



Restoring Fluid Balance. Transforming Care.

Nuwellis, Inc. Announces Fourth Quarter and Full Year 2023 Financial Results

March 5, 2024

Strengthens Its Foundation for Growth, Strong Pediatric Sales, Expanding Margins and Increases Number of New Hospital Accounts

MINNEAPOLIS, March 05, 2024 (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 fourth quarter and full year ended December 31, 2023.

Highlights:

- Record quarter revenue of \$2.6 million, a 9% increase over prior-year period. Full year revenue of \$8.9 million, a 4% increase over 2022.
- Fourth quarter pediatric revenue grew 35% year over year; 28% increase in utilization and a 49% increase in console sales. Four new pediatric accounts.
- Fourth quarter gross margin of 54.4%. Full year 2023 gross margin of 56.2%, a 56-basis point increase over full year 2022.
- Added two products: The new 12 cm dELC catheter and the Quelimune™ SCD pediatric device.
- New clinical case series expands the use of Aquadex® into end-stage liver disease.
- New real-world clinical data continues to show Aquadex clinical evidence benefits pediatric patients.
- Nuwellis hosted a symposium on March 4 at the Technology and Heart Failure Therapeutics (THT) conference, where two late breaking clinical trials and one lecture session will be presented on the Aquadex system.

"Nuwellis continues to execute on its strategic growth initiatives, with the highest total quarter of organic revenue in company history," said Nestor Jaramillo, President and CEO of Nuwellis. "Led by Pediatrics, which saw steady increases in existing console utilization and new account openings expanded Aquadex market penetration. We expect our accelerating momentum to continue in 2024, with further support from our growing body of clinical evidence, paving the way for new Aquadex applications such as in end-stage liver disease, as well as new product introductions."

Nuwellis announced the FDA HDE approval for Quelimune, received by its exclusive U.S. license and distribution partner, SeaStar, further bolstering its pediatric portfolio for Nuwellis' fast-growing customer category and foundation for growth. Additionally, the introduction of Nuwellis' recently FDA cleared specialty dual lumen 12 cm catheter will provide clinicians with an additional venous access option to use the company's Aquadex ultrafiltration system. The company also announced a new clinical case series featured in [Clinical Transplantation](#) demonstrating the use of Aquadex to safely and effectively remove fluid volume for end-stage liver disease patients, representing an additional clinical application for Aquadex already within its current FDA labeling. In this case series, Aquadex was shown to reduce cirrhosis-related frailty and enhanced patients' ability to receive a life-saving liver transplant. Finally, the company announced new real-world data featured in [Pediatric Nephrology](#) that showed the proprietary hematocrit sensor within the Aquadex system facilitated guided therapy of fluid overloaded pediatric patients without hemodynamic instability or other complications.

"We overcame challenges like hospital budgetary constraints and nursing shortages in the first half of 2023, achieving 27% revenue growth in the second half of 2023 versus the first half of 2023," added Mr. Jaramillo. "We've confidently transitioned beyond prior headwinds and anticipate a strong revenue year in 2024, marked by achieving key milestones including the three podium presentations at the THT conference, one of which establishes the clinical superiority of Aquadex over diuretics, new products for our existing pediatric customers, completion of the DaVita Pilot phase, and the IDE submission for our pediatric dedicated renal disease device branded Vivian. We are balancing the multiple growth catalysts mentioned above with the need to raise capital this year. We have recently undertaken steps to reduce our monthly cash burn rate by approximately 40%, balanced against our strategic growth initiatives, which will provide more flexibility in anticipation of tougher capital market conditions for microcap companies like Nuwellis."

Fourth Quarter 2023 Financial Results

Revenue for the fourth quarter of 2023 was \$2.6 million, a 9% increase compared to \$2.3 million in the prior-year period. The year over year increase is attributable to an increase in disposable utilization and record international sales.

Gross margin was 54.4% for the fourth quarter of 2023, compared to 56.9% in the prior-year period, a decrease of 250 basis points. The decline was due to product and geographical sales mix and lower fixed overhead manufacturing absorption, leading to more efficient inventory levels.

Selling, general and administrative expenses for the fourth quarter of 2023 were \$3.6 million, compared to \$4.7 million in the prior-year period. The decrease in SG&A expenses was primarily due to reduced headcount and related compensation expense.

