

**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 9, 2022**

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 9, 2022, Nuwellis, Inc. (the “Company”) issued a press release reporting its financial results for the three and six months ended June 30, 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 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 9, 2022, reporting the financial results of Nuwellis, Inc. for the three and six months ended June 30, 2022.

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 9, 2022

NUWELLIS, INC.

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



Nuwellis, Inc. Announces Second Quarter 2022 Financial Results

Minneapolis, MN, August 9, 2022 (GLOBE NEWSWIRE) -- Nuwellis, Inc. (Nasdaq: NUWE) announced today its results for the second quarter ended June 30, 2022, which included the following highlights:

- Generated \$2.2 million in total revenue for the second quarter 2022, up 15% sequentially from the first quarter of 2022,
- Enrolled first patient in REVERSE-HF, a randomized controlled multi-center clinical trial designed to validate clinical outcomes and the economic value of Aquadex therapy, and
- Decreased operating expenses 14% compared to the second quarter of 2021 to minimize cash utilization while continuing to fund key strategic initiatives.

“I am very happy with our strong sequential performance in the quarter and remain encouraged by our considerable progress in executing our strategy to make the Aquadex System the standard of care for diuretic resistant patients needing fluid balance in the ICU or because of suffering from heart failure,” said Nestor Jaramillo, CEO of Nuwellis. “This includes securing reimbursement for outpatient ultrafiltration therapy, initiating a key pivotal trial, and making strategic enhancements to our product portfolio. We believe these key initiatives position Nuwellis favorably as we look to the back half of 2022 and enter 2023. These results represent the second consecutive quarter where we have reported strong double-digit sequential sales growth, suggesting that the Aquadex System is gaining traction in key academic institutions across the country.”

Second Quarter 2022 Financial Results

Total revenue for the second quarter of 2022 was \$2.2 million, an increase of 15% compared to the first quarter of 2022 and a reduction of 12% compared to the prior-year period. Sequential revenue growth in the quarter was driven primarily by strong growth in the Pediatric and Critical Care segments, fueled by higher console sales and increased utilization in certain key accounts.

Gross margin was 48.0% for the second quarter of 2022, compared to 60.2% in the prior-year period. The decline in gross margin compared to the second quarter of 2021 was primarily due to lower fixed overhead absorption, along with a \$0.1 million non-cash inventory write-off resulting from the discontinuation of a distribution agreement, partly offset by favorable pricing. Pro forma gross margin would have been 53.1% excluding the one-time inventory charge.

Selling, general and administrative expenses for the second quarter of 2022 were \$4.3 million, compared to \$5.1 million in the prior-year period. This reduction resulted from continued expense vigilance and certain non-recurring administrative costs in the prior-year period.

Second-quarter research and development expenses were \$1.1 million dollars, compared to \$1.2 million dollars in the second quarter of 2021, while we continue to advance new product development initiatives.

The net loss for the second quarter of 2022 was \$4.3 million, compared to a net loss of \$4.7 million in the prior-year period.

Cash and cash equivalents were approximately \$15.3 million as of June 30, 2022.

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.

Investors interested in listening to the conference call may do so by following one of the below links:

- Webcast link for interested listeners:
 - o <https://edge.media-server.com/mmc/p/frxpm437>
- Dial-in registration for sell-side research analysts:
 - o <https://register.vevent.com/register/B1ea28b3e149034b04b99b65da059db74a>

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 device company dedicated to transforming the lives of patients suffering from fluid overload through science, collaboration, and innovation. The Company is focused on developing, manufacturing and commercializing the Aquadex SmartFlow® system for ultrafiltration therapy. Nuwellis is headquartered in Minneapolis, MN, with a wholly owned subsidiary in Ireland.

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 are 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 2022 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.

