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): **February 6, 2024**

Nuwellis, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-35312**	**No. 68-0533453**
(State or Other Jurisdiction of Incorporation or Organization)	**(Commission File Number)**	**(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 8.01 Other Events.

On February 6, 2024, Nuwellis, Inc. issued a press release announcing the publication of new data demonstrating the potential value of the Aquadex SmartFlow® system's aquapheresis therapy when treating patients with fluid overload as a result of end-stage liver disease.

A copy of this press release is filed herewith as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Information contained on or accessible through any website reference in the press release is not part of, or incorporated by reference in, this Current Report on Form 8-K, and the inclusion of such website addresses in this Current Report on Form 8-K by incorporation by reference of the press release is as inactive textual references only.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Number	Description
99.1	Press Release, dated February 6, 2024
104	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: February 6, 2024

NUWELLIS, INC.

By: /s/ Nestor Jaramillo, Jr
Name: Nestor Jaramillo, Jr.
Title: President and Chief Executive Officer

Exhibit 99.1

New Case Series Demonstrates Potential of Aquadex Therapy for End-Stage Liver Disease Patients with Fluid Overload

Early findings suggest Aquadex as a potential solution to safely and effectively remove fluid volume for liver disease patients who don't respond to diuretics

MINNEAPOLIS — Feb. 6, 2024 — Nuwellis, Inc. (Nasdaq: NUWE), a medical technology company focused on transforming the lives of people with fluid overload, today announced the publication of new data demonstrating the potential value of the Aquadex SmartFlow® system's aquapheresis therapy when treating patients with fluid overload as a result of end-stage liver disease. The publication, "Utilization of Aquapheresis Among Hospitalized Patients with End-Stage Liver Disease: A Case Series and Literature Review," is a single-center retrospective case series featured in *Clinical Transplantation*.

"This study presents an exciting new market opportunity for Nuwellis, and we look forward to gathering additional data demonstrating how Aquadex can benefit these patients," said Nestor Jaramillo, Jr., president and chief executive officer of Nuwellis. "Four and a half million adults in the U.S. have been diagnosed with liver disease.[1] To date, there has been little to no clinical evidence gathered demonstrating the benefits of aquapheresis for patients with liver disease. This publication lays the foundation for a new clinical application already within our current labeling that requires no additional regulatory clearances from the FDA."

The case series assessed the utilization of aquapheresis therapy with Aquadex in the intensive care unit (ICU) setting at Mount Sinai Hospital between January 2020 and July 2023. Fourteen severely ill patients with end-stage liver disease were treated with aquapheresis during this period. The most common cause of liver disease was alcohol-related, with nine of the 14 patients presenting with alcohol-associated cirrhosis. Key findings from the case series include:

- Six patients were able to receive physical therapy following treatment to help improve their mobility while in the ICU.
- Five patients were transferred out of the ICU following treatment, three of whom were discharged from the hospital.
- There were no catheter-related bloodstream infections or circuit complications attributed to aquapheresis access.

"For clinicians treating patients with end-stage liver disease, it can be an enormous challenge to safely and effectively remove fluid when patients don't respond to or can't tolerate diuretic therapy," said John Jefferies, M.D., chief medical officer of Nuwellis. "In such cases, fluid removal via aquapheresis can enhance patients' mobility and allow them to receive more effective physical therapy. This can reduce cirrhosis-related frailty and enhance their ability to receive a life-saving liver transplant in a more timely manner."

Patients with end-stage liver disease are currently treated with diuretics, but studies show that the longer a patient is on diuretics, the less effective they become.[2,3] End-stage liver disease patients are also prone to developing ascites, which requires paracentesis – a painful procedure using a needle to remove fluid from the peritoneal cavity. In this case series, Aquadex was shown to provide a potential additional solution to mitigate these clinical gaps.

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[1] CDC. Chronic Liver Disease and Cirrhosis. https://www.cdc.gov/nchs/fastats/liver-disease.htm
[2] Felker MG and Mentz RJ. J Am Coll Cardiol. 2012;59(24):2145-53.
[3] Doering A, et al. Int J Emerg Med. 2017;10(17).

Aquadex is proven to simply, safely, and precisely remove excess fluid from patients suffering from fluid overload who have not responded to conventional medical management, including diuretics. Providers can specify and adjust the rate of fluid removed for each individual patient, resulting in a gradual reduction of excess fluid. The device's built-in, customizable hematocrit monitoring technology provides real-time measurement of percent blood volume changes that can be tailored to individual patients' needs. A customizable fluid removal rate is particularly important for pediatric patients who have a small amount of blood in their bodies. The Aquadex system is cleared by the U.S. Food and Drug Administration (FDA) for use in adults and pediatric patients weighing 20 kg (44 lbs.) or more.

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 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 X.

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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