

**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): **December 17, 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)

Title of each class	Securities registered pursuant to Section 12(b) of the Act:	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	Trading Symbol(s) 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 8.01 Other Events.

As previously, disclosed on May 29, 2024 and June 10, 2024, Nuwellis, Inc. (the “*Company*”) was notified by the Listing Qualifications staff (the “*Staff*”) of The Nasdaq Stock Market LLC (“*Nasdaq*”) that the Company did not satisfy Nasdaq Listing Rules 5550(b)(1) (the “*Stockholders’ Equity Requirement*”) and 5550(a)(2) (the “*Minimum Bid Price Requirement*”), respectively, and was therefore subject to delisting from Nasdaq unless the Company timely requested a hearing before the Nasdaq Hearings Panel (the “*Panel*”), which it did.

On July 18, 2024, Nasdaq notified the Company that it had regained compliance with the Minimum Bid Price Requirement. At a hearing before the Panel on July 23, 2024, the Company presented its plan of compliance to regain compliance with the Stockholders’ Equity Requirement.

On August 8, 2024, the Company was notified by Nasdaq that the Panel had granted the Company’s request for continued listing, subject to, among other things, the Company’s filing of its Quarterly Report on Form 10-Q for the period ending September 30, 2024, evidencing compliance with the Stockholders’ Equity Requirement. On November 12, 2024, the Company filed its Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 evidencing compliance with the Stockholders’ Equity Requirement.

On December 17, 2024, the Company received a letter from Nasdaq confirming that the Company has regained compliance with the Stockholders’ Equity Requirement, as required by the Panel’s August 2024 decision.

Pursuant to Nasdaq Listing Rule 5815(d)(4)(B), the Company will be subject to a mandatory panel monitor for a period of one year from the date of the December 17, 2024 letter. If, within that one-year monitoring period, the Staff finds that the Company is no longer in compliance with the Stockholders’ Equity Requirement, then, notwithstanding Nasdaq Listing Rule 5810(c)(2), the Company will not be permitted to provide the Staff with a plan of compliance with respect to such deficiency and the Staff will not be permitted to grant additional time for the Company to regain compliance with respect to such deficiency, nor will the Company be afforded an applicable cure or compliance period pursuant to Nasdaq Listing Rule 5810(c)(3). Instead, the Staff will issue a Delist Determination Letter and the Company will have an opportunity to request a new hearing with the initial Panel or a newly convened Hearings Panel if the initial Panel is unavailable. The Company will have the opportunity to respond/present to the Hearings Panel as provided by Nasdaq Listing Rule 5815(d)(4)(C) and the Company’s securities may at that time be delisted from Nasdaq.

On December 19, 2024, the Company issued a press release announcing its compliance with the Stockholders’ Equity Requirement and Minimum Bid Price Requirement. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.**(c) Exhibits**

99.1	Press Release dated December 19, 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: December 19, 2024

NUWELLIS, INC.

By: /s/ NESTOR JARAMILLO, JR

Name: Nestor Jaramillo, Jr.

Title: President and Chief Executive Officer

Nuwellis Regains Compliance with Nasdaq Listing Requirements

MINNEAPOLIS — Dec. 19, 2024 — Nuwellis, Inc. (Nasdaq: NUWE) (the “Company” or “Nuwellis”), today announced that the Company received formal written notice from The Nasdaq Stock Market LLC (“Nasdaq”) that the Company has regained compliance with Nasdaq’s minimum bid price requirement (the “Bid Price Requirement”) set forth in Nasdaq Listing Rule 5550(a)(2), as well as Nasdaq’s stockholders’ equity requirement (“Equity Requirement”) set forth in Nasdaq Listing Rule 5550(b)(1). The Company’s Common Stock will continue to trade on The Nasdaq Capital Market tier of Nasdaq under the symbol “NUWE”.

This confirmation follows the Company’s successful efforts to improve its balance sheet by raising new equity, reducing outstanding liabilities, and reclassifying certain prior warrant liabilities as equity. As a result, Nuwellis now exceeds Nasdaq’s stockholders’ Equity Requirement of at least \$2.5 million, which was previously reported on our Form 10-Q for the period ending September 30, 2024.

Nestor Jaramillo, President and CEO of Nuwellis said: “We are pleased to receive Nasdaq’s written notification confirming Nuwellis has regained compliance with both the minimum stockholders’ Equity Requirement and the Bid Price Requirement. Over the past few months, we have made significant strides in improving our balance sheet and expanding our business. This includes the successful raise of \$5.1 million in gross proceeds from warrant exercises and through our recent warrant inducement transaction in November. In addition, we implemented a reverse stock split of 1:35 on June 26, 2024.”

As part of the compliance confirmation, Nuwellis will be subject to a mandatory panel monitor for a year from the date the letter was received, December 17, 2024.

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 www.nuwellis.com or visit us on LinkedIn or Twitter.

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 Company's ability to maintain the continued listing of the Company's securities on Nasdaq. 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:

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