

**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 9, 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 November 9, 2021, Nuwellis, Inc. (the “Company”) issued a press release reporting its financial results for the three and nine months ended September 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 November 9, 2021, reporting the financial results of Nuwellis, Inc. for the three and nine months ended September 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: November 9, 2021

NUWELLIS, INC.

By: /s/ Nestor Jaramillo

Name: Nestor Jaramillo

Title: President and Chief Executive Officer



Nuwellis, Inc. Announces Third Quarter 2021 Financial Results

Minneapolis, MN, November 9, 2021 (GLOBE NEWSWIRE) -- Nuwellis, Inc. (Nasdaq: NUWE) announced today its results for the third quarter ended September 30, 2021, which included the following highlights:

- Generated \$1.9 million in total revenue, representing a decline of 3% compared to the prior-year period
- Generated \$6.3 million in total revenue year-to-date through September 30, representing 16% growth compared to the prior-year period and a 52% increase above the comparable pre-pandemic period in 2019
- Opened three new pediatric accounts in the third quarter, the largest quarterly addition in 2021
- Announced R&D partnership with Koronis Biomedical Technologies Corporation (KBT) to design and develop a product for children under 20kg with limited kidney function, following a \$1.7 million development grant from the National Institutes of Health
- Completed an all-common stock capital raise of \$10.0 million gross proceeds, ending the quarter with \$28.4 million in cash and no debt

“Although the third quarter was a challenging environment due to COVID headwinds, we were able to continue adding new pediatric customers and drive increased utilization within our Critical Care business at key accounts,” said Nestor Jaramillo, CEO of Nuwellis. “Similar to previous cycles where COVID cases drop following spikes in geographic hot spots, we believe we will be able execute