

**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): **November 7, 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.

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**Item 2.02 Results of Operations and Financial Condition.**

On November 7, 2023, Nuwellis, Inc. (the “Company”) issued a press release reporting its financial results for the three and nine months ended September 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**

<a href="#">99.1</a>	Press Release, dated November 7, 2023, reporting the financial results of Nuwellis, Inc. for the three and nine months ended September 30, 2023.
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**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: November 7, 2023

**NUWELLIS, INC.**

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

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### Nuwellis, Inc. Announces Third Quarter 2023 Financial Results

Minneapolis, MN, November 7, 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 third quarter ended September 30, 2023.

- Revenue of \$2.4 million for the third quarter 2023, increased 16% over the prior quarter and increased 17% over the prior-year period.
- Therapy utilization, or the number of circuits per placed console, increased 26% over the prior year, reflecting continued increases in the number of patients treated with the Aquadex® therapy.
- By customer category, third quarter 2023 revenue in Heart Failure increased 27% over the same period last year, Critical Care and Pediatrics increased 16% and 9%, respectively.
- Despite continuing hospital capital budget constraints, our installed console base increased. In the third quarter, we sold 20 consoles, an increase of 11 units vs prior quarter.

“Our 17% annual revenue growth in the third quarter was driven by steady progress on our key strategic initiatives, including leveraging our growing body of clinical evidence to increase the number of patients treated with the Aquadex Ultrafiltration System. We believe these efforts drove both adoption and growth, with a 26% increase in therapy utilization and continued revenue growth across all customer categories.” said Nestor Jaramillo, Jr., President and CEO of Nuwellis. “In addition to the strong sales results, we are very excited with our two strategic collaborations with SeaStar and DaVita. We congratulate SeaStar on its recent receipt of an Approvable Letter from the FDA for its Pediatric SCD device, as to which we have exclusive U.S. distribution rights. We continue to make progress in the pilot phase of our Supply and Collaboration Agreement with DaVita. With focused execution across multiple growth levers, our team is committed to make Aquadex ultrafiltration therapy the new standard of care for fluid overload patients resistant to diuretics,” concluded Mr. Jaramillo.

#### Third Quarter 2023 Financial Results

Revenue for the third quarter of 2023 was \$2.4 million, a 17% growth over the prior-year period. Results in the quarter were driven by a 26% increase in circuit sales.

Gross margin was 57.3% for the third quarter of 2023, compared to 61.0% in the prior-year period. The decline in gross margin was primarily driven by lower console manufacturing volumes. US disposable product margins are 74.0% which are in-line with medical technology industry standards.

Selling, general and administrative expenses for the third quarter of 2023 were \$3.4 million, compared to \$4.2 million in the prior-year period. The \$800,000 decrease was primarily due to reduced headcount and related compensation expense.

Third quarter research and development expenses were \$1.1 million, compared to \$928 thousand in the third quarter of 2022, reflecting a modest increase in spend related to the final phases of the development of our new pediatric dedicated CRRT device as we approach IDE submission.

Total operating expense of \$4.5 million was down 12% year over year and down 26% sequentially; due to cost saving measures implemented early in Q3.

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Net loss for the third quarter of 2023 was \$3.4 million, or a loss of \$1.81 per share, compared to a net loss of \$3.9 million, or a loss of \$36.72 per common share, in the prior-year period. The decrease in net loss per share is due to an increase in sales, lower spend, and an increase in weighted average share count.

At September 30, 2023, the Company had no debt and cash and cash equivalents of \$4.9 million, with approximately 1.9 million common shares outstanding. On October 17, Nuwellis closed an underwritten public offering with gross proceeds of \$2.25 million before deducting underwriting discounts and commissions related to the offering.

### **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: 10182705. 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](http://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.

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## CONTACTS

### INVESTORS:

Vivian Cervantes

Gilmartin Group

[ir@nuwellis.com](mailto:ir@nuwellis.com)

