

**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 8, 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 November 8, 2022, Nuwellis, Inc. (the “Company”) issued a press release reporting its financial results for the three and nine months ended September 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 November 8, 2022, reporting the financial results of Nuwellis, Inc. for the three and nine months ended September 30, 2022.
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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 8, 2022

NUWELLIS, INC.

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



Nuwellis, Inc. Reports Third Quarter 2022 Financial Results

Minneapolis, MN, November 8, 2022 (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 third quarter ended September 30, 2022.

Q3 Results and Recent Highlights:

- Revenue of \$2.1 million in the third quarter 2022, an 11% increase over the same year ago period
- Gross margin of 61% was consistent with the same period last year
- Activated three additional sites for pivotal REVERSE-HF clinical study
- Announced AVOID-HF clinical study analysis demonstrating statistically superior benefit of ultrafiltration over diuretics for fluid-overloaded heart failure patients at 30 and 90 days
- Announced clinical data demonstrating reduced mortality rates, with 100% survival rate in post-operative CABG patients at 30 days following use of ultrafiltration
- Awarded U.S. patent for novel innovation that improves fluid balance and safety in pediatric dialysis and hemofiltration
- Closed an underwritten public offering on October 18, with \$11.0 million of gross proceeds

“We made meaningful progress this quarter on the continued execution of our key strategic initiatives and achieved 11% year-over-year revenue growth. These results not only demonstrate that we are gaining traction on the sales front but also continuing to achieve key milestones toward making the Aquadex system the standard of care for restoring fluid balance. We are confident that continued expansion of our field sales team, including clinical education specialists, bolstered by our market penetration initiatives and growing body of clinical evidence, will position Nuwellis well for strong growth in 2023 and beyond,” said Nestor Jaramillo, CEO of Nuwellis.

Third Quarter 2022 Financial Results

Total revenue for the third quarter of 2022 was \$2.1 million, an increase of 11% compared to the third quarter of 2021.

Gross margin was 61.0% for the third quarter of 2022 compared to 60.4% in the prior-year period.

Selling, general and administrative expenses for the third quarter of 2022 were \$4.3 million, compared to \$4.6 million in the prior-year period. This reduction resulted from continued spending vigilance, as well as some open positions in the current year quarter.

Third quarter research and development expenses were \$0.9 million, compared to \$1.7 million in the third quarter of 2021, while continuing to advance the most critical new product development initiatives.

The net loss for the third quarter of 2022 was \$3.9 million, or a loss of \$0.37 per basic and diluted common share, compared to a net loss of \$5.3 million, or a loss of \$0.75 per basic and diluted common share in the prior-year period.

Cash and cash equivalents were approximately \$12.1 million at September 30, 2022. On October 18, Nuwellis closed an underwritten public offering with gross proceeds of \$11.0 million. After deducting underwriting discounts and commissions on the offering, pro forma cash at the end of the third quarter would have been \$21.9 million.

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 1-844-825-9789 (U.S) or 1-412-317-5180 (international) and using the conference ID: 10172214. 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 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 superior 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 healthcare provider, in 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.

CONTACTS

INVESTORS:

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FINANCIAL STATEMENTS

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

	<u>September 30,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
	<u>(unaudited)</u>	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 12,053	\$ 24,205
Accounts receivable	1,100	750
Inventories	2,919	2,843
Other current assets	368	328
Total current assets	16,440	28,126
Property, plant and equipment, net	1,027	1,188
Operating lease right-of-use asset	949	1,082
Other assets	21	21
TOTAL ASSETS	\$ 18,437	\$ 30,417
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,561	\$ 1,414
Accrued compensation	1,751	1,664
Current portion of operating lease liability	191	167
Current portion of finance lease liability	35	26
Other current liabilities	73	36
Total current liabilities	3,611	3,307
Operating lease liability	810	956
Finance lease liability	—	28
Other long-term liability	—	179
Total liabilities	4,421	4,470
Commitments and contingencies		
Stockholders' equity		
Series A junior participating preferred stock as of September 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 September 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 September 30, 2022 and December 31, 2021, par value \$0.0001 per share; authorized 39,969,873 shares, none outstanding	—	—
Common stock as of September 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	279,570	278,873
Accumulated other comprehensive income:		
Foreign currency translation adjustment	(10)	(11)
Accumulated deficit	(265,545)	(252,916)
Total stockholders' equity	14,016	25,947
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 18,437	\$ 30,417

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,	
	2022	2021	2022	2021
Net sales	\$ 2,065	\$ 1,853	\$ 6,204	\$ 6,279
Cost of goods sold	806	733	2,780	2,682
Gross profit	<u>1,259</u>	<u>1,120</u>	<u>3,424</u>	<u>3,597</u>
Operating expenses:				
Selling, general and administrative	4,251	4,645	12,920	14,945
Research and development	928	1,726	3,141	3,847
Total operating expenses	<u>5,179</u>	<u>6,371</u>	<u>16,061</u>	<u>18,792</u>
Loss from operations	(3,920)	(5,251)	(12,637)	(15,195)
Other income (expense), net	52	(19)	14	(22)
Loss before income taxes	(3,868)	(5,270)	(12,623)	(15,217)
Income tax expense	(2)	(2)	(6)	(7)
Net loss	<u>\$ (3,870)</u>	<u>\$ (5,272)</u>	<u>\$ (12,629)</u>	<u>\$ (15,224)</u>
Basic and diluted loss per share	<u>\$ (0.37)</u>	<u>\$ (0.75)</u>	<u>\$ (1.20)</u>	<u>\$ (2.72)</u>
Weighted average shares outstanding – basic and diluted	10,538	7,098	10,538	5,624
Other comprehensive loss:				
Foreign currency translation adjustments	\$ 2	\$ —	\$ 1	\$ (3)
Total comprehensive loss	<u>\$ (3,868)</u>	<u>\$ (5,272)</u>	<u>\$ (12,628)</u>	<u>\$ (15,227)</u>

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

	Nine months ended	
	2022	September 30,
	2021	2021
Operating Activities:		
Net loss	\$ (12,629)	\$ (15,224)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	301	383
Stock-based compensation expense, net	697	993
Changes in operating assets and liabilities:		
Accounts receivable	(350)	(164)
Inventory	(113)	(105)
Other current assets	(40)	(183)
Other assets and liabilities	(142)	279
Accounts payable and accrued expenses	254	333
Net cash used in operating activities	(12,022)	(13,688)
Investing Activities:		
Purchases of property and equipment	(103)	(191)
Net cash used in investing activities	(103)	(191)
Financing Activities:		
Proceeds from public stock offerings, net	—	27,896
Proceeds from warrant exercises	—	1
Payments on finance lease liability	(28)	(21)
Net cash provided (used in) by financing activities	(28)	27,876
Effect of exchange rate changes on cash	1	(3)
Net increase (decrease) in cash and cash equivalents	(12,152)	13,994
Cash and cash equivalents - beginning of period	24,205	14,437
Cash and cash equivalents - end of period	\$ 12,053	\$ 28,431
Supplemental cash flow information		
Inventory transferred to property, plant and equipment	\$ 37	\$ 257