

**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): **February 23, 2023**

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 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 2.02 Results of Operations and Financial Condition.

On February 28, 2023, Nuwellis, Inc. (the “*Company*”) issued a press release reporting its financial results for the twelve months ended December 31, 2022. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information included in this Item on Current Report on Form 8-K (including Exhibit 99.1) is furnished pursuant to Item 2.02 and shall not be deemed to be “filed” for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section.

Item 8.01 Other Events.

On February 23, 2023, the Board of Directors (the “*Board*”) of the Company adopted the Second Amendment (the “*Second Amendment*”) to the 2021 Inducement Plan (the “*Inducement Plan*”), increasing the aggregate number of shares of common stock that may be issued pursuant to equity incentive awards under the Inducement Plan by 44,078 shares for a total of 46,928 shares of common stock that may be issued pursuant to equity incentive awards under the Inducement Plan. The Company believes that the increase in the shares reserved under the Inducement Plan is necessary to allow it to attract qualified employees to continue the commercialization of the Aquadex FlexFlow(R) System.

The forgoing description of the terms of the Second Amendment is qualified in its entirety by reference to the actual terms of the Second Amendment, which is attached hereto as Exhibit 10.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit

No. Description

10.1	Second Amendment to 2021 Inducement Plan.
99.1	Press Release, dated February 28, 2023, reporting the financial results of Nuwellis, Inc. for the twelve months ended December 31, 2022.
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: February 28, 2023

NUWELLIS, INC.

By: /s/ NESTOR JARAMILLO, JR.

Name: Nestor Jaramillo, Jr.

Title: Chief Executive Officer

SECOND AMENDMENT TO

THE NUWELLIS, INC.

2021 INDUCEMENT PLAN

The Nuwellis, Inc. 2021 Inducement Plan, as amended (the “**Plan**”) is hereby amended in the following respects, effective February 23, 2023, in accordance with Section 2(b)(vi) of the Plan.

The first sentence of Section 3(a) of the Plan is deleted in its entirety and replaced with the following sentence:

“Subject to Section 9(a) relating Capitalization Adjustments, the aggregate number of shares of Common Stock that may be issued pursuant to Awards will not exceed 46,928 shares (the “**Share Reserve**”).”



**Nuwellis, Inc. Announces Fourth Quarter and Full Year 2022 Financial Results
Q4 Revenue Up 42%; Expansion of Clinical Evidence Sets Stage for 2023 Growth**

Minneapolis, MN, February 28, 2023 (GLOBE NEWSWIRE) -- Nuwellis, Inc. (Nasdaq: NUWE), a medical technology company focused on transforming the lives of people with fluid overload, today reported financial results for the fourth quarter and full year ended December 31, 2022.

- Revenue of \$2.3 million for the fourth quarter 2022, a 42% increase over the prior-year period. Full year revenue of \$8.5 million, an 8% increase over 2021.
- Gross margin of 56.9% in the fourth quarter 2022, an increase of 250 basis points from the same period last year. Full year 2022 gross margin of 55.7%, a decrease of 100 basis points from 2021.
- By segment, fourth quarter 2022 revenue was led by Pediatrics, followed by Heart Failure and Critical Care, which increased approximately 92%, 47%, and 24% over the same period last year, respectively. Full year 2022 revenue by segment was led by Pediatrics and Heart Failure, which increased approximately 28% and 9%, respectively.
- Entered into an exclusive U.S. license and distribution agreement for SeaStar Medical's Selective Cytopheretic Device (SCD) for pediatric Acute Kidney Injury (AKI). Approximately 4,000 children with AKI who are at high risk of mortality require therapy annually.
- Announced peer-reviewed publication of results from a 10-year, real-world retrospective study supporting lower heart failure hospitalizations and readmissions with Aquadex. Data demonstrated 81% lower heart failure hospitalizations per year and a 48% decrease in rehospitalizations at 30 days from the national average.
- Announced peer-reviewed data demonstrating 71% survival with kidney replacement therapy using Aquadex in low birth-weight preterm neonates.
- Announced AVOID-HF clinical study analysis demonstrating clinical data that strongly favored adjustable ultrafiltration using Aquadex over adjustable IV diuretics in reducing cardiovascular mortality and subsequent HF events when patients are unresponsive to diuretics treatment.
- Continued site activations for the Company's REVERSE-HF clinical trial, with nine sites activated to date, on track to complete twelve activations by the end of first quarter 2023.
- Appointed Chief Medical Officer, John Jefferies, M.D., and Chief Financial Officer, Lynn Blake, to the Executive Leadership team.
- Cash, cash equivalents, and marketable securities of \$18.3 million and no debt as of December 31, 2022.