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

	<u>September 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
	<u>(unaudited)</u>	
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 4,930	\$ 17,737
Marketable securities	—	569
Accounts receivable	1,425	1,406
Inventories, net	2,336	2,661
Other current assets	947	396
<b>Total current assets</b>	<b>9,638</b>	<b>22,769</b>
Property, plant and equipment, net	912	980
Operating lease right-of-use asset	762	903
Other assets	120	21
<b>TOTAL ASSETS</b>	<b>\$ 11,432</b>	<b>\$ 24,673</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable and accrued liabilities	\$ 1,707	\$ 2,245
Accrued compensation	1,021	2,161
Current portion of operating lease liability	211	196
Current portion of finance lease liability	8	28
Other current liabilities	45	58
<b>Total current liabilities</b>	<b>2,992</b>	<b>4,688</b>
Common stock warrant liability	—	6,868
Operating lease liability	601	760
<b>Total liabilities</b>	<b>3,593</b>	<b>12,316</b>
Commitments and contingencies		
<b>Stockholders' equity</b>		
Series A junior participating preferred stock as of September 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 September 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 September 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 September 30, 2023 and December 31, 2022, par value \$0.0001 per share; authorized 39,969,873 shares, none outstanding	—	—
Common stock as of September 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	289,980	279,736
Accumulated other comprehensive income:		
Foreign currency translation adjustment	(24)	(18)
Unrealized gain on marketable securities	—	56
Accumulated deficit	(282,117)	(267,417)
<b>Total stockholders' equity</b>	<b>7,839</b>	<b>12,357</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 11,432</b>	<b>\$ 24,673</b>

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 September 30		Nine months ended September 30	
	2023	2022	2023	2022
<b>Net sales</b>	\$ 2,412	\$ 2,065	\$ 6,313	\$ 6,204
Cost of goods sold	1,031	806	2,718	2,780
Gross profit	<u>1,381</u>	<u>1,259</u>	<u>3,595</u>	<u>3,424</u>
<b>Operating expenses:</b>				
Selling, general and administrative	3,428	4,251	13,582	12,920
Research and development	1,117	928	4,050	3,141
Total operating expenses	<u>4,545</u>	<u>5,179</u>	<u>17,632</u>	<u>16,061</u>
Loss from operations	(3,164)	(3,920)	(14,037)	(12,637)
Other income (expense), net	(204)	52	98	14
Change in fair value of warrant liability	—	—	(755)	—
Loss before income taxes	<u>(3,368)</u>	<u>(3,868)</u>	<u>(14,694)</u>	<u>(12,623)</u>
Income tax expense	(2)	(2)	(6)	(6)
<b>Net loss</b>	<u>\$ (3,370)</u>	<u>\$ (3,870)</u>	<u>\$ (14,700)</u>	<u>\$ (12,629)</u>
<b>Basic and diluted loss per share</b>	<u>\$ (1.81)</u>	<u>\$ (36.72)</u>	<u>\$ (10.21)</u>	<u>\$ (119.85)</u>
Weighted average shares outstanding – basic and diluted	1,864	105	1,439	105
<b>Other comprehensive loss:</b>				
Foreign currency translation adjustments	\$ —	\$ 2	\$ (6)	\$ 1
<b>Total comprehensive loss</b>	<u>\$ (3,370)</u>	<u>\$ (3,868)</u>	<u>\$ (14,706)</u>	<u>\$ (12,628)</u>

See notes to the condensed consolidated financial statements.

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

	<b>Nine months ended</b>	
	<b>September 30</b>	
	<b>2023</b>	<b>2022</b>
<b>Operating Activities:</b>		
Net loss	\$ (14,700)	\$ (12,629)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	253	301
Stock-based compensation expense, net	513	697
Change in fair value of warrant liability	755	—
Net realized gain on marketable securities	(65)	—
Changes in operating assets and liabilities:		
Accounts receivable	(19)	(350)
Inventory, net	325	(113)
Other current assets	(551)	(40)
Other assets and liabilities	(16)	(142)
Accounts payable and accrued expenses	(1,678)	254
<b>Net cash used in operating activities</b>	<b>(15,183)</b>	<b>(12,022)</b>
<b>Investing Activities:</b>		
Proceeds from sale of marketable securities	578	—
Additions to intangible assets	(99)	—
Purchases of property and equipment	(185)	(103)
<b>Net cash provided by (used in) investing activities</b>	<b>294</b>	<b>(103)</b>
<b>Financing Activities:</b>		
Proceeds from ATM stock offerings, net	2,108	—
Payments on finance lease liability	(20)	(28)
<b>Net cash provided by (used in) financing activities</b>	<b>2,088</b>	<b>(28)</b>
Effect of exchange rate changes on cash	(6)	1
Net decrease in cash and cash equivalents	(12,807)	(12,152)
Cash and cash equivalents - beginning of period	17,737	24,205
<b>Cash and cash equivalents - end of period</b>	<b>\$ 4,930</b>	<b>\$ 12,053</b>
<b>Supplemental cash flow information</b>		
Inventory transferred to property, plant and equipment	\$ —	\$ 37
Non-cash impact of conversion of warrants to common stock (see Note 3)	\$ 6,868	\$ —

See notes to the condensed consolidated financial statements.