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): **December 27, 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 1.01 Entry into a Material Definitive Agreement.

On December 27, 2022, Nuwellis, Inc. (the "***Company***") entered into a license and distribution agreement (the "***Distribution Agreement***") with SeaStar Medical Holding Corporation ("***SeaStar***"), pursuant to which SeaStar appointed the Company as its exclusive distributor for the sale and distribution of SeaStar's Selective Cytopheretic Device ("***SCD***") product throughout the United States following the receipt by SeaStar from the United States Food and Drug Administration ("***FDA***") of a written authorization to market such product for pediatric use pursuant to the Humanitarian Device Exemption application submitted by SeaStar. Pursuant to the Distribution Agreement, SeaStar will receive an upfront payment, milestone payments upon achievement of certain milestones and royalties on gross sales of the SCD product. The Distribution Agreement has an initial term commencing on December 27, 2022 and shall end on the three (3) year anniversary from the date that is the earlier of (a) ninety (90) days after SeaStar receives FDA authorization to market such SCD product for pediatric use and (b) the first commercial sale of the SCD product. The term of the Distribution Agreement may be automatically extended for additional terms of one (1) year and for a total of two (2) extensions. Each party has the right to terminate the Distribution Agreement for material breach if such breach is not cured within ninety (90) days after written notice. SeaStar has additional rights to terminate the Distribution Agreement in accordance with other terms set forth in the Distribution Agreement.

The foregoing description of the Distribution Agreement is qualified in its entirety by reference to the full text of such agreement, which will be filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ending December 31, 2022.

On December 29, 2022, the Company and SeaStar issued a joint press release announcing the signing of the Distribution Agreement. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release, dated December 29, 2022.
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: December 29, 2022

NUWELLIS, INC.

By: /s/ Nestor Jaramillo, Jr

Name: Nestor Jaramillo, Jr.

Title: President and Chief Executive Officer

Exhibit 99.1

SeaStar Medical and Nuwellis Enter into a U.S. License and Distribution Agreement for SeaStar Medical's Selective Cytopheretic Device (SCD) for Pediatric Acute Kidney Injury (AKI)

Approximately 4,000 children in the U.S. with AKI require Continuous Kidney Replacement Therapy (CKRT)

DENVER and MINNEAPOLIS (December 29, 2022) – SeaStar Medical Holding Corporation (Nasdaq: ICU) (SeaStar Medical) and Nuwellis, Inc. (Nasdaq: NUWE) (Nuwellis) announce an exclusive U.S. license and distribution agreement by Nuwellis of SeaStar Medical's Selective Cytopheretic Device (SCD) for the treatment of acute kidney injury (AKI) in children. Nuwellis will market and distribute the SCD through its direct salesforce to nephrologists and intensive care physicians who are trained in pediatric extracorporeal therapy. SeaStar Medical expects the U.S. Food and Drug Administration (FDA) to complete a substantive review of a Humanitarian Device Exemption (HDE) for the use of SCD in children (>20 kg.) with AKI during the first quarter of 2023, with a potential commercial introduction in the second quarter of 2023.

SCD is a patented, cell-directed extracorporeal therapy that selectively targets the most activated pro-inflammatory neutrophils and monocytes to stop the cytokine storm that frequently causes organ failure and possible death in critically ill patients. The therapy works with CKRT to target and neutralize pro-inflammatory neutrophils and monocytes, allowing the body to return to homeostasis. Clinical studies have demonstrated SCD's potential to eliminate dialysis dependency, shorten ICU time and restore the lives of critically ill patients.[1,2,3]

"Nuwellis' established relationships with pediatric nephrology and intensive care key opinion leaders make them the ideal marketing partner for SCD in this indication," said Eric Schlorff, Chief Executive Officer of SeaStar Medical. "With Nuwellis, we have a proven, efficient means to reach our target customers while allowing SeaStar Medical to advance additional indications including a planned pivotal clinical trial in the adult acute kidney injury population, which we expect to initiate during the first quarter of 2023."