"2022 proved to be a year of growth for Nuwellis, with 42% year-over-year revenue growth in the fourth quarter and 8% revenue growth for the full year. In 2023, we remain focused on the execution of our key strategic growth initiatives, with targeted expansion of our commercial team, investments in market penetration initiatives, and leverage of our growing body of clinical evidence to drive continued sales momentum. We are committed to making Aquadex the standard of care for patients with fluid overload who are not responsive to diuretics and driving increased utilization of ultrafiltration therapy in 2023 and beyond," said Nestor Jaramillo, President and CEO of Nuwellis.

Fourth Quarter 2022 Financial Results

Revenue for the fourth quarter of 2022 was \$2.3 million, compared to \$1.6 million in the prior-year period.

Gross margin was 56.9% for the fourth quarter of 2022, compared to 54.4% in the prior-year period, an increase of 250 basis points, resulting from increased sales volume.

Selling, general and administrative expenses for the fourth quarter of 2022 were \$4.7 million, compared to \$4.1 million in the prior-year period. The increase in SG&A was primarily due to higher professional service fees and variable compensation expense, balanced with continued spending vigilance.

Fourth quarter research and development expenses were \$1.2 million, compared to \$1.1 million in the fourth quarter of 2021, reflecting a slight increase in product development expenses.

Net loss for the fourth quarter of 2022 was \$1.9 million, or a loss of \$5.00 per basic and diluted common share, compared to a net loss of \$4.3 million, or a loss of \$41.09 per basic and diluted common share in the prior-year period. The current period net loss includes \$2.6 million of Other Income related to the year-end revaluation of warrants issued in conjunction with the Company's October financing.

At December 31, 2022, the Company had cash, cash equivalents, and marketable securities of approximately \$18.3 million and no debt. Outstanding shares as of February 24 were approximately 1.2 million, reflecting the Company's December reverse stock split and the exercise of warrants issued in conjunction with the Company's October financing.

Webcast and Conference Call Information

The Company will host a conference call and webcast at 8:30 AM ET today to discuss its financial results and provide an update on the Company's performance.

To access the live webcast, please visit the Investors page of the Nuwellis website at <https://ir.nuwellis.com>. Alternatively, you may access the live conference call by dialing 1-844-825-9789 (U.S) or 1-412-317-5180 (international) and using the conference ID: 10175088. An audio archive of the webcast will be available following the call on the Investors page at <https://ir.nuwellis.com>.

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](#).

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 as a result of new information, future events or otherwise.

CONTACTS

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NUWELLIS, INC. AND SUBSIDIARY
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	December 31, 2022	December 31, 2021
	(unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 17,737	\$ 8,742
Marketable securities	569	15,463
Accounts receivable	1,406	750
Inventories, net	2,661	2,843
Other current assets	396	328
Total current assets	22,769	28,126
Property, plant and equipment, net	980	1,188
Operating lease right-of-use asset	903	1,082
Other assets	21	21
TOTAL ASSETS	\$ 24,673	\$ 30,417
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 2,245	\$ 1,414
Accrued compensation	2,161	1,664
Current portion of operating lease liability	196	167
Current portion of finance lease liability	28	26
Other current liabilities	58	36
Total current liabilities	4,688	3,307
Common stock warrant liability	6,868	—
Operating lease liability	760	956
Finance lease liability	—	28
Other long-term liability	—	179
Total liabilities	12,316	4,470
Commitments and contingencies		
Stockholders' equity		
Series A junior participating preferred stock as of December 31, 2022 and December 31, 2021, par value \$0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Series F convertible preferred stock as of December 31, 2022 and December 31, 2021, par value \$0.0001 per share; authorized 127 shares, issued and outstanding 127 shares	—	—
Series I convertible preferred stock as of December 31, 2022 and December 31, 2021, par value \$0.0001 per share; authorized 1,049,280 and none, issued and outstanding 1,049,280 and none, respectively	—	—
Preferred stock as of December 31, 2022 and December 31, 2021, par value \$0.0001 per share; authorized 39,969,873 shares, none outstanding	—	—
Common stock as of December 31, 2022 and December 31, 2021, par value \$0.0001 per share; authorized 100,000,000 shares, issued and outstanding 536,394 and 105,376, respectively	—	—
Additional paid-in capital	279,736	278,874
Accumulated other comprehensive income:		
Foreign currency translation adjustment	(18)	(11)
Unrealized gain (loss) on marketable securities	56	(24)
Accumulated deficit	(267,417)	(252,892)
Total stockholders' equity	12,357	25,947
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 24,673	\$ 30,417

