

**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 20, 2024**

Nuwellis, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of Incorporation or
Organization)

001-35312
(Commission File Number)

No. 68-0533453
(I.R.S. Employer Identification No.)

12988 Valley View Road, Eden Prairie, MN
(Address of Principal Executive Offices)

55344
(Zip Code)

(952) 345-4200
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

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))

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

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 1.02 Termination of Material Definitive Agreement.

On October 20, 2024 (the “*Effective Date*”), Nuwellis, Inc. (the “*Company*”) and SeaStar Medical Holding Corporation (“*SeaStar*”) entered into a Confidential Settlement Agreement and Release (the “*Settlement Agreement*”), which terminated the License and Distribution Agreement entered into by the Company and SeaStar, dated as of December 27, 2022 (the “*Distribution Agreement*”) and the Supplier and Distributor Quality Agreement dated as of March 5, 2024 (the “*Supply Agreement*,” and together with the Distribution Agreement, the “*SeaStar Agreements*”) pursuant to which SeaStar appointed the Company as its exclusive distributor for the sale and distribution of SeaStar’s product, QUELIMMUNE™.

On May 20, 2024, SeaStar provided notice of breach of the Distribution Agreement to the Company, which the Company disputed as without merit. Without admitting any liability, fault or wrongdoing, the Company and SeaStar entered into the Settlement Agreement. As a result of the Settlement Agreement, SeaStar agreed to pay the Company an aggregate of \$900,000 payable in three installments through December 31, 2024. The termination of the SeaStar Agreements was effective as of the Effective Date.

The description of the terms of the Distribution Agreement is included in the Company’s Current Report on Form 8-K filed on [December 29, 2022](#) and is incorporated herein by reference.

The foregoing summary of the Settlement Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the Settlement Agreement filed as Exhibit 10.1 hereto and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.**(d) Exhibits**

Exhibit

Number

Exhibit Description

[10.1](#) Confidential Settlement Agreement & Release, dated October 20, 2024

104 Cover Page 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: October 23, 2024

NUWELLIS, INC.

By: /s/ NESTOR JARAMILLO, JR

Name: Nestor Jaramillo, Jr.

Title: President and Chief Executive Officer

CONFIDENTIAL SETTLEMENT AGREEMENT & RELEASE

This Confidential Settlement Agreement and Release (“Settlement Agreement”) is made between SeaStar Medical Holding Corporation (“SeaStar”), on the one hand, and Nuwellis, Inc. (“Nuwellis”), on the other hand (each singularly a “Party” and together the “Parties”).

RECITALS

WHEREAS, the Parties entered into a License and Distribution Agreement (“Agreement”) on or about December 27, 2022;

WHEREAS, Nuwellis and SeaStar Medical, Inc. (a wholly-owned subsidiary of SeaStar, “SeaStar Sub”), entered into a Supplier and Distributor Quality Agreement (“Quality Agreement”) on March 5, 2024;

WHEREAS, SeaStar provided notice of termination of the Agreement to Nuwellis, with an effective date of termination as per the notice of August 18, 2024, thereby also terminating the Quality Agreement pursuant to its terms;

WHEREAS, Nuwellis has disputed the validity of SeaStar’s termination of the Agreement;

WHEREAS, without admitting to any liability, fault, or wrongdoing of any kind and for the purpose of avoiding the further cost, expense, and business interruption associated with litigation, the Parties mutually desire to compromise all disputes between them.

TERMS OF SETTLEMENT AGREEMENT

NOW THEREFORE, in light of the foregoing and in consideration of the promises and the mutual covenants, representations, warranties, and terms contained in this Settlement Agreement, and other good and valuable consideration, the receipt and sufficiency of which the Parties acknowledge, each Party warrants, represents, acknowledges, covenants, and agrees as follows:

1. Settlement Payment. SeaStar shall pay to Nuwellis a total amount of \$900,000.00 (Nine hundred thousand dollars) on the following schedule:

(i) \$500,000.00 (Five hundred thousand dollars), less all amounts owed by Nuwellis to SeaStar pursuant to Sections 4.3 (Transfer Pricing) and 4.5 (Royalties; Reports) of the Agreement for Products (as defined in the Agreement) supplied to Nuwellis prior to the date hereof even if such amounts are not yet due, within 2 business days of the Effective Date of this Settlement Agreement.

