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): **May 31, 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 1.01 Entry into a Material Definitive Agreement.

On May 31, 2024, Nuwellis, Inc. (the "***Company***") entered into a first amendment (the "***Amendment***") to the Supply and Collaboration Agreement (the "***Supply Agreement***") with DaVita Inc., a Delaware corporation ("***DaVita***"), dated June 19, 2023, pursuant to which DaVita will pilot the Aquadex ultrafiltration therapy system to treat adult patients with congestive heart failure and related conditions within select U.S. markets. Pursuant to the Supply Agreement, the pilot program launched at the end of the third quarter of 2023 and extended through the earlier of (i) the treatment of not less than 150 patients or (ii) December 31, 2023 (the "***Pilot Term***"); provided however, that DaVita could extend the Pilot Term until May 31, 2024 upon written notice to the Company, which such extension was requested (the "***Pilot***"). The Amendment modified Section 2.1(a) of the Supply Agreement to extend the term of the Pilot through the earlier of (i) the treatment of not less than 150 patents or (ii) August 31, 2024. Except as expressly set forth in the Amendment, the terms of the Supply Agreement remain unchanged and in full force and effect.

The foregoing description of the Amendment does not purport to be complete and is qualified in its entirety by reference to the full text of the Amendment, which is filed as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 8.01 Other Events.

On June 6, 2024, the Company issued a press release announcing the Amendment disclosed herein. A copy of the press release is furnished herewith as Exhibit 99.1 hereto and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
10.1	First Amendment to Supply and Collaboration Agreement dated as of May 31, 2024 by and between the Company and DaVita Inc.
99.1	Press Release, dated June 6, 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: June 6, 2024

NUWELLIS, INC.

By: /s/ Nestor Jaramillo, Jr

Name: Nestor Jaramillo, Jr.

Title: President and Chief Executive Officer

[Signature Page to First Amendment]

Exhibit 10.1

FIRST AMENDMENT TO THE SUPPLY AND COLLABORATION AGREEMENT

This First Amendment to the Supply and Collaboration Agreement (the "First Amendment") is effective as of May 31, 2024 (the "Effective Date"), by and between DaVita Inc., a Delaware corporation, for the benefit of DaVita and its Affiliates (collectively referred to as "DaVita"), and Nuwellis, Inc., a Delaware corporation ("Nuwellis"). DaVita and Nuwellis may be referred to herein individually as a "Party" and collectively as the "Parties". Capitalized terms used but not otherwise defined herein shall have the meanings set forth in the Agreement.

WHEREAS, the Parties entered into the Supply and Collaboration Agreement, dated as of June 19, 2023 (the "Agreement") and wish to amend the terms of the Agreement as set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises and mutual covenants, agreements, representations, and warranties contained in this First Amendment, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, DaVita and Nuwellis agree to the foregoing and as follows:

1.0 Amendment. Section 2.1(a) of the Agreement is hereby amended and restated in its entirety to state:

"(a) This Agreement shall commence on the Effective Date and shall remain in full force and effective through the earlier to occur of (i) the treatment of not less than 150 patients or (ii) August 31, 2024 ("Pilot Term")."

1.1 No Implied Amendments. Except as specifically amended by this First Amendment, the Agreement shall remain in full force and effect in accordance with its terms.

1.2 Effectiveness of Amendment. This First Amendment shall be deemed to be a modification to the Agreement in accordance with Section 12.14 of the Agreement.

1.3 Headings. The headings contained in this First Amendment are for reference purposes only and shall not affect in any way the meaning or interpretation of this First Amendment.

1.4 Governing Law. This First Amendment and all actions (whether at law, in contract, in tort or otherwise) arising out of or relating to this First Amendment, the negotiation, validity or performance of this First Amendment shall be governed by, and construed in accordance with, the laws of the State of Delaware, regardless of the laws that might otherwise govern under applicable principles of conflicts of laws. Any dispute with respect to this First Amendment shall be subject to the dispute resolution provisions set forth in the Agreement.

1.5 Counterparts; Facsimile. This First Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including PDF or any electronic signature complying with the U.S. federal ESIGN Act of 2000) or other transmission method, and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

1.6 References to the Agreement. On and after the Effective Date, each reference in the Agreement to "this Agreement," "hereunder," "hereof" or words of like import referring to the Agreement shall mean the Agreement as amended by this First Amendment.

IN WITNESS WHEREOF, the Parties hereby indicate their acceptance of the terms of this First Amendment as of the Effective Date by the signatures of their authorized representatives.

DAVITA:

By: /s/ Ray Follett
Name: Ray Follett
Title: Group Vice President

NUWELLIS:

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

[Signature Page to First Amendment]

Exhibit 99.1

Nuwellis and DaVita Extend Supply and Collaboration Agreement Pilot Phase

Pilot Collaboration for Aquadex® Ultrafiltration Therapy for Adult Patients with Congestive Heart Failure is extended to August 31, 2024

MINNEAPOLIS — Jun. 6, 2024 — Nuwellis, Inc. Nuwellis, Inc. (Nasdaq: NUWE), a medical technology company dedicated to transforming the lives of patients with fluid overload, today announced the extension of its pilot phase under its previously announced supply and collaboration agreement with DaVita Inc. (NYSE: DVA) until August 31, 2024.

This program aims to pilot Aquadex® ultrafiltration therapy for adult patients suffering from congestive heart failure and related conditions in select U.S. markets. Today, DaVita serves as a leading provider of kidney care services, including acute and outpatient dialysis care for patients in-center and at home. The extension of the pilot will allow additional time to evaluate ultrafiltration therapy using the Aquadex SmartFlow system with high-need patients in the hospital.

At the conclusion of the pilot, DaVita may extend the supply agreement with Nuwellis for continued provision of both inpatient and outpatient ultrafiltration services for up to 10 years. This opportunity for long-term collaboration highlights the commitment of both companies to advancing patient care through innovative medical solutions.

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 DaVita
DaVita (NYSE: DVA) is a healthcare provider focused on transforming care delivery to improve quality of life for patients globally. The company is one of the largest providers of kidney care services in the U.S. and has been a leader in clinical quality and innovation for more than 20 years. DaVita cares for patients at every stage and setting along their kidney health journey—from slowing the progression of kidney disease to helping to support transplantation, from acute hospital care to dialysis at home. As of December 31, 2022, DaVita served 200,000 patients at 2,724 outpatient dialysis centers in the United States. The company also operated 350 outpatient dialysis centers in 11 other countries worldwide. DaVita has reduced hospitalizations, improved mortality, and worked collaboratively to propel the kidney care industry to adopt an equitable and high-quality standard of care for all patients, everywhere. To learn more, visit www.davita.com/About.

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 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

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