NUWELLIS, INC. AND SUBSIDIARY
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except per share amounts)

	Three months ended December 31,		Twelve months ended December 31,	
	2022	2021	2022	2021
	(unaudited)	(unaudited)	(unaudited)	
Net sales	\$ 2,339	\$ 1,642	\$ 8,543	\$ 7,921
Cost of goods sold	1,008	748	3,788	3,430
Gross profit	<u>1,331</u>	<u>894</u>	<u>4,755</u>	<u>4,491</u>
Operating expenses:				
Selling, general and administrative	4,664	4,094	17,584	19,039
Research and development	1,201	1,131	4,342	4,978
Total operating expenses	<u>5,865</u>	<u>5,225</u>	<u>21,926</u>	<u>24,017</u>
Loss from operations	(4,534)	(4,331)	(17,171)	(19,526)
Other income (expense), net				
Other income (expense), net	61	3	75	(19)
Financing expense	(9,247)	—	(9,247)	—
Change in fair value of warrant liability	11,827	—	11,827	—
Loss before income taxes	<u>(1,893)</u>	<u>(4,328)</u>	<u>(14,516)</u>	<u>(19,545)</u>
Income tax expense	(3)	(2)	(9)	(9)
Net loss	<u>\$ (1,896)</u>	<u>\$ (4,330)</u>	<u>\$ (14,525)</u>	<u>\$ (19,554)</u>
Basic and diluted loss per share	<u>\$ (5.00)</u>	<u>\$ (41.09)</u>	<u>\$ (83.55)</u>	<u>\$ (285.36)</u>
Weighted average shares outstanding – basic and diluted	379	105	174	69
Other comprehensive loss:				
Unrealized gain (loss) on marketable securities	6	(24)	80	(24)
Foreign currency translation adjustments	<u>\$ (7)</u>	<u>\$ —</u>	<u>\$ (7)</u>	<u>\$ (4)</u>
Total comprehensive loss	<u>\$ (1,897)</u>	<u>\$ (4,354)</u>	<u>\$ (14,452)</u>	<u>\$ (19,582)</u>

NUWELLIS, INC. AND SUBSIDIARY
Condensed Consolidated Statements of Cash Flows
(In thousands)

	For the years ended December 31,	
	2022 (unaudited)	2021
Operating Activities		
Net loss	\$ (14,525)	\$ (19,554)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	372	488
Stock-based compensation expense, net	862	1,314
Change in fair value of warrant liability	(11,827)	—
Financing expense	9,247	—
Net realized and unrealized gains on marketable securities	124	13
Changes in operating assets and liabilities:		
Accounts receivable	(656)	155
Inventory	140	(143)
Other current assets	(68)	(91)
Other assets and liabilities	(96)	186
Accounts payable and accrued expenses	1,278	(211)
Net cash used in operations	(15,149)	(17,843)
Investing activities:		
Purchases of marketable securities	—	(18,850)
Proceeds from sales of marketable securities	14,850	3,350
Purchase of property and equipment	(122)	(219)
Net cash provided (used) in investing activities	14,728	(15,719)
Financing activities:		
Proceeds from public stock offerings, net	9,449	27,896
Proceeds from warrant exercises	—	1
Payments on finance lease liability	(26)	(26)
Net cash provided by financing activities	9,423	27,871
Effect of exchange rate changes on cash	(7)	(4)
Net increase in cash and cash equivalents	8,995	(5,695)
Cash and cash equivalents—beginning of year	8,742	14,437
Cash and cash equivalents—end of year	\$ 17,737	\$ 8,742
Supplemental schedule of non-cash activities		
Inventory transferred to property, plant and equipment	\$ 42	\$ 257
Operating right-of-use asset recorded as an operating lease liability	\$ —	\$ 901
Supplemental cash flow information		
Cash paid for income taxes	\$ 9	\$ 11