

**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): **August 8, 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 August 8, 2023, Nuwellis, Inc. (the “Company”) issued a press release reporting its financial results for the three and six months ended June 30, 2023. 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 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 9.01 Financial Statements and Exhibits.**(d) Exhibits****Exhibit No. Description**

[99.1](#) Press Release, dated August 8, 2023, reporting the financial results of Nuwellis, Inc. for the three and six months ended June 30, 2023.

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: August 8, 2023

NUWELLIS, INC.

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



Nuwellis, Inc. Announces Second Quarter 2023 Financial Results

Minneapolis, MN, August 8, 2023 (GLOBE NEWSWIRE) -- Nuwellis, Inc. (Nasdaq: NUWE), a medical technology company dedicated to transforming the lives of people with fluid overload, today reported financial results for the second quarter ended June 30, 2023.

- Revenue of \$2.1 million for the second quarter 2023, representing a 14% increase over the prior quarter and a 6% decrease over the prior-year period.
- Utilization, or the number of circuits per console, increased 14% over the same period last year, reflecting an increase in the number of patients treated with the Aquadex therapy.
- By segment, second quarter 2023 revenue in Heart Failure increased approximately 8% over the same period last year, while Critical Care and Pediatrics declined approximately 20% and 5%, respectively. Pediatrics increased 72% from the first quarter.
- Gross margin rate of 55.3% in the second quarter 2023, representing a 730-basis point improvement compared to a gross margin rate of 48% in the same period last year.
- Entered into a Supply and Collaboration Agreement with DaVita Inc. to pilot Aquadex ultrafiltration therapy to treat adult patients with congestive heart failure and related conditions in select U.S. markets.
- Announced the appointment of Mike McCormick to the Board of Directors.
- Cash and cash equivalents of approximately \$9 million and no debt as of June 30, 2023.

“We are pleased to report a rebound in our business in the second quarter, with Pediatrics increasing 72% from first quarter, steady growth in the number of patients treated with Aquadex therapy compared to last year, and continued momentum in Heart Failure, supported by growing awareness of our clinical evidence,” said Nestor Jaramillo, President and CEO of Nuwellis. “As we continue to execute on our goal of transforming the lives of patients suffering from fluid overload, we are excited to collaborate with DaVita to potentially help accelerate clinical adoption of our Aquadex ultrafiltration therapy when first-line medical treatments are ineffective. We are currently in active planning for and look forward to initiating the pilot program with DaVita,” concluded Mr. Jaramillo.

Second Quarter 2023 Financial Results

Revenue for the second quarter of 2023 was \$2.1 million, compared to \$2.2 million in the prior-year period. Results in the quarter were driven by an increase of 14% in circuit sales offset by lower console sales.

Gross margin was 55.3% for the second quarter of 2023, a 730-basis point improvement year over year, primarily due to favorable product sales mix and a \$0.1 million non-cash inventory write-off related to the discontinuation of a distribution agreement in the prior-year period.

Selling, general and administrative expenses for the second quarter of 2023 were \$4.7 million, compared to \$4.3 million in the prior-year period. The increase was primarily due to increased professional fees in the current year quarter.

Second quarter research and development expenses were \$1.5 million, compared to \$1.1 million in the second quarter of 2022, reflecting higher spend on the new pediatric CRRT device as we ramp up the development effort in preparation for the IDE submission.

Total operating expense of \$6.2 million was up 15% year over year and down 11% sequentially; this decrease was primarily due to a consolidation of sales territories in the quarter aimed at increasing efficiency.

Net loss for the second quarter of 2023 was \$4.8 million, or a loss of \$3.65 per share, compared to a net loss of \$4.3 million, or a loss of \$40.67 per common share, in the prior-year period. The decrease in net loss per share is due to the fact that weighted average shares outstanding for the second quarter of 2023 were approximately 1.3 million, compared to weighted average shares outstanding of approximately 105,000 in the prior-year quarter.

At June 30, 2023, the Company had cash and cash equivalents of approximately \$9 million and no debt, with approximately 1.9 million common shares outstanding.

