

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 29, 2022**

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.

As previously reported, on June 3, 2022, Nuwellis, Inc. (the “*Company*”) received a letter from the Listing Qualifications Department (the “*Staff*”) of The Nasdaq Stock Market LLC (“*Nasdaq*”) indicating that, based upon the closing bid price of the Company’s common stock, par value \$0.0001 per share (the “*Common Stock*”) for the prior 30 consecutive business days, the Company was not in compliance with the requirement to maintain a minimum bid price of \$1.00 per share for continued listing on The Nasdaq Global Market, as set forth in Nasdaq Listing Rule 5550(a)(2) (the “*Minimum Bid Price Requirement*”). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company was provided a grace period of 180 days, or until November 28, 2022, to regain compliance with the Minimum Bid Price Requirement.

On November 29, 2022 the Company received a letter from Nasdaq advising that the Company had been granted a 180-day extension to May 29, 2023, to regain compliance with the Minimum Bid Price Requirement, in accordance with Nasdaq Listing Rule 5810(c)(3)(A).

The Company will continue to monitor the closing bid price of the Common Stock and may, if appropriate, consider implementing available options, including but not limited to, implementing a reverse stock split of its outstanding securities, to regain compliance with the Minimum Bid Price Requirement. If the Company does not regain compliance within the allotted compliance period, Nasdaq will provide notice that the Common Stock will be subject to delisting. The Company would then be entitled to appeal that determination to a Nasdaq hearings panel. There can be no assurance that the Company will regain compliance with the Minimum Bid Price Requirement during this additional 180-day extension.

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, 2021, filed with the Securities and Exchange Commission (the “*SEC*”) on March 3, 2022, its Quarterly Report on Form [10-Q](#) for the period ended March 31, 2022, filed with the SEC on May 13, 2022, its Quarterly Report on Form [10-Q](#) for the period ended June 30, 2022, filed with the SEC on August 11, 2022 and its Quarterly Report on Form [10-Q](#) for the period ended September 30, 2022, filed with the SEC on November 8, 2022.

Risks Related to our Common Stock

Our failure to maintain compliance with Nasdaq’s continued listing requirements could result in the desilting of our common stock

On June 3, 2022, we received a letter from the Listing Qualifications Staff of the Nasdaq Stock Market, LLC (“*Nasdaq*”) indicating that, based upon the closing bid price of our common stock for the last 30 consecutive business days, we are not in compliance with the requirement to maintain a minimum bid price of \$1.00 per share for continued listing on the Nasdaq Global Market, as set forth in Nasdaq Listing Rule 5550(a)(2) (the “*Notice*”). We were provided a compliance period of 180 calendar days from the date of the Notice, or until November 28, 2022, to regain compliance with the minimum closing bid requirement, pursuant to Nasdaq Listing Rule 5810(c)(3)(A). On November 29, 2022, we were provided an additional compliance period of 180 calendar days, or until May 29, 2023, to regain compliance with the minimum closing bid requirement.

We will continue to monitor the closing bid price of our common stock and seek to regain compliance with all applicable Nasdaq requirements within the allotted compliance periods and may, if appropriate, consider available options, including implementation of a reverse stock split, to regain compliance with the minimum closing bid requirement. If we seek to implement a reverse stock split in order to remain listed on Nasdaq, the announcement or implementation of such a reverse stock split could negatively affect the price of our common stock. If we do not regain compliance within the allotted compliance periods, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that the our common stock will be subject to delisting. We would then be entitled to appeal that determination to a Nasdaq hearings panel. There can be no assurance that we will regain compliance with the minimum bid price requirement during the 180-day compliance period or maintain compliance with the other Nasdaq listing requirements. A delisting could substantially decrease trading in our common stock, adversely affect the market liquidity of our common stock as a result of the loss of market efficiencies associated with Nasdaq and the loss of federal preemption of state securities laws, adversely affect our ability to obtain financing on acceptable terms, if at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. Additionally, the market price of our common stock may decline further and stockholders may lose some or all of their investment.

On November 30, 2022, the Company issued a press release announcing the extension of the compliance period granted by Nasdaq, a copy of which is attached as Exhibit 99.1 to this Current Report and is incorporated herein by reference. Information contained on or accessible through any website reference in the press releases is not part of, or incorporated by reference in, this Current Report, and the inclusion of such website addresses in this Current Report by incorporation by reference of the press releases is as inactive textual references only.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release, dated November 30, 2022.
104	Cover Page Interactive Data File (embedded within 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 30, 2022

NUWELLIS, INC.

By: /s/ NESTOR JARAMILLO, JR

Name: Nestor Jaramillo, Jr.

Title: President and Chief Executive Officer



Nuwellis, Inc. Receives 180-Day Extension to Meet Nasdaq Minimum Bid Price Requirement

Minneapolis, Minn. /GLOBENEWSWIRE/November 30, 2022/ Nuwellis, Inc. (Nasdaq: NUWE), a medical technology company, announced today it received an extension of 180 calendar days from the Nasdaq Stock Market LLC (“Nasdaq”) to regain compliance with the Nasdaq’s minimum \$1.00 bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on the Nasdaq Capital Market (the “Bid Price Requirement”), following the expiration of the initial 180 calendar days period to regain compliance on November 28, 2022.

As a result of the extension, the Company now has until May 29, 2023 to regain compliance with the Bid Price Requirement. If at any time before May 29, 2023, the bid price of the Company’s common shares closes at or above USD \$1.00 per share for a minimum of 10 consecutive business days, Nasdaq will provide written notification to the Company that it has achieved compliance with the Bid Price Requirement.

This current notification from Nasdaq has no immediate effect on the listing or trading of the Company’s shares, which will continue to trade on the Nasdaq Capital Market under the symbol “NUWE.”

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 developing, manufacturing, and commercializing the Aquadex SmartFlow® system for ultrafiltration therapy. Nuwellis is headquartered in Minneapolis, Minnesota, with a wholly owned subsidiary in Ireland.

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 2022 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 impact of the COVID-19 pandemic, 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 as a result of new information, future events or otherwise.

###

CONTACTS

INVESTORS:

Vivian Cervantes
Gilmartin Group LLC
ir@nuwellis.com

12988 Valley View Road • Eden Prairie, Minnesota 55344 USA • Corporate (952) 345-4200 • Fax (952) 224 0181
www.nuwellis.com
