quarter, we received notice of a 297% increase to \$1,639 per day in reimbursement from the Centers for Medicare and Medicaid Services (CMS) which greatly expands the outpatient marketplace for fluid removal. This reimbursement increase is effective January 1, 2025.

**Third Quarter 2024 Financial Results**

Revenue for the third quarter of 2024 was \$2.4 million, a 2% decrease compared to the prior-year quarter. The year-over-year decrease is attributable to a decrease in consumables utilization, a decrease in US console sales offset by a one-time increase in SeaStar Medical Quelimune sales.

Gross margin was 70% for the third quarter of 2024, compared to 57.3% in the prior-year quarter. The increase was primarily driven by higher manufacturing volumes of consumables and lower fixed overhead manufacturing expenses.

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Selling, general and administrative expenses (SG&A) for the third quarter of 2024 decreased to \$2.7 million, compared to \$3.4 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.

Third quarter research and development (R&D) expenses were \$486 thousand, compared to \$1.1 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 third quarter of 2024 were \$3.2 million, a 30% decrease compared to \$4.5 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 third quarter of 2024 decreased to \$1.5 million compared to an operating loss of \$3.2 million in the prior-year quarter.

Net income attributable to common shareholders for the third quarter of 2024 was \$2.4 million, or a gain of \$1.74 per basic and diluted common share, compared to a net loss attributable to common shareholders of \$3.4 million, or a loss of \$63.27 per basic and diluted common share in the prior-year quarter. Third quarter net income improvement was primarily the result of the revaluation of a prior period warrant liability, resulting in a \$3.9 million dollar benefit.

As of September 30, 2024, the Company had no debt, cash and cash equivalents of approximately \$1.9 million, and approximately 1.9 million common shares outstanding. Shareholder equity was \$3.2 million, which we intend to submit to Nasdaq in support of our continued listing on the Nasdaq Stock Market.

### **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 1-800-445-7795 (U.S) or 1-785-424-1789 (international) and using the conference ID: NUWEQ3. 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 device 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](https://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.

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**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

Gilmartin Group

[ir@nuwellis.com](mailto:ir@nuwellis.com)

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

	<b>September 30, 2024</b>	<b>December 31, 2023</b>
	(Unaudited)	
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 1,907	\$ 3,800
Accounts receivable	1,293	1,951
Inventories, net	1,864	1,997
Other current assets	430	461
<b>Total current assets</b>	<b>5,494</b>	<b>8,209</b>
Property, plant and equipment, net	551	728
Operating lease right-of-use asset	563	713
Other assets	120	120
<b>TOTAL ASSETS</b>	<b>\$ 6,728</b>	<b>\$ 9,770</b>
<b>LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
<b>Current liabilities</b>		
Accounts payable and accrued liabilities	\$ 1,822	\$ 2,380
Accrued compensation	597	525
Current portion of operating lease liability	232	216
Other current liabilities	50	51
<b>Total current liabilities</b>	<b>2,701</b>	<b>3,172</b>
Common stock warrant liability	480	2,843
Operating lease liability	368	544
<b>Total liabilities</b>	<b>3,549</b>	<b>6,559</b>
Commitments and contingencies		
<b>Mezzanine Equity</b>		
Series J Convertible Preferred Stock as of September 30, 2024 and December 31, 2023, par value \$0.0001 per share; authorized 600,000 shares, issued and outstanding 95 and 11,950, respectively	2	221
<b>Stockholders' equity</b>		
Series A junior participating preferred stock as of September 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 September 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 September 30, 2024 and December 31, 2023, par value \$0.0001 per share; authorized 39,352,000 shares, none outstanding	—	—
Common stock as of September 30, 2024 and December 31, 2023, par value \$0.0001 per share; authorized 100,000,000 shares, issued and outstanding 1,866,890 and 162,356, respectively	—	—
Additional paid-in capital	300,546	290,647
Accumulated other comprehensive income: Foreign currency translation adjustment	(46)	(31)
Accumulated deficit	(297,323)	(287,626)
<b>Total stockholders' equity</b>	<b>3,177</b>	<b>2,990</b>
<b>TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY</b>	<b>\$ 6,728</b>	<b>\$ 9,770</b>

