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 10, 2023**

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 10, 2023, Nuwellis Inc. (the "***Company***") issued a press release announcing that its distribution partner, SeaStar Medical Holding Corporation, a Delaware corporation ("***SeaStar***"), received correspondence from the U.S. Food and Drug Administration's Center for Biologics Evaluation and Research (the "***Agency***") indicating that the Agency considers SeaStar's Selective Cytopheretic Device Pediatric to be approvable under a Humanitarian Device Exemption for use in children weighing 10 kilograms or more with acute kidney injury and sepsis or a septic condition requiring continuous kidney replacement therapy in the hospital intensive care unit. A copy of the press release is attached hereto as Exhibits 99.1 and is incorporated herein by reference.

This Current Report on Form 8-K and Exhibit 99.1 hereto contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward looking statements are based on current expectations and assumptions and are not guarantees of future performance. Further, the forward-looking statements are subject to the limitations listed in Exhibit 99.1 and in the other reports of the Company filed with the Securities and Exchange Commission, including that actual events or results may differ materially from those in the forward-looking statements. Forward-looking statements speak only as of the date when made. The Company does not assume any obligation to publicly update or revise any forward-looking statements, whether due to new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Company Press Release dated October 10, 2023.
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: October 10, 2023

NUWELLIS, INC.

By: /s/ Nestor Jaramillo, Jr

Name: Nestor Jaramillo, Jr.

Title: President and Chief Executive Officer

Exhibit 99.1

Nuwellis Provides Regulatory Update on SeaStar Medical's Selective Cytopheretic Device Use in Pediatric Acute Kidney Injury Under a Humanitarian Device Exemption

Minneapolis, MN, October 10, 2023 (GLOBE NEWSWIRE) -- Nuwellis, Inc. (Nasdaq: NUWE) (Nuwellis), a medical technology company dedicated to transforming the lives of people with fluid overload, today announced that its distribution partner, SeaStar Medical (SeaStar), received correspondence from the U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) indicating that the Agency considers SeaStar's Selective Cytopheretic Device (SCD) Pediatric (SCD-PED) to be approvable under a Humanitarian Device Exemption (HDE) for use in children weighing 10 kilograms or more with acute kidney injury (AKI) and sepsis or a septic condition requiring continuous kidney replacement therapy (CKRT) in the hospital intensive care unit (ICU).

The correspondence indicates that an Approvable Letter is expected to be issued within a month. The Approvable Letter will outline conditions, including language for safety, probable benefit and labeling for intended use, which will be required for formal marketing approval.

In December of 2022, Nuwellis and SeaStar entered into a U.S. license and distribution agreement for SeaStar Medical's SCD for pediatric AKI. Under this agreement, Nuwellis will market and distribute the SCD through its direct salesforce to nephologists and intensive care physicians who are trained in pediatric extracorporeal therapy.

"This regulatory update is an important milestone for our partner, SeaStar, who intends to follow the regulatory path laid out by the FDA for marketing approval to commercialize SCD for the pediatric indication by the end of 2023," said Nestor Jaramillo, Jr., President and CEO of Nuwellis. "Nuwellis' pediatric team is excited to finally bring this lifesaving therapy to serve the needs of its growing network in the pediatric clinical community."

Each year in the U.S. approximately 4,000 children with AKI require CKRT and those patient profiles are associated with high mortality. The mortality rate in children with AKI requiring CKRT is approximately 50 percent. Children who survive an AKI episode are at risk for long-term conditions, including chronic kidney disease (CKD).[1]

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, Minnesota with a wholly owned subsidiary in Ireland. For more information visit **www.nuwellis.com** or visit us on **LinkedIn**.

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 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 due to new information, future events or otherwise.

[1] Goldstein, Stuart L., et al. “Use of the Selective Cytopheretic Device in Critically Ill Children.” *Kidney International Reports*, vol. 6, no. 3, 18 Dec. 2020, pp. 775–784., https://doi.org/10.1016/j.ekir.2020.12.010.

CONTACTS

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