

# Restoring Fluid Balance. Transforming Care.

# Nuwellis, Inc. Announces Third Quarter 2024 Financial Results and Recent Highlights

November 11, 2024

MINNEAPOLIS, Nov. 11, 2024 (GLOBE NEWSWIRE) -- Nuwellis, Inc. (Nasdaq: NUWE), a medical device company focused on transforming the lives of people with fluid overload, today reported financial results for the third quarter ended September 30, 2024.

#### Recent Highlights:

- Received a 297% CMS reimbursement increase to \$1,639 for Aquadex facility fee, effective January 1, 2025.
- Revenue of \$2.4 million.
- Pediatrics revenue growth of 28% compared to the prior year quarter.
- Gross margin of 70%, compared to 57.3% in the prior-year quarter.
- Total operating cost reduction of 30% compared to the prior-year quarter.
- New study published in Current Problems in Cardiology highlighted statistically significant reduction in Heart Failure readmissions at 60 days when using Aquadex.
- Added three new pediatric accounts and two new adult accounts.
- Received \$5.1 million in gross proceeds through the November exercise of outstanding warrants.

"We commend the hard work and dedication of the Nuwellis team, fueling steady market adoption of our Aquadex ultrafiltration therapy, with revenue in the third quarter 2024 led by console sales and new account wins in our Pediatric customer category, which posted 28% annual growth," said Nestor Jaramillo, President and CEO of Nuwellis. "We continue to see momentum with new accounts steadily opening on increasing awareness of the efficacy and supporting clinical evidence for Aquadex ultrafiltration therapy in the adult and pediatric customer categories. We believe these newly published clinical results will have a positive impact in growing our business and supporting Aquadex in becoming the standard of care for fluid removal when diuretics are ineffective. Following the closing of the quarter, we received notice of a 297% increase to \$1,639 per day in reimbursement from the Centers for Medicare and Medicaid Services (CMS) which greatly expands the outpatient marketplace for fluid removal. This reimbursement increase is effective January 1, 2025."

## Third Quarter 2024 Financial Results

Revenue for the third quarter of 2024 was \$2.4 million, a 2% decrease compared to the prior-year quarter. The year-over-year decrease is attributable to a decrease in consumables utilization, a decrease in US console sales offset by a one-time increase in SeaStar Medical Quelimmune sales.

Gross margin was 70% for the third quarter of 2024, compared to 57.3% in the prior-year quarter. The increase was primarily driven by higher manufacturing volumes of consumables and lower fixed overhead manufacturing expenses.

Selling, general and administrative expenses (SG&A) for the third quarter of 2024 decreased to \$2.7 million, compared to \$3.4 million in the prior-year quarter. The decrease in SG&A expense was primarily realized through efficiency initiatives enacted in the second half of 2023.

Third quarter research and development (R&D) expenses were \$486 thousand, compared to \$1.1 million in the prior-year quarter. The decrease in R&D expense was primarily due to reduced consulting fees and compensation related expenses.

Total operating expenses for the third quarter of 2024 were \$3.2 million, a 30% decrease compared to \$4.5 million in the prior-year quarter as we continue to realize savings from operating efficiency initiatives enacted in the second half of 2023.

Operating loss for the third quarter of 2024 decreased to \$1.5 million compared to an operating loss of \$3.2 million in the prior-year quarter.

Net income attributable to common shareholders for the third quarter of 2024 was \$2.4 million, or a gain of \$1.74 per basic and diluted common share, compared to a net loss attributable to common shareholders of \$3.4 million, or a loss of \$63.27 per basic and diluted common share in the prior-year quarter. Third quarter net income improvement was primarily the result of the revaluation of a prior period warrant liability, resulting in a \$3.9 million dollar benefit.

As of September 30, 2024, the Company had no debt, cash and cash equivalents of approximately \$1.9 million, and approximately 1.9 million common shares outstanding. Shareholder equity was \$3.2 million, which we intend to submit to Nasdaq in support of our continued listing on the Nasdaq Stock Market.

### **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 <a href="https://ir.nuwellis.com">https://ir.nuwellis.com</a>. Alternatively, you may access the live conference call by dialing 1-800-445-7795 (U.S) or 1-785-424-1789 (international) and using the conference ID: NUWEQ3. An audio archive of the webcast will be available following the call on the Investors page at <a href="https://ir.nuwellis.com">https://ir.nuwellis.com</a>.

#### **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 commercializing the Aquadex SmartFlow® system for ultrafiltration therapy. Nuwellis is headquartered in Minneapolis, with a wholly owned subsidiary in Ireland. For more information visit <u>ir.nuwellis.com</u> or visit us on <u>LinkedIn</u> 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:

Vivian Cervantes Gilmartin Group ir@nuwellis.com

# NUWELLIS, INC. AND SUBSIDIARY Condensed Consolidated Balance Sheets

(in thousands, except share and per share amounts)

