

**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 1, 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**  
(Address of Principal Executive Offices)

**55344**  
(Zip Code)

**(952) 345-4200**  
(Registrant's Telephone Number, Including Area Code)

**Not Applicable**  
(Former Name or Former Address, if Changed Since Last Report)

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))

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

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 1, 2024, Nuwellis, Inc. (the “*Company*”) issued a press release reporting its preliminary financial results for the quarter 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 Number	Exhibit Description
<a href="#">99.1</a>	Company Press Release, dated November 1, 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: November 1, 2024

**NUWELLIS, INC.**

By: /s/ NESTOR JARAMILLO, JR.

Name: Nestor Jaramillo, Jr.

Title: President and Chief Executive Officer

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### Nuwellis Announces Preliminary Results for Third Quarter of 2024

**MINNEAPOLIS — November 1, 2024** — Nuwellis, Inc. (Nasdaq: NUWE), a medical device company dedicated to transforming the lives of patients suffering from fluid overload, today announced certain preliminary, unaudited results for the quarter ended September 30, 2024. The company plans to report its complete results and host its earnings conference call for the third quarter of 2024 on November 11, 2024.

Based on preliminary, unaudited results, management expects the Company to report the following in respect of its quarterly period ended September 30, 2024:

- Revenue of approximately \$2.4 million.
- Revenue growth of 28% in the Pediatric customer category compared to the same period in 2023.
- 70% gross margin, a 12.7% improvement compared to 57.3% in the same period in 2023.
- Total operating cost reduction of approximately 30% compared to the same period in 2023.

Cash used in operations for the quarter was approximately \$2.5 million. At quarter end, the Company held cash and cash equivalents of approximately \$1.9 million. As previously reported in the Company's Current Report on Form 8-k, dated October 23, 2024, the Company and SeaStar Medical Holding Corporation (Nasdaq: ICU) agreed to terminate their license and distribution agreement and entered into a Settlement Agreement, whereby SeaStar Medical agreed to pay the Company an aggregate of \$900,000 by December 31, 2024, approximately \$500,000 of which has been paid to date.

The financial information in this press release is preliminary, unaudited, based on currently available information, and subject to adjustment in the final financial statements to be filed with the Company's Quarterly Report on Form 10-Q for the three months ended September 30, 2024.

"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 are pleased to report continued momentum in our business, with the acquisition of five new accounts. This growth is attributed to the increasing recognition of Aquadex ultrafiltration therapy's efficacy, substantiated by recent clinical studies."

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**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<sup>®</sup> system for ultrafiltration therapy. Nuwellis is headquartered in Minneapolis, with a wholly owned subsidiary in Ireland. For more information visit [ir.nuwellis.com](http://ir.nuwellis.com) or visit us on LinkedIn or X.

**About the Aquadex SmartFlow<sup>®</sup> 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.

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**CONTACTS****Investors:**

Vivian Cervantes

Gilmartin Group

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