(ii) \$250,000.00 (Two hundred fifty thousand dollars) due by November 30, 2024.

(iii) \$150,000.00 (One hundred fifty thousand dollars) due by December 31, 2024.

All payments under this Settlement Agreement shall be made by ACH transfer. Before executing this Settlement Agreement, Nuwellis shall provide SeaStar with a W-9 and the information necessary to make the ACH transfer.

2. Delivery of Remaining Inventory. Within 5 business days of the Effective Date of this Settlement Agreement, Nuwellis shall deliver to SeaStar at such address (or email) as designated by SeaStar, any Inventory of QUELIMMUNE.

3. Termination of the Agreement & Quality Agreement. The Parties agree that the Agreement and Quality Agreement will be deemed terminated as of the date hereof, and this Settlement Agreement does not modify or supersede any provisions of the Agreement or Quality Agreement that survives termination.

4. Mutual Releases. Subject to those provisions of the Agreement and Quality Agreement that survive such agreement's termination that require performance after the date of termination (but for clarity, not Section 5.3 of the Agreement), as of the Effective Date, the Parties and each Party's respective officers, directors, shareholders, members, employees, insurers, attorneys, successors and/or assigns, and each Party's affiliated, parent, and subsidiary companies and their respective officers, directors, shareholders, members, employees, insurers, attorneys, successors and/or assigns, mutually release and forever discharge each other Party and each other Party's respective officers, directors, shareholders, members, employees, insurers, attorneys, successors and/or assigns, and each other Party's affiliated, parent, and subsidiary companies and their respective officers, directors, shareholders, members, employees, insurers, attorneys, successors and/or assigns, from any and all claims, damages, debts, liabilities, demands, costs, expenses, interest, suits, attorneys' fees, inconveniences or any other actions or causes of action of any kind and nature, direct or indirect, in law or in equity, whether known or unknown, suspected or unsuspected, past or present, which each other Party now has, has had, or may have had as of the Effective Date, including, but not limited to, any claims asserted or that could have been asserted in connection with the Agreement or Quality Agreement and any claims that each Party could assert now or in the future in any way connected with, arising out of, or related to the Agreement or Quality Agreement, including, but not limited to, in any civil, administrative, equitable, or criminal court or with any agency, administrative body, board, or commission.

5. Ownership Of Matters Subject To Release. The Parties hereby warrant and represent that they are the sole and lawful owners of all rights, title, and interest in and to all matters released herein, and that they have not heretofore assigned or transferred, or purported to assign or transfer, any of such released matters, in whole or in part, to any other person or entity.

6. No Admission Of Liability. This Settlement Agreement implements the compromise and settlement of disputed and contested claims and is entered into by the Parties to avoid the expense and inconvenience of litigation. Nothing contained in this Settlement Agreement shall be construed as an admission by any Party of any liability of any kind to anyone.

7. No Third-Party Rights. Except as specifically provided herein, nothing in this Settlement Agreement is intended to (and nothing in this Settlement Agreement will) confer any rights or remedies under or by reason of this Settlement Agreement on any persons other than the Parties and their respective successors and permitted assigns, nor is anything in this Settlement Agreement intended to relieve or discharge the obligation or liability of any third persons to any Party, nor shall any provisions give any third persons any right or subrogation over or action against any Party.

8. Authority. The Parties certify that they have the full power and authority to execute this Settlement Agreement and certify that they have obtained any necessary authorization for their signature on behalf of any entity.

9. Confidentiality. The Parties agree that, except as reasonably may be required for tax reporting, audit, and related proceedings, neither they nor their attorneys or representatives shall reveal the terms or conditions of this Settlement Agreement to any third party, except (i) with the written consent of all parties to this Settlement Agreement, (ii) as required by validly enforceable court process obtained by a nonparty to this Settlement Agreement, (iii) as required for complying with applicable laws and regulations (including the rules and regulations of the Securities and Exchange Commission or any national securities exchange) as determined by the reasonable opinion of such Party's counsel, or (iv) as may be reasonably necessary to enforce the provisions of this Settlement Agreement in any judicial proceeding. If asked about the Agreement, the Parties will only respond that the Agreement has been terminated.