**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 September 30		Nine months ended September 30	
	2024	2023	2024	2023
<b>Net sales</b>	\$ 2,367	\$ 2,412	\$ 6,418	\$ 6,313
Cost of goods sold	711	1,031	2,097	2,718
Gross profit	<u>1,656</u>	<u>1,381</u>	<u>4,321</u>	<u>3,595</u>
<b>Operating expenses:</b>				
Selling, general and administrative	2,702	3,428	10,544	13,582
Research and development	486	1,117	2,378	4,050
Total operating expenses	3,188	4,545	12,922	17,632
Loss from operations	(1,532)	(3,164)	(8,601)	(14,037)
Other income (expense), net	8	(204)	(87)	98
Financing Expense	—	—	(5,607)	—
Change in fair value of warrant liability	3,882	—	4,602	(755)
Income (loss) before income taxes	2,358	(3,368)	(9,693)	(14,694)
Income tax expense	—	(2)	(4)	(6)
<b>Net income (loss)</b>	<u>\$ 2,358</u>	<u>\$ (3,370)</u>	<u>\$ (9,697)</u>	<u>\$ (14,700)</u>
Deemed dividend attributable to Series J Convertible Preferred Stock	—	—	541	—
<b>Net income (loss) attributable to common shareholders</b>	<u>\$ 2,358</u>	<u>\$ (3,370)</u>	<u>\$ (9,156)</u>	<u>\$ (14,700)</u>
<b>Basic and diluted net income (loss) per share</b>	<u>\$ 1.74</u>	<u>\$ (63.27)</u>	<u>\$ (14.99)</u>	<u>\$ (357.42)</u>
Weighted average shares outstanding – basic and diluted	1,351,939	53,265	647,079	41,128
<b>Other comprehensive loss:</b>				
Foreign currency translation adjustments	\$ (4)	\$ —	\$ (15)	\$ (6)
<b>Total comprehensive income (loss)</b>	<u>\$ 2,354</u>	<u>\$ (3,370)</u>	<u>\$ (9,171)</u>	<u>\$ (14,706)</u>



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

	<b>Nine months ended September 30</b>	
	<b>2024</b>	<b>2023</b>
<b>Operating Activities:</b>		
Net loss	\$ (9,697)	\$ (14,700)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	227	253
Stock-based compensation expense	374	513
Change in fair value of warrant liability	(4,602)	755
Warrant financing costs	5,607	—
Net realized gain on marketable securities	—	(65)
Changes in operating assets and liabilities:		
Accounts receivable	658	(19)
Inventory, net	120	325
Other current assets	(275)	(551)
Other assets and liabilities	(13)	(16)
Accounts payable and accrued expenses	(486)	(1,678)
<b>Net cash used in operating activities</b>	<b>(8,087)</b>	<b>(15,183)</b>
<b>Investing Activities:</b>		
Proceeds from sale of marketable securities	—	578
Additions to intangible assets	—	(99)
Purchases of property and equipment	(37)	(185)
<b>Net cash provided by (used in) investing activities</b>	<b>(37)</b>	<b>294</b>
<b>Financing Activities:</b>		
Issuance of common stock from offering	2,403	—
Proceeds from the exercise of Series J Convertible Preferred Warrants	501	—
Proceeds from the exercise of April 2024 Warrants	1,182	—
Issuance of July and August 2024 Common Stock and Warrants	2,160	—
Proceeds from ATM stock offerings, net	—	2,108
Payments on finance lease liability	—	(20)
<b>Net cash provided by financing activities</b>	<b>6,246</b>	<b>2,088</b>
Effect of exchange rate changes on cash	(15)	(6)
Net decrease in cash and cash equivalents	(1,893)	(12,807)
Cash and cash equivalents - beginning of period	3,800	17,737
<b>Cash and cash equivalents - end of period</b>	<b>\$ 1,907</b>	<b>\$ 4,930</b>