

**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 23, 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 3.01. Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

On May 23, 2024, Nuwellis, Inc. (the “**Company**”) received a letter (the “**Notice**”) from the Listing Qualifications Department (the “**Staff**”) of the Nasdaq Stock Market (“**Nasdaq**”) informing the Company that it was not in compliance with the minimum stockholders’ equity requirement for continued listing on The Nasdaq Capital Market, under Listing Rule 5550(b)(1), because the Company’s stockholders’ equity of \$885,000, as reported in the Company’s Quarterly Report on Form 10-Q for the period ended March 31, 2024, was below the required minimum of \$2.5 million, and because, as of May 23, 2024, the Company did not meet the alternative compliance standards, relating to the market value of listed securities of \$35 million or net income from continuing operations of \$500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years.

The Notice has no immediate impact on the listing of the Company’s common stock, which will continue to be listed and traded on The Nasdaq Capital Market, subject to the Company’s compliance with the other continued listing requirements. The Company has 45 calendar days from May 23, 2024, or through Monday, July 8, 2024, to submit to Nasdaq a plan to regain compliance with Listing Rule 5550(b)(1). If Nasdaq accepts the Company’s plan, Nasdaq may grant an extension of up to 180 calendar days from May 23, 2024, or through Tuesday, November 19, 2024, to regain compliance. If Nasdaq does not accept the Company’s plan, the Company will have the right to appeal such decision to a Nasdaq hearings panel.

The Company intends to submit to Nasdaq, within the requisite time period, a plan to regain compliance with Listing Rule 5550(b)(1). There can be no assurance that Nasdaq will accept the Company’s plan or that the Company will be able to regain compliance with Listing Rule 5550(b)(1) or maintain compliance with any other Nasdaq requirement in the future.

The Company, by filing this Current Report on Form 8-K (this “**Report**”), discloses its receipt of the notification from Nasdaq in accordance with Listing Rule 5810(b).

Item 8.01 Other Events.

The Company is including the below update to its risk factors, for the purpose of supplementing and updating the disclosure contained in its Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (“**Form 10-K**”), filed with the Securities and Exchange Commission (the “**SEC**”) on March 11, 2024 and its Quarterly Report on Form 10-Q for the period ended March 31, 2024 (“**Form 10-Q**”), filed with the SEC on May 8, 2024.

Except as described below, no other changes have been made to the Form 10-K or Form 10-Q, as applicable, and this Report does not otherwise amend, update or change the financial statements or other disclosures in the Form 10-K or Form 10-Q, as applicable. This Report speaks as of the filing date of the Form 10-K and Form 10-Q, as applicable. Among other things, forward-looking statements made in the Form 10-K or Form 10-Q, as applicable, have not been revised to reflect events, results or developments that occurred or facts that became known to us after the date of the Form 10-K or Form 10-Q, as applicable, and such statements should be read in conjunction with our filings with the SEC subsequent to the Form 10-K or Form 10-Q, as applicable. This Report should be read in conjunction with the Company’s other filings with the SEC subsequent to March 11, 2024 and May 8, 2024, as applicable.

Our failure to maintain compliance with the minimum stockholders’ equity requirement of Nasdaq’s continued listing requirements could result in the delisting of our common stock.

Our common stock is currently listed for trading on The Nasdaq Capital Market. We must satisfy the continued listing requirements of The Nasdaq Stock Market LLC (or Nasdaq) to maintain the listing of our common stock on The Nasdaq Capital Market.

On May 23, 2024, we received notice from the Listing Qualifications Staff (the “**Staff**”) of Nasdaq indicating that we were not in compliance with the \$2.5 million minimum stockholders’ equity requirement for continued listing of our common stock on The Nasdaq Capital Market, as set forth in Nasdaq Listing Rule 5550(b)(1) (the “**Minimum Stockholders’ Equity Rule**”). In that regard, we reported stockholders’ equity of \$885,000 in our Quarterly Report on Form 10-Q for the period ended March 31, 2024 (we did not then, and do not now, meet the alternative compliance standards relating to the market value of listed securities of \$35 million or net income from continuing operations of \$500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years).

We intend to submit to Nasdaq, within the requisite time period, a plan to regain compliance with the Minimum Stockholders' Equity Rule. There can be no assurance that Nasdaq will accept our plan or that we will be able to regain compliance with the Minimum Stockholders' Equity Rule or maintain compliance with any other Nasdaq requirement in the future. In the event that we are unable to regain compliance with the Minimum Stockholders' Equity Rule, our common stock may be delisted from The Nasdaq Capital Market.

If our common stock were delisted from The Nasdaq Capital Market, trading of our common stock would most likely take place on an over-the-counter market established for unlisted securities, such as the OTCQB or the Pink Market maintained by OTC Markets Group Inc. An investor would likely find it less convenient to sell, or to obtain accurate quotations in seeking to buy, our common stock on an over-the-counter market, and many investors would likely not buy or sell our common stock due to difficulty in accessing over-the-counter markets, policies preventing them from trading in securities not listed on a national exchange or other reasons. In addition, as a delisted security, our common stock would be subject to SEC rules as a "penny stock," which impose additional disclosure requirements on broker-dealers. The regulations relating to penny stocks, coupled with the typically higher cost per trade to the investor of penny stocks due to factors such as broker commissions generally representing a higher percentage of the price of a penny stock than of a higher-priced stock, would further limit the ability of investors to trade in our common stock. In addition, delisting would materially and adversely affect our ability to raise capital on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. For these reasons and others, delisting would adversely affect the liquidity, trading volume and price of our common stock, causing the value of an investment in us to decrease and having an adverse effect on our business, financial condition and results of operations, including our ability to attract and retain qualified employees and to raise capital.

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 29, 2024

NUWELLIS, INC.

By: /s/ NESTOR JARAMILLO, JR

Name: Nestor Jaramillo, Jr.

Title: President and Chief Executive Officer
