

**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 10, 2021**

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 10, 2021, Nuwellis, Inc. (the “Company”) issued a press release reporting its financial results for the three and six months ended June 30, 2021. 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 10, 2021, reporting the financial results of Nuwellis, Inc. for the three and six months ended June 30, 2021.

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 10, 2021

NUWELLIS, INC.

By: /s/ Nestor Jaramillo

Name: Nestor Jaramillo

Title: President and Chief Executive Officer



Nuwellis, Inc. Announces 35 Percent Increase in Revenue for Second Quarter 2021 Over Previous Year and Provides Company Update

Eden Prairie, MN, August 10, 2021 (GLOBE NEWSWIRE) -- Nuwellis, Inc. (Nasdaq: NUWE) announced today its results for the second quarter ended June 30, 2021, which included the following highlights:

- Reported record quarterly revenue of \$2.5 million, a 35 percent increase compared to the prior year period
- Realized strong sequential growth across all customer markets and recorded the sixth consecutive quarter with double-digit revenue growth vs. prior year
- Welcomed George Montague, former CFO and COO of Smiths Medical, as new CFO
- Welcomed Neil Ayotte, a 16-year veteran of Medtronic plc and most recently EVP & General Counsel of Bluestem Group, as Senior VP, General Counsel, Secretary and Chief Compliance Officer
- Received Category III CPT code for the use of therapeutic ultrafiltration, effective January 1, 2022
- Announced a three-year national purchase agreement with Premier, Inc., one of the nation's largest group purchasing organizations
- Ended the quarter with \$24.0 million in cash and no debt

"I am proud to report that Nuwellis achieved record quarterly revenues for the second quarter 2021 with strong sequential growth across all segments," said Nestor Jaramillo, CEO of Nuwellis. "We continue to execute and deliver on key strategic initiatives that produce impressive double-digit growth rates seen over the past six quarters. With the recent addition of a CPT code for treating patients suffering from fluid overload, we believe we are positioned to continue to accelerate the growth of our business in the future."

Second Quarter 2021 Financial Results

Revenue for the second quarter of 2021 was \$2.5 million, an increase of 35% compared to \$1.9 million in the prior year period. Revenue growth in the second quarter of 2021 was driven by both increased capital equipment sales and strong utilization of disposables.

- Critical Care continued its strong momentum, driven by increased utilization and unit placements at hospitals in the ICU setting across the country. With COVID-related hospitalizations in the U.S. having significantly declined since the vaccine rollout, increased utilization among non-COVID critically ill patients remains a durable growth trend.
- Pediatric revenue delivered strong double-digit sequential revenue growth for the second straight quarter primarily due to increased penetration and utilization at established accounts, in addition to console sales to new customers.
- Heart Failure revenue increased sequentially due to more normalized patient behavior and increased access to hospitals as COVID-19 infection rates decline.

Gross margin was 60.2% for the second quarter 2021, compared to 64.4% in the prior year period. The decline in gross margins was primarily due to a production ramp last year to support the launch of the Aquadex SmartFlow system and to meet expected future demand. Gross margins should benefit in future periods as production volumes increase and fixed overhead get allocated over a larger base.

Selling, general and administrative (“SG&A”) expenses for the second quarter of 2021 were \$5.1 million, an increase of 20% compared to the prior year period. The increase in SG&A was primarily due to our continued investment in sales and marketing activities, along with nonrecurring leadership transition costs. Research and development (“R&D”) expenses in the second quarter of 2021 were \$1.2 million, an increase of 33% compared to the prior year period. The increase in R&D expenses was driven primarily by investments in new products and clinical support of our pediatric registry.

The net loss for the second quarter of 2021 was \$4.7 million, compared to a net loss of \$3.9 million in the prior year period.

Cash and cash equivalents were approximately \$24.0 million with no debt as of June 30, 2021. During the second quarter of 2021, the Company used \$3.9 million of cash from operations.

2021 Full-Year Outlook

The Company expects quarterly revenue to continue increasing sequentially for the remainder of 2021 as it continues to build its commercial presence and seeks to increase utilization of Aquadex therapy. This outlook includes several assumptions, including no significant change in utilization or procedure volumes associated with COVID-19 resurgences.

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 <http://ir.nuwellis.com>. Alternatively, you may access the live conference call by dialing (877) 303-9826 (U.S.) or (224) 357-2194 (international) and using conference ID: 1396749. An audio archive of the webcast will be available following the call at <http://ir.nuwellis.com>.