	Se	September 30, 2024		ecember 31, 2023
ASSETS	(1	Jnaudited)	· -	
Current assets				
Cash and cash equivalents	\$	1,907	\$	3,800
Accounts receivable		1,293		1,951
Inventories, net		1,864		1,997
Other current assets		430		461
Total current assets		5,494		8,209
Property, plant and equipment, net		551		728
Operating lease right-of-use asset		563		713
Other assets	<u> </u>	120		120
TOTAL ASSETS	\$	6,728	\$	9,770
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY				
Current liabilities				
Accounts payable and accrued liabilities	\$	1,822	\$	2,380
Accrued compensation		597		525
Current portion of operating lease liability		232		216
Other current liabilities		50		51
Total current liabilities		2,701		3,172
Common stock warrant liability		480		2,843
Operating lease lightlifts		368		544
Operating lease liability				
Total liabilities		3,549		6,559

## Stockholders' equity

Series A junior participating preferred stock as of September 30, 2024 and December 31, 2023, par value				
\$0.0001 per share; authorized 30,000 shares, none outstanding		_		_
Series F convertible preferred stock as of September 30, 2024 and December 31, 2023, par value \$0.0001 pe share; authorized 18,000 shares, issued and outstanding 127 shares	r	_		_
Preferred stock as of September 30, 2024 and December 31, 2023, par value \$0.0001 per share; authorized				
39,352,000 shares, none outstanding		_		_
Common stock as of September 30, 2024 and December 31, 2023, par value \$0.0001 per share; authorized				
100,000,000 shares, issued and outstanding 1,866,890 and 162,356, respectively		_		_
Additional paid-in capital		300,546		290,647
Accumulated other comprehensive income: Foreign currency translation adjustment		(46)		(31)
Accumulated deficit		(297,323)	 	(287,626)
Total stockholders' equity	_	3,177		2,990
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY	\$	6,728	\$	9,770

## **NUWELLIS, INC. AND SUBSIDIARY** Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)

(in thousands, except per share amounts and weighted average shares outstanding)

	Three months ended September 30				Nine months ended September 30			
	2024		2023		2024		2023	
Net sales	\$ 2,367	\$	2,412	\$	6,418	\$	6,313	
Cost of goods sold	 711	_	1,031		2,097		2,718	
Gross profit	1,656	_	1,381		4,321		3,595	
Operating expenses:								
Selling, general and administrative	2,702		3,428		10,544		13,582	
Research and development	 486	_	1,117		2,378		4,050	
Total operating expenses	3,188		4,545		12,922		17,632	
Loss from operations	(1,532)		(3,164)		(8,601)		(14,037)	
Other income (expense), net	8		(204)		(87)		98	
Financing Expense	_		_		(5,607)		_	
Change in fair value of warrant liability	 3,882	_	_		4,602		(755)	
Income (loss) before income taxes	2,358		(3,368)		(9,693)		(14,694)	
Income tax expense	 	_	(2)		(4)		(6)	
Net income (loss)	\$ 2,358	\$_	(3,370)	\$	(9,697)	\$	(14,700)	
Deemed dividend attributable to Series J Convertible Preferred Stock	_		_		541		_	
Net income (loss) attributable to common shareholders	\$ 2,358)	\$_	(3,370)	\$	(9,156)	\$	(14,700)	
Basic and diluted net income (loss) per share	\$ 1.74	\$_	(63.27)	\$ <u></u>	(14.99)	\$	(357.42)	
Weighted average shares outstanding – basic and diluted	1,351,939		53,265		647,079		41,128	
Other comprehensive loss:								
Foreign currency translation adjustments	\$ (4)	\$_		\$	(15)	\$	(6)	
Total comprehensive income (loss)	\$ 2,354	\$	(3,370)	\$	(9,171)	\$	(14,706)	

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

Nine months ended September 30 2024 2023

Operating	VC+IMITIOS.
Operating	ACLIVILICS.

Operating Activities.		
Net loss	\$ (9,697) \$	(14,700)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	227	253
Stock-based compensation expense	374	513
Change in fair value of warrant liability	(4,602)	755
Warrant financing costs	5,607	_
Net realized gain on marketable securities	_	(65)
Changes in operating assets and liabilities:		
Accounts receivable	658	(19)
Inventory, net	120	325
Other current assets	(275)	(551)
Other assets and liabilities	(13)	(16)
Accounts payable and accrued expenses	 (486)	(1,678)
Net cash used in operating activities	(8,087)	(15,183)
Investing Activities:		
Proceeds from sale of marketable securities	_	578
Additions to intangible assets	_	(99)
Purchases of property and equipment	 (37)	(185)
Net cash provided by (used in) investing activities	(37)	294
Financing Activities:		
Issuance of common stock from offering	2,403	_
Proceeds from the exercise of Series J Convertible Preferred Warrants	501	_
Proceeds from the exercise of April 2024 Warrants	1,182	_
Issuance of July and August 2024 Common Stock and Warrants	2,160	_
Proceeds from ATM stock offerings, net	_	2,108
Payments on finance lease liability	_	(20)
Net cash provided by financing activities	6,246	2,088
Effect of exchange rate changes on cash	(15)	(6)
Net decrease in cash and cash equivalents	 (1,893)	(12,807)
Cash and cash equivalents - beginning of period	3,800	17,737
Cash and cash equivalents - end of period	\$ 1,907 \$	4,930



Source: Nuwellis, Inc.