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): **October 3, 2022**

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 October 3, 2022, Nuwellis, Inc. issued a press release announcing data demonstrating statistically superior clinical benefit of Aquadex therapy in reducing heart failure events and mortality. A copy of the press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated October 3, 2022
104	Cover Page Interactive Data File (embedded within the 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: October 3, 2022

NUWELLIS, INC.

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

Exhibit 99.1

NUWELLIS ANNOUNCES DATA DEMONSTRATING STATISTICALLY SUPERIOR CLINICAL BENEFIT OF AQUADEX THERAPY IN REDUCING HEART FAILURE EVENTS AND MORTALITY AT THE 2022 HFSA MEETING

Statistically Significant Reduction in CV Mortality and HF Rehospitalizations as Compared to IV Diuretics at 30 and 90 Days

MINNEAPOLIS, October 3, 2022 (GLOBE NEWSWIRE) -- Nuwellis, Inc. (Nasdaq: NUWE), a commercial-stage company focused on transforming the lives of people with fluid overload, today announced the results of the AVOID-HF clinical study analysis presented at the Heart Failure Society of America's (HFSA) 2022 Annual Scientific Meeting. The results of the analysis performed using the Finkelstein-Schoenfeld method of Win-Ratios (WR) demonstrated a statistically superior benefit when using ultrafiltration over diuretics for fluid-overloaded heart failure patients.

"The re-evaluation of AVOID-HF, using the Win-Ratios calculation, shows that adjustable ultrafiltration is safe and more effective than adjustable IV diuretics in reducing heart failure events for hospitalized heart failure patients," said Maria DeVita, M.D., Professor of Medicine at Hofstra School of Medicine/Northwell and Chief of the Division of Nephrology at Lenox Hill Hospital. "The results favored ultrafiltration over diuretics in reducing heart failure events within 30 days and cardiovascular mortality within 90 days. These results give us great confidence in REVERSE-HF, the ongoing prospective, multicenter, randomized controlled trial."

The AVOID-HF outcomes were evaluated using a composite endpoint consisting of cardiovascular (CV) mortality within 90 days, heart failure (HF) events within 30-days, and time-to-first HF event within 90 days. Adjustable Ultrafiltration (AUF) was statistically superior compared to Adjustable IV Loop Diuretics (ALD) with 81% more wins (Win Ratio=1.81, p=0.0429). A secondary WR analysis was also performed with a composite endpoint consisting of CV mortality within 30 days, HF events within 30-days, and time-to-first HF event within 90 days and found that AUF was statistically superior to ALD with 109% more wins (Win Ratio=2.09, p=0.0278). Results from this analysis are aligned with multiple systematic reviews that have demonstrated adjustable ultrafiltration to be more effective than diuretics in fluid removal, weight loss, and reducing hospital readmissions.[1-3]

"The results of this analysis support the clinical benefits of providing ultrafiltration with the Aquadex System in reducing readmissions and rehospitalization in fluid overloaded heart failure patients," said Nestor Jaramillo, Jr., President and CEO of Nuwellis. "The Aquadex System creates the potential to provide significant cost savings to hospitals and the health care system, but more importantly, improved quality of life for many patients. We're grateful to Drs. Pinney, DeVita, and Costanzo, the authors of this manuscript, for leading this reanalysis of the AVOID-HF data. Nuwellis is committed to making Aquadex therapy the standard of care for fluid management in heart failure patients that are unresponsive to diuretics."

The AVOID-HF (Aquapheresis Versus Intravenous Diuretics and Hospitalization for Heart Failure) prospective, multicenter, randomized controlled trial tested the hypothesis that patients hospitalized for heart failure (HF) and treated with ultrafiltration would have a longer time to their first heart failure event within 90 days after hospital discharge compared to those receiving IV loop diuretics. The study was trending favorably when the study sponsor terminated it before reaching full enrollment for reasons unrelated to patient safety or clinical futility. At the time, analysis of the AVOID-HF trial data was inconclusive due to the lower-than-planned sample size. However, the Finkelstein-Schoenfeld method of hierarchical Win Ratios increases statistical precision in demonstrating significant differences in clinical outcomes between treatment arms, while requiring a smaller study sample size.

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 developing, manufacturing and 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 proven therapy using a simple, flexible and predictable 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.

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1. Wang, M.J., et al. Medicine (Baltimore), 2021. 100(50): p. e28029.
2. Wobbe, B., et al. Heart Fail Rev, 2021. 26(3): p. 577-585.
3. Jain, A., et al. Heart Fail Rev, 2016. 21(5): p. 611-9.