About Nuwellis

Nuwellis, Inc. (Nasdaq: NUWE) is a medical device company dedicated to changing 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, Minn., 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 2021 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 risk 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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FINANCIAL STATEMENTS

NUWELLIS, INC. AND SUBSIDIARIES
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,	
	2021	2020	2021	2020
Net sales	\$ 2,508	\$ 1,863	\$ 4,426	\$ 3,493
Cost of goods sold	997	664	1,949	1,460
Gross profit	<u>1,511</u>	<u>1,199</u>	<u>2,477</u>	<u>2,033</u>
Operating expenses:				
Selling, general and administrative	5,063	4,234	10,300	8,770
Research and development	1,174	885	2,121	1,749
Total operating expenses	<u>6,237</u>	<u>5,119</u>	<u>12,421</u>	<u>10,519</u>
Loss from operations	<u>(4,726)</u>	<u>(3,920)</u>	<u>(9,944)</u>	<u>(8,486)</u>
Other income (expense), net	(2)	—	(3)	—
Loss before income taxes	(4,728)	(3,920)	(9,947)	(8,486)
Income tax expense	(3)	(2)	(5)	(4)
Net loss	<u>\$ (4,731)</u>	<u>\$ (3,922)</u>	<u>\$ (9,952)</u>	<u>\$ (8,490)</u>
Basic and diluted loss per share	<u>\$ (0.72)</u>	<u>\$ (3.10)</u>	<u>\$ (2.04)</u>	<u>\$ (11.31)</u>
Weighted average shares outstanding – basic and diluted	6,532	1,264	4,887	906
Other comprehensive loss:				
Foreign currency translation adjustments	\$ —	\$ (2)	\$ (3)	\$ (5)
Total comprehensive loss	<u>\$ (4,731)</u>	<u>\$ (3,924)</u>	<u>\$ (9,955)</u>	<u>\$ (8,495)</u>

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

	June 30, 2021 (unaudited)	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	\$ 23,978	\$ 14,437
Accounts receivable	1,177	905
Inventories	2,656	2,957
Other current assets	413	237
Total current assets	28,224	18,536
Property, plant and equipment, net	1,260	1,200
Operating lease right-of-use asset	156	255
Other assets	—	21
TOTAL ASSETS	\$ 29,640	\$ 20,012
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,787	\$ 1,097
Accrued compensation	1,577	2,192
Current portion of operating lease liability	160	206
Current portion of finance lease liability	25	24
Other current liabilities	54	66
Total current liabilities	3,603	3,585
Operating lease liability	—	55
Finance lease liability	41	54
Total liabilities	3,644	3,694
Commitments and contingencies		
Stockholders' equity		
Series A junior participating preferred stock as of June 30, 2021 and December 31, 2020, par value \$0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Series F convertible preferred stock as of both June 30, 2021 and December 31, 2020, par value \$0.0001 per share; authorized 127 shares, issued and outstanding 127 shares	—	—
Preferred stock as of both June 30, 2021 and December 31, 2020, par value \$0.0001 per share; authorized 39,969,873 shares, none outstanding	—	—
Common stock as of June 30, 2021 and December 31, 2020, par value \$0.0001 per share; authorized 100,000,000 shares, issued and outstanding 6,532,018 and 2,736,060, respectively	—	—
Additional paid-in capital	269,296	249,663
Accumulated other comprehensive loss:		
Foreign currency translation adjustment	(10)	(7)
Accumulated deficit	(243,290)	(233,338)
Total stockholders' equity	25,996	16,318
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 29,640	\$ 20,012

NUWELLIS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
(unaudited, in thousands)

	Six months ended June 30,	
	2021	2020
Operating Activities:		
Net loss	\$ (9,952)	\$ (8,490)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	256	151
Stock-based compensation expense, net	736	727
Loss on disposal of property and equipment	—	46
Changes in operating assets and liabilities:		
Accounts receivable	(272)	(179)
Inventory	122	(1,104)
Other current assets	(176)	20
Other assets and liabilities	9	112
Accounts payable and accrued expenses	75	(43)
Net cash used in operating activities	(9,202)	(8,760)
Investing Activities:		
Purchases of property and equipment	(137)	(69)
Net cash used in investing activities	(137)	(69)
Financing Activities:		
Proceeds from public stock offerings, net	18,896	13,040
Proceeds from warrant exercises	1	2,340
Payments on finance lease liability	(14)	(4)
Net cash provided by financing activities	18,883	15,376
Effect of exchange rate changes on cash	(3)	(5)
Net increase in cash and cash equivalents	9,541	6,542
Cash and cash equivalents - beginning of period	14,437	1,279
Cash and cash equivalents - end of period	\$ 23,978	\$ 7,821
Supplemental cash flow information		
Inventory transferred to property, plant and equipment	\$ 179	\$ 112
Equipment acquired through finance lease liability	\$ —	\$ 67

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