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): **July 17, 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 7.01 Regulation FD Disclosure.

On July 17, 2024, Nuwellis, Inc. (the "***Company***") announced its first commercial sale of QUELIMMUNE™ Therapy to Cincinnati Children's Hospital. A copy of the press release, which discusses this matter, is furnished hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "***Exchange Act***") or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933 (the "***Securities Act***") or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

Press Release

On July 17, 2024, the Company announced its first commercial sale of QUELIMMUNE™ Therapy to Cincinnati Children's Hospital. QUELIMMUNE™ is a novel therapy developed by SeaStar Medical Holding Corporation ("***SeaStar***") for pediatric patients suffering from an uncontrolled inflammatory response triggered by their immune systems. The Company is distributing QUELIMMUNE™ pursuant to the terms of its exclusive U.S. license and distribution agreement with SeaStar.

Forward- Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act and Private Securities Litigation Reform Act, as amended, including those relating to the Company's distribution of products, timelines, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the U.S. Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release, dated July 17, 2024
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: July 17, 2024

NUWELLIS, INC.

By: /s/ Nestor Jaramillo, Jr

Name: Nestor Jaramillo, Jr.

Title: President and Chief Executive Officer

Exhibit 99.1

Nuwellis Marks First Commercial Sale of QUELIMMUNE™ Therapy to Cincinnati Children's

MINNEAPOLIS — Jul. 17, 2024 — Nuwellis, Inc. (Nasdaq: NUWE), a medical technology company dedicated to transforming the lives of patients suffering from fluid overload, is proud to announce its first commercial sale of QUELIMMUNE™, a novel therapy developed by SeaStar Medical Holding Corporation for pediatric patients suffering from an uncontrolled inflammatory response triggered by their immune systems, to Cincinnati Children's. We believe this milestone marks a significant advancement in pediatric critical care and underscores Nuwellis' commitment to revolutionizing pediatric patient outcomes.

QUELIMMUNE, or Selective Cytopheretic Device for pediatrics, represents a transformative solution for pediatric patients suffering from acute kidney injury (AKI) due to sepsis or a septic condition on antibiotic therapy and requiring kidney replacement therapy (KRT). Early clinical data suggest a 77% survival rate for patients treated with this new therapy[1]. Through Nuwellis' exclusive U.S. license and distribution agreement with SeaStar Medical (Nasdaq: ICU), the developer of QUELIMMUNE, this therapy is now accessible under a Humanitarian Device Exemption (HDE) from the Food and Drug Administration (FDA) to medical institutions like Cincinnati Children's, giving nephrologists and intensive care physicians a novel option to address the needs of these critically ill pediatric patients.

Dr. Stuart Goldstein, Director of the Center for Acute Care Nephrology at Cincinnati Children's Hospital, and Principal Investigator of the multi-center studies that led to FDA clearance of QUELIMMUNE, expressed his enthusiasm for the introduction of QUELIMMUNE as standard of care: "We are excited to integrate QUELIMMUNE into our arsenal of therapies for critically ill children with sepsis and AKI requiring CKRT. This innovative treatment offers new hope for this population that had not seen improvement in outcomes for the last 20 years."

Nestor Jaramillo, President and CEO of Nuwellis, emphasized the company's dedication to advancing pediatric healthcare through strategic collaborations and innovative solutions: "The first commercial sale of QUELIMMUNE marks a significant achievement in our pediatric business development strategy. We are excited to collaborate with SeaStar Medical to deliver this life-saving therapy to critically ill patients, reinforcing Nuwellis' commitment to driving positive change in pediatric critical care."

About QUELIMMUNE
QUELIMMUNE is a patented cell-directed extracorporeal device that employs immunomodulating technology to selectively target proinflammatory neutrophils and monocytes during KRT and reduces the hyperinflammatory milieu including the cytokine storm that causes inflammation, organ failure and possible death in critically ill patients. Unlike pathogen removal and other blood-purification tools, the device is integrated with KRT hemofiltration systems to selectively target and transition proinflammatory monocytes to a reparative state and promote activated neutrophils to be less inflammatory. QUELIMMUNE selectively targets the most highly activated proinflammatory neutrophils and monocytes. These cells are then returned back into the body through the blood, and the body is signaled to lower its inflammatory environment and focus on repair. This unique immunomodulation approach may promote long-term organ recovery and eliminate the need for future KRT, including dialysis.

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.

About SeaStar Medical
SeaStar Medical Holding Corporation is a commercial-stage medical technology company that is redefining how extracorporeal therapies may reduce the consequences of excessive inflammation on vital organs. SeaStar Medical's novel technologies rely on science and innovation to provide life-saving solutions to critically ill patients. SeaStar Medical is developing and commercializing cell-directed extracorporeal therapies that target the effector cells that drive systemic inflammation, causing direct tissue damage and secreting a range of pro-inflammatory cytokines that initiate and propagate imbalanced immune responses. For more information visit https://seastarmedical.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 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.

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CONTACTS

Investors:
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1) Goldstein, Stuart L., et al. Use of the Selective Cytopheretic Device to Support Critically Ill Children Requiring Continuous Renal Replacement Therapy: A Probable Benefit-Risk Assessment. medRxiv, 2023.08.22.23294378; doi: https://doi.org/10.1101/2023.08.22.23294378