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

	June 30, 2022	December 31, 2021
	(unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 15,345	\$ 24,205
Accounts receivable	1,313	750
Inventories	3,010	2,843
Other current assets	252	328
Total current assets	19,920	28,126
Property, plant and equipment, net	1,063	1,188
Operating lease right-of-use asset	994	1,082
Other assets	21	21
TOTAL ASSETS	\$ 21,998	\$ 30,417
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,550	\$ 1,414
Accrued compensation	1,633	1,664
Current portion of operating lease liability	186	167
Current portion of finance lease liability	27	26
Other current liabilities	63	36
Total current liabilities	3,459	3,307
Operating lease liability	860	956
Finance lease liability	15	28
Other long-term liability	—	179
Total liabilities	4,334	4,470
Commitments and contingencies		
Stockholders' equity		
Series A junior participating preferred stock as of June 30, 2022 and December 31, 2021, par value \$0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Series F convertible preferred stock as of both June 30, 2022 and December 31, 2021, par value \$0.0001 per share; authorized 127 shares, issued and outstanding 127 shares	—	—
Preferred stock as of both June 30, 2022 and December 31, 2021, par value \$0.0001 per share; authorized 39,969,873 shares, none outstanding	—	—
Common stock as of June 30, 2022 and December 31, 2021, par value \$0.0001 per share; authorized 100,000,000 shares, issued and outstanding 10,537,606 shares	1	1
Additional paid-in capital	279,350	278,873
Accumulated other comprehensive income:		
Foreign currency translation adjustment	(12)	(11)
Accumulated deficit	(261,675)	(252,916)
Total stockholders' equity	17,664	25,947
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 21,998	\$ 30,417

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,	
	2022	2021	2022	2021
Net sales	\$ 2,213	\$ 2,508	\$ 4,139	\$ 4,426
Cost of goods sold	1,150	997	1,974	1,949
Gross profit	<u>1,063</u>	<u>1,511</u>	<u>2,165</u>	<u>2,477</u>
Operating expenses:				
Selling, general and administrative	4,257	5,063	8,669	10,300
Research and development	1,107	1,174	2,213	2,121
Total operating expenses	<u>5,364</u>	<u>6,237</u>	<u>10,882</u>	<u>12,421</u>
Loss from operations	(4,301)	(4,726)	(8,717)	(9,944)
Other income (expense), net	17	(2)	(38)	(3)
Loss before income taxes	(4,284)	(4,728)	(8,755)	(9,947)
Income tax expense	(2)	(3)	(4)	(5)
Net loss	<u>\$ (4,286)</u>	<u>\$ (4,731)</u>	<u>\$ (8,759)</u>	<u>\$ (9,952)</u>
Basic and diluted loss per share	<u>\$ (0.41)</u>	<u>\$ (0.72)</u>	<u>\$ (0.83)</u>	<u>\$ (2.04)</u>
Weighted average shares outstanding – basic and diluted	10,538	6,532	10,538	4,887
Other comprehensive loss:				
Foreign currency translation adjustments	\$ 1	\$ —	\$ (1)	\$ (3)
Total comprehensive loss	<u>\$ (4,285)</u>	<u>\$ (4,731)</u>	<u>\$ (8,760)</u>	<u>\$ (9,955)</u>

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

Six months ended
June 30,
2022 **2021**

Operating Activities:

Net loss	\$	(8,759)		\$	(9,952)
Adjustments to reconcile net loss to cash flows used in operating activities:					
Depreciation and amortization		206			256
Stock-based compensation expense, net		477			736
Changes in operating assets and liabilities:					
Accounts receivable		(563)			(272)
Inventory		(167)			122
Other current assets		76			(176)
Other assets and liabilities		(152)			9
Accounts payable and accrued expenses		117			75
Net cash used in operating activities		(8,765)			(9,202)

Investing Activities:

Purchases of property and equipment		(81)		(137)
Net cash used in investing activities		(81)		(137)

Financing Activities:

Proceeds from public stock offerings, net		—		18,896
Proceeds from warrant exercises		—		1
Payments on finance lease liability		(13)		(14)
Net cash provided (used in) by financing activities		(13)		18,883

Effect of exchange rate changes on cash		(1)		(3)
Net increase (decrease) in cash and cash equivalents		(8,860)		9,541
Cash and cash equivalents - beginning of period		24,205		14,437
Cash and cash equivalents - end of period	\$	15,345	\$	23,978

Supplemental cash flow information

Inventory transferred to property, plant and equipment	\$	—	\$	179
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INVESTOR CONTACTS:

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