Fourth quarter research and development expenses were \$1.4 million, compared to \$1.2 million in the prior-year period, reflecting a modest increase in R&D spend related to the development of our new pediatric dedicated CRRT device as we approach IDE submission.

In the current year period, the company recorded a non-recurring expense reduction of approximately \$800 thousand, reducing incentive compensation, impacting both SG&A and R&D. Additionally, the company recorded a \$550 thousand SG&A expense, in the current year period, for contractual spend related to the SeaStar license and distribution agreement.

Total operating expenses for the fourth quarter of 2023 were \$5.0 million, a 15% decrease compared to \$5.9 million in the prior-year period. The \$884 thousand decrease was due to cost saving measures implemented early in the second half of the year and carried through year-end 2023 as we continue to drive operating efficiencies.

Operating loss for the fourth quarter of 2023 was \$3.6 million compared to an operating loss of \$4.5 million in the prior year period, resulting in a \$941 thousand period over period reduction.

Net loss attributable to common shareholders for the fourth quarter of 2023 was \$7.9 million, or a loss of \$2.24 per basic and diluted common share, compared to a net loss attributable to common shareholders of \$1.9 million, or a loss of \$5.00 per basic and diluted common share in the prior-year period. The current period net loss attributable to common shareholders includes \$2.0 million of 'Other Expense' and \$2.4 million of a deemed dividend and PIK dividend related to the Company's October 2023 financing. The prior year period net loss attributable to common shareholders includes \$2.6 million of 'Other Income' related to the Company's October 2022 financing.

At December 31, 2023, the Company had no debt, cash and cash equivalents of approximately \$3.8 million, and approximately 5.7 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: 10185035. 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 ir.nuwellis.com or visit us on [LinkedIn](#) or [X](#).

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 2024 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, 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 due to new information, future events or otherwise.

CONTACTS

INVESTORS:

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

	<u>December 31,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
	(unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 3,800	\$ 17,737
Marketable securities	—	569

Accounts receivable	1,951	1,406
Inventories, net	1,997	2,661
Other current assets	461	396
Total current assets	8,209	22,769
Property, plant and equipment, net	728	980
Operating lease right-of-use asset	713	903
Other assets	120	21
TOTAL ASSETS	\$ 9,770	\$ 24,673

LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY

Current liabilities

Accounts payable and accrued liabilities	\$ 2,380	\$ 2,245
Accrued compensation	525	2,161
Current portion of operating lease liability	216	196
Current portion of finance lease liability	—	28
Other current liabilities	51	58
Total current liabilities	3,172	4,688
Common stock warrant liability	2,843	6,868
Operating lease liability	544	760
Total liabilities	6,559	12,316

Commitments and contingencies

Mezzanine Equity

Series J Convertible Preferred Stock as of December 31, 2023 and December 31, 2022, par value \$0.0001 per share; authorized 600,000 and none, issued and outstanding 11,950 and none, respectively	221	—
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Stockholders' equity

Series A junior participating preferred stock as of December 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 December 31, 2023 and December 31, 2022, par value \$0.0001 per share; authorized 18,000 shares, issued and outstanding 127 shares	—	—
Series I convertible preferred stock as of December 31, 2023 and December 31, 2022, par value \$0.0001 per share; authorized 1,049,280, issued and outstanding none and 1,049,280, respectively	—	—
Preferred stock as of December 31, 2023 and December 31, 2022, par value \$0.0001 per share; authorized 39,802,000 shares, none outstanding	—	—
Common stock as of December 31, 2023 and December 31, 2022, par value \$0.0001 per share; authorized 100,000,000 shares, issued and outstanding 5,682,461 and 536,394, respectively	1	—
Additional paid-in capital	290,646	279,736
Accumulated other comprehensive income:		
Foreign currency translation adjustment	(31)	(18)
Unrealized gain on marketable securities	—	56
Accumulated deficit	(287,626)	(267,417)
Total stockholders' equity	2,990	12,357
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 9,770	\$ 24,673

See notes to the consolidated financial statements.