Webcast and Conference Call Information

The company will host a conference call and webcast at 9:00 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 1-833-816-1404 (U.S) or 1-412-317-0497 (international) and using the conference ID: 10180182. 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, Minnesota 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 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, 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

INVESTORS:

Vivian Cervantes

Gilmartin Group

ir@nuwellis.com

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

	June 30, 2023	December 31, 2022
	(unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 8,896	\$ 17,737
Marketable securities	—	569
Accounts receivable	1,176	1,406
Inventories, net	2,733	2,661
Other current assets	943	396
Total current assets	13,748	22,769
Property, plant and equipment, net	875	980
Operating lease right-of-use asset	810	903
Other assets	120	21
TOTAL ASSETS	\$ 15,553	\$ 24,673
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 2,311	\$ 2,245
Accrued compensation	1,234	2,161
Current portion of operating lease liability	206	196
Current portion of finance lease liability	14	28
Other current liabilities	60	58
Total current liabilities	3,825	4,688
Common stock warrant liability	—	6,868
Operating lease liability	654	760
Total liabilities	4,479	12,316
Commitments and contingencies		
Stockholders' equity		
Series A junior participating preferred stock as of June 30, 2023 and December 31, 2022, par value \$0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Series F convertible preferred stock as of both June 30, 2023 and December 31, 2022, par value \$0.0001 per share; authorized 127 shares, issued and outstanding 127 shares	—	—
Series I convertible preferred stock as of June 30, 2023 and December 31, 2022, par value \$0.0001; authorized 1,049,280, issued and outstanding none and 1,049,280, respectively	—	—
Preferred stock as of both June 30, 2023 and December 31, 2022, par value \$0.0001 per share; authorized 39,969,873 shares, none outstanding	—	—
Common stock as of June 30, 2023 and December 31, 2022, par value \$0.0001 per share; authorized 100,000,000 shares, issued and outstanding 1,864,265 and 536,394 shares, respectively	—	—
Additional paid-in capital	289,845	279,736
Accumulated other comprehensive income:		
Foreign currency translation adjustment	(24)	(18)
Unrealized gain on marketable securities	—	56
Accumulated deficit	(278,747)	(267,417)
Total stockholders' equity	11,074	12,357
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 15,553	\$ 24,673

See notes to the condensed consolidated financial statements.

NUWELLIS, INC. AND SUBSIDIARY
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

(in thousands, except per share amounts)

	Three months ended June 30		Six months ended June 30	
	2023	2022	2023	2022
Net sales	\$ 2,075	\$ 2,213	\$ 3,901	\$ 4,139
Cost of goods sold	928	1,150	1,687	1,974
Gross profit	<u>1,147</u>	<u>1,063</u>	<u>2,214</u>	<u>2,165</u>
Operating expenses:				
Selling, general and administrative	4,664	4,257	10,154	8,669
Research and development	1,505	1,107	2,933	2,213
Total operating expenses	<u>6,169</u>	<u>5,364</u>	<u>13,087</u>	<u>10,882</u>
Loss from operations	(5,022)	(4,301)	(10,873)	(8,717)
Other income (expense), net	179	17	302	(38)
Change in fair value of warrant liability	—	—	(755)	—
Loss before income taxes	(4,843)	(4,284)	(11,326)	(8,755)
Income tax expense	(2)	(2)	(4)	(4)
Net loss	<u>\$ (4,845)</u>	<u>\$ (4,286)</u>	<u>\$ (11,330)</u>	<u>\$ (8,759)</u>
Basic and diluted loss per share	<u>\$ (3.65)</u>	<u>\$ (40.67)</u>	<u>\$ (9.23)</u>	<u>\$ (83.12)</u>
Weighted average shares outstanding – basic and diluted	1,328	105	1,227	105
Other comprehensive loss:				
Foreign currency translation adjustments	\$ 1	\$ 1	\$ (6)	\$ (1)
Total comprehensive loss	<u>\$ (4,844)</u>	<u>\$ (4,285)</u>	<u>\$ (11,336)</u>	<u>\$ (8,760)</u>

See notes to the condensed consolidated financial statements.

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

	Six months ended	
	June 30	
	2023	2022
Operating Activities:		
Net loss	\$ (11,330)	\$ (8,759)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	169	206
Stock-based compensation expense, net	378	477
Change in fair value of warrant liability	755	—
Net realized gain on marketable securities	(65)	—
Changes in operating assets and liabilities:		
Accounts receivable	230	(563)
Inventory, net	(72)	(167)
Other current assets	(547)	76
Other assets and liabilities	(20)	(152)
Accounts payable and accrued expenses	(856)	117
Net cash used in operating activities	(11,358)	(8,765)
Investing Activities:		
Proceeds from sale of marketable securities	578	—
Additions to intangible assets	(99)	—
Purchases of property and equipment	(64)	(81)
Net cash provided by (used in) investing activities	415	(81)
Financing Activities:		
Proceeds from ATM stock offerings, net	2,108	—
Payments on finance lease liability	—	(13)
Net cash provided by (used in) financing activities	2,108	(13)
Effect of exchange rate changes on cash	(6)	(1)
Net decrease in cash and cash equivalents	(8,841)	(8,860)
Cash and cash equivalents - beginning of period	17,737	24,205
Cash and cash equivalents - end of period	\$ 8,896	\$ 15,345

See notes to the condensed consolidated financial statements.