

**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 9, 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 May 9, 2023, Nuwellis, Inc. (the “Company”) issued a press release reporting its financial results for the three months ended March 31, 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 May 9, 2023, reporting the financial results of Nuwellis, Inc. for the three months ended March 31, 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: May 9, 2023

NUWELLIS, INC.

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



Nuwellis, Inc. Announces First Quarter 2023 Financial Results

Minneapolis, MN, May 9, 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 first quarter ended March 31, 2023.

- Revenue of \$1.8 million for the first quarter 2023, a 5% decrease over the prior-year period.
- By segment, first quarter 2023 revenue in Heart Failure increased approximately 21% over the same period last year, while Pediatrics and Critical Care declined approximately 28% and 4%, respectively. The decline in Pediatrics was primarily driven by lower patient volume in large hospital accounts.
- Gross margin of 58.4% in the first quarter 2023 increased 120 basis points from the same period last year.
- Announced peer-reviewed publication of clinical trials analysis by A. Kazory, et al, advocating earlier and expanded use of ultrafiltration for diuretics-resistant patients suffering from heart failure as well as kidney disease, sepsis, and other indications.
- Cash, cash equivalents, and marketable securities of \$12.1 million and no debt as of March 31, 2023.

“With growth in our heart failure segment fueled by new clinical evidence, and an active pipeline of business development activities, our team is excited to continue executing on our growth agenda, utilizing our growing body of clinical evidence that supports use of the Aquadex ultrafiltration therapy as a mechanical fluid removal solution for fluid-overloaded patients across multiple hospital specialty units. We remain committed to making Aquadex the standard of care for patients with fluid overload who are not responsive to conventional diuretics, and we look forward to increased sales momentum as we continue to build awareness and drive market penetration,” said Nestor Jaramillo, Jr., President & CEO of Nuwellis.

First Quarter 2023 Financial Results

Revenue for the first quarter of 2023 was \$1.8 million, compared to \$1.9 million in the prior-year period.

Gross margin was 58.4% for the first quarter of 2023, compared to 57.2% in the prior-year period, an increase of 120 basis points, driven primarily by pricing increases that were effective in the second quarter of 2022.

Selling, general and administrative expenses for the first quarter of 2023 were \$5.5 million, compared to \$4.4 million in the prior-year period. The increase was primarily due to increased professional fees associated with strategic initiatives and increased audit and legal expenses.

First quarter research and development expenses were \$1.4 million, compared to \$1.1 million in the first quarter of 2022, reflecting increased product development costs related to the ongoing development of the Company’s dedicated pediatric device.

Net loss for the first quarter of 2023 was \$6.5 million, or a loss of \$5.76 per basic and diluted common share, compared to a net loss of \$4.5 million, or a loss of \$42.45 per basic and diluted common share, in the prior-year period. The current period loss includes a non-recurring, non-cash expense of approximately \$755,000 related to the revaluation of the warrant liability associated with the Company’s October 2022 financing.

At March 31, 2023, the Company had cash, cash equivalents, and marketable securities of approximately \$12.1 million and no debt, with approximately 1.2 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: 10177112. 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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PART I—FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS
NUWELLIS, INC. AND SUBSIDIARY
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	March 31, 2023	December 31, 2022
	(unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 11,515	\$ 17,737
Marketable securities	575	569
Accounts receivable	1,301	1,406
Inventories, net	2,742	2,661
Other current assets	477	396
Total current assets	16,610	22,769
Property, plant and equipment, net	907	980
Operating lease right-of-use asset	856	903
Other assets	106	21
TOTAL ASSETS	\$ 18,479	\$ 24,673
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 2,524	\$ 2,245
Accrued compensation	1,312	2,161
Current portion of operating lease liability	201	196
Current portion of finance lease liability	21	28
Other current liabilities	49	58
Total current liabilities	4,107	4,688
Common stock warrant liability	—	6,868
Operating lease liability	708	760
Total liabilities	4,815	12,316
Commitments and contingencies	—	—
Stockholders' equity		
Series A junior participating preferred stock as of March 31, 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 March 31, 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 March 31, 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 March 31, 2023 and December 31, 2022, par value \$0.0001 per share; authorized 39,969,873 shares, none outstanding	—	—
Common stock as of March 31, 2023 and December 31, 2022, par value \$0.0001 per share; authorized 100,000,000 shares, issued and outstanding 1,206,932 and 536,394 shares, respectively	—	—
Additional paid-in capital	287,529	279,736
Accumulated other comprehensive income:		
Foreign currency translation adjustment	(25)	(18)
Unrealized gain on marketable securities	62	56
Accumulated deficit	(273,902)	(267,417)
Total stockholders' equity	13,664	12,357
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 18,479	\$ 24,673

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

	Three months ended	
	March 31,	
	2023	2022
Net sales	\$ 1,826	\$ 1,926
Cost of goods sold	759	824
Gross profit	<u>1,067</u>	<u>1,102</u>
Operating expenses:		
Selling, general and administrative	5,490	4,412
Research and development	1,428	1,106
Total operating expenses	<u>6,918</u>	<u>5,518</u>
Loss from operations	(5,851)	(4,416)
Other income (expense), net	123	(55)
Change in fair value of warrant liability	(755)	—
Loss before income taxes	<u>(6,483)</u>	<u>(4,471)</u>
Income tax expense	(2)	(2)
Net loss	<u>\$ (6,485)</u>	<u>\$ (4,473)</u>
Basic and diluted loss per share	<u>\$ (5.76)</u>	<u>\$ (42.45)</u>
Weighted average shares outstanding – basic and diluted	1,126	105
Other comprehensive loss:		
Unrealized gain on marketable securities	6	—
Unrealized foreign currency translation adjustments	\$ (7)	\$ (2)
Total comprehensive loss	<u>\$ (6,486)</u>	<u>\$ (4,475)</u>

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

	Three months ended	
	March 31,	
	2023	2022
Operating Activities:		
Net loss	\$ (6,485)	\$ (4,473)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	86	105
Stock-based compensation expense, net	181	241
Change in fair value of warrant liability	755	—
Changes in operating assets and liabilities:		
Accounts receivable	105	(201)
Inventory, net	(81)	(451)
Other current assets	(81)	(22)
Other assets and liabilities	(16)	(80)
Accounts payable and accrued expenses	(570)	54
Net cash used in operating activities	(6,106)	(4,827)
Investing Activities:		
Additions to intangible assets	(85)	—
Purchases of property and equipment	(13)	(70)
Net cash used in investing activities	(98)	(70)
Financing Activities:		
Issuance costs related to 2022 common stock offering	(11)	—
Payments on finance lease liability	—	(6)
Net cash used in financing activities	(11)	(6)
Effect of exchange rate changes on cash	(7)	(2)
Net decrease in cash and cash equivalents	(6,222)	(4,905)
Cash and cash equivalents - beginning of period	17,737	24,205
Cash and cash equivalents - end of period	\$ 11,515	\$ 19,300