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

	Three months ended December 31,		Twelve months ended December 31,	
	2023	2022	2023	2022
	(unaudited)	(unaudited)	(unaudited)	
Net sales	\$ 2,551	\$ 2,339	\$ 8,864	\$ 8,543
Cost of goods sold	1,163	1,008	3,881	3,788
Gross profit	1,388	1,331	4,983	4,755
Operating expenses:				
Selling, general and administrative	3,609	4,664	17,191	17,584

Research and development	1,372	1,201	5,422	4,342
Total operating expenses	<u>4,981</u>	<u>5,865</u>	<u>22,613</u>	<u>21,926</u>
Loss from operations	(3,593)	(4,534)	(17,630)	(17,171)
Other income (expense), net				
Other income	56	61	154	75
Financing expense	(3,483)	(9,247)	(3,483)	(9,247)
Change in fair value of warrant liability	<u>1,513</u>	<u>11,827</u>	<u>758</u>	<u>11,827</u>
Loss before income taxes	(5,507)	(1,893)	(20,201)	(14,516)
Income tax expense	<u>(2)</u>	<u>(3)</u>	<u>(8)</u>	<u>(9)</u>
Net loss	(5,509)	(1,896)	(20,209)	(14,525)
Deemed dividend attributable to Series J Convertible Preferred Stock	(2,297)	—	(2,297)	—
Dividend on Series J Convertible Preferred Stock	<u>(121)</u>	<u>—</u>	<u>(121)</u>	<u>—</u>
Net loss attributable to common stockholders	<u>\$ (7,927)</u>	<u>\$ (1,896)</u>	<u>\$ (22,627)</u>	<u>\$ (14,525)</u>
Basic and diluted loss per share	<u>\$ (2.24)</u>	<u>\$ (5.00)</u>	<u>\$ (11.52)</u>	<u>\$ (83.55)</u>
Weighted average shares outstanding – basic and diluted	3,539,185	379,254	1,964,406	173,846
Other comprehensive loss:				
Net loss	\$ (5,509)	\$ (1,896)	\$ (20,209)	\$ (14,525)
Unrealized gain (loss) on marketable securities	—	6	—	80
Foreign currency translation adjustments	<u>(6)</u>	<u>(7)</u>	<u>(13)</u>	<u>(7)</u>
Total comprehensive loss	<u>\$ (5,515)</u>	<u>\$ (1,897)</u>	<u>\$ (22,222)</u>	<u>\$ (14,452)</u>

See notes to the consolidated financial statements.

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

	For the years ended December 31,	
	2023	2022
	(unaudited)	
Operating Activities		
Net loss	\$ (20,209)	\$ (14,525)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	362	372
Stock-based compensation expense	670	862
Change in fair value of warrant liability	(758)	(11,827)
Financing expense	3,483	9,247
Net realized and unrealized gains on marketable securities	(65)	124
Changes in operating assets and liabilities:		
Accounts receivable	(545)	(656)
Inventory	697	140
Other current assets	(65)	(68)
Other assets and liabilities	(7)	(96)
Accounts payable and accrued expenses	<u>(1,500)</u>	<u>1,278</u>
Net cash used in operations	<u>(17,937)</u>	<u>(15,149)</u>
Investing activities:		
Additions to intangible assets	(99)	—
Proceeds from sales of marketable securities	578	14,850
Purchase of property and equipment	<u>(149)</u>	<u>(122)</u>
Net cash provided by investing activities	<u>330</u>	<u>14,728</u>
Financing activities:		
Proceeds from public stock offerings, net	2,109	9,449
Proceeds from Series J Preferred Stock and Warrants	1,482	—
Proceeds from the exercise of warrants	120	—
Payments on finance lease liability	<u>(28)</u>	<u>(26)</u>
Net cash provided by financing activities	<u>3,683</u>	<u>9,423</u>

Effect of exchange rate changes on cash	(13)	(7)
Net increase in cash and cash equivalents	(13,937)	8,995
Cash and cash equivalents—beginning of year	17,737	8,742
Cash and cash equivalents—end of year	\$ 3,800	\$ 17,737

Supplemental schedule of non-cash activities

Inventory transferred to property, plant and equipment	\$ 41	\$ 42
Issuance of Common Stock for exercise of Series I Warrants	\$ 7,623	\$ —
Issuance of Series J Preferred Stock for exercise of Warrants	\$ 2,927	\$ —
Deemed dividend on Series J Preferred Stock	\$ 2,297	\$ —
Series J Preferred Stock issued for payment in kind dividend	\$ 121	\$ —

Supplemental cash flow information

Cash paid for income taxes	\$ 12	\$ 9
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See notes to the consolidated financial statements.