"We share a commitment with SeaStar Medical to bring potentially lifesaving therapies to children undergoing CKRT therapy," said Nestor Jaramillo, Jr., President and CEO of Nuwellis. "To this end, we are also currently developing a new, fully integrated pediatric CKRT device designed to provide care for small babies and children under 20 kg., and we remain committed to developing and bringing to market safe innovations to address these critical unmet needs. As with fluid overload, critical care clinicians face an uphill battle to save pediatric patients from potentially deadly hyperinflammation. SCD's unique approach has shown a significant impact on saving lives and reducing hospital stays."

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. 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**.

About SeaStar Medical Holding Corporation

SeaStar Medical is a medical technology company focusing on 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. The Company is developing and commercializing 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 **www.seastarmedical.com** or visit us on **LinkedIn** or **Twitter**.

Nuwellis 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 due to new information, future events or otherwise.

SeaStar Medical Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1955. These forward-looking statements include, without limitation, SeaStar Medical's expectations with respect to the timing of regulatory approval of its products and other corporate milestones, the ability of SCD to treat patients with AKI, and the potential benefits of SCD to treat other diseases. Words such as "believe," "project," "expect," "anticipate," "estimate," "intend," "strategy," "future," "opportunity," "plan," "may," "should," "will," "would," "will be," "will continue," "will likely result," and similar expressions are intended to identify such forward-looking statements. 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 significant risks and uncertainties that could cause the actual results to differ materially from the expected results. Most of these factors are outside SeaStar Medical's control and are difficult to predict. Factors that may cause actual future events to differ materially from the expected results, include, but are not limited to: (i) the inability to recognize the anticipated benefits of the business combination with LMAO, which may be affected by, among other things, competition and the ability of the post-combination company to grow and manage growth profitability and retain its key employees, (ii) costs related to the business combination, (iii) the outcome of any legal proceedings that may be instituted against SeaStar Medical following the business combination, (iv) the ability to maintain the listing of its securities on NASDAQ, (v) the ability to implement business plans, forecasts, and other expectations after the completion of the business combination, and identify and realize additional opportunities, (vi) the risk of downturns and the possibility of rapid change in the highly competitive industry in which SeaStar Medical operates, (vii) the risk that SeaStar Medical and its current and future collaborators are unable to successfully develop and commercialize its products or services, or experience significant delays in doing so, including failure to achieve approval of its products by applicable federal and state regulators, (viii) the risk that SeaStar Medical may never achieve or sustain profitability; (ix) the risk that SeaStar Medical may need to raise additional capital to execute its business plan, which may not be available on acceptable terms or at all; (x) the risk that third-parties suppliers and manufacturers are not able to fully and timely meet their obligations, (xi) the risk of product liability or regulatory lawsuits or proceedings relating to SeaStar Medical's products and services, (xii) the risk that SeaStar Medical is unable to secure or protect its intellectual property, and (xiii) other risks and uncertainties indicated from time to time in SeaStar Medical's registration statement on Form S-4, as amended (File No. 333-264993), including those under the "Risk Factors" section therein and in SeaStar Medical's other filings with the SEC. The foregoing list of factors is not exhaustive. Forward-looking statements speak only as of the date they are made. Readers are cautioned not to put undue reliance on forward-looking statements, and SeaStar Medical assume no obligation and do not intend to update or revise these forward-looking statements, whether as a result of 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.
2. Tumlin, James A., et al. "A Multi-Center, Randomized, Controlled, Pivotal Study to Assess the Safety and Efficacy of a Selective Cytopheretic Device in Patients with Acute Kidney Injury." *PLOS ONE*, vol. 10, no. 8, 2015, https://doi.org/10.1371/journal.pone.0132482.
3. Yessayan, Lenar T., et al. "Extracorporeal Immunomodulation Treatment and Clinical Outcomes in ICU COVID-19 Patients." *Critical Care Explorations*, vol. 4, no. 5, 19 May 2022, https://doi.org/10.1097/cce.0000000000000694.

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