

**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): **January 9, 2023**

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 January 9, 2023, Nuwellis, Inc. (the “*Company*”) issued a press release reporting its preliminary revenue results for the three and twelve months ended December 31, 2022. 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	Exhibit Description
99.1	Press Release dated January 9, 2023
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: January 9, 2023

NUWELLIS, INC.

By: /s/ NESTOR JARAMILLO, JR

Name: Nestor Jaramillo, Jr.

Title: President and Chief Executive Officer

Nuwellis Reports Preliminary Fourth Quarter and Full Year 2022 Revenue Results

MINNEAPOLIS, January 9, 2022 (GLOBE NEWSWIRE) -- Nuwellis, Inc. (Nasdaq: NUWE) (“Nuwellis” or the “Company”), a medical technology company focused on transforming the lives of people with fluid overload, today announced preliminary unaudited results for fourth quarter and full year 2022.

Preliminary unaudited revenue for the fourth quarter and full year 2022 is anticipated to be approximately \$2.3 million and \$8.5 million, respectively, representing an increase of 42% and 8% over the same periods last year. The fourth quarter growth rate reflects benefits from the Company’s commercial team expansion and focused sales strategy, as well as continued market traction in line with the Company’s penetration of market segments beyond heart failure patients. Fourth quarter revenue by segment was led by Pediatrics, followed by Heart Failure and Critical Care, which increased approximately 92%, 47%, and 24% over the same period last year, respectively.

“Preliminary 2022 revenue growth of approximately 42% for the fourth quarter and 8% for the full year demonstrates continued meaningful progress on the execution of our key strategic initiatives, as the expansion of our field sales team and clinical education specialists, bolstered by our market penetration initiatives and growing body of clinical evidence, drove strong sales momentum in the fourth quarter. We are committed to making the Aquadex SmartFlow® system the standard of care for patients with fluid overload who are not responsive to diuretics, driving strong growth in 2023 and beyond,” said Nestor Jaramillo, President and CEO of Nuwellis.

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.

About the Aquadex SmartFlow® System

The Aquadex SmartFlow system delivers clinically superior 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 2023 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.

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CONTACTS

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