10. Representation By Counsel. The Parties acknowledge that they have been represented by counsel in the negotiation and execution of this Settlement Agreement, and that they have had a full and complete opportunity and have availed themselves of such opportunity for the advice of counsel in regard to all matters addressed herein. This Settlement Agreement is the product of negotiation, and any rule of contract construction under which this Settlement Agreement would be construed against the drafter shall have no application.

11. Mutual Non-Disparagement. The Parties acknowledge and mutually agree that they will not disparage, defame, or compromise the goodwill, name, or reputation of any Party, or make any statements, verbal or written, in any form either directly or indirectly through a third-party, including, but not limited to, posting, publishing, and/or communicating any derogatory or negative comments about the other Party anywhere at any time. Subject to this Section 11, and notwithstanding anything else to the contrary in this Settlement Agreement, the Parties acknowledge and agree that each may make any required SEC reports as shall be deemed necessary in the exercise of such Party's reasonable judgment.

12. Amendments & Waivers. Any amendment to this Settlement Agreement shall be in writing and conform to the same formalities as this Settlement Agreement. No failure to exercise, and no delay in exercising, any right, remedy, or power under this Settlement Agreement shall operate as a waiver thereof, nor shall any single or partial exercise of any right, remedy, or power under this Settlement Agreement preclude any other or further exercise thereof, or the exercise of any other right, remedy or power provided herein or by law or in equity.

13. Successors & Assigns. This Settlement Agreement shall inure to the benefit of and shall be binding on the Parties hereto and their respective heirs, executors, administrators, principals, parent and affiliated companies, successors, and assigns.

14. Severability. If any term or provision of this Settlement Agreement or the application thereof be held invalid or unenforceable to any extent, the remainder of this Settlement Agreement and the application of such terms and provisions other than those held invalid or unenforceable shall be conformed by the Parties hereto in an equitable manner and shall be enforceable.

15. Costs, Fees & Expenses. Each Party shall bear its own costs, attorneys' fees, and expenses in connection with this Settlement Agreement or the matters subject to release.

16. Further Assurances. The Parties agree to execute such other documents and to take such other action as may be reasonably necessary to further the purposes of this Settlement Agreement.

17. Entire Agreement. This Settlement Agreement constitutes the complete, final agreement between the Parties with respect to the subject matter of this Agreement and supersedes any and all prior oral or written agreements and understandings between the Parties relating to the subject matter of this Settlement Agreement.

18. No Reliance. Each Party acknowledges it is executing this Settlement Agreement without reliance upon any agreement, representation, understanding, or communication by or on behalf of any other Party.

19. Venue. The Parties agree that any disputes concerning this Settlement Agreement shall be brought exclusively in a court of competent jurisdiction within the State of Delaware.

20. Governing Law. This Settlement Agreement shall be construed and interpreted according to the laws of the State of Delaware without giving effect to its conflict of law provisions.

21. Enforcement. The Parties agree that in the event litigation is instituted to enforce any rights or obligations arising under this Settlement Agreement, the prevailing Party in such litigation shall be entitled to recover reasonable attorneys' fees and costs of such suit.

22. Counterparts. This Settlement Agreement may be executed and delivered by electronic means, in one or more counterparts, each of which when so executed shall be deemed to be an original, all of which taken together shall constitute one and the same Settlement Agreement. A portable document format (pdf) copy of any execution of a counterpart shall have the same force and effect as if the same were an original.

IN WITNESS WHEREOF, the Parties have caused this Settlement Agreement to be effective as of the date of its full execution by each Party (“Effective Date”).

NUWELLIS INC.

By: /s/ Nestor Jaramillo, Jr.

Name: Nestor Jaramillo, Jr.

Title: President & CEO

Date: October 20, 2024

SEASTAR MEDICAL HOLDING CORPORATION

By: /s/ Eric Schlorff

Name: Eric Schlorff

Title: Chief Executive Officer

Date: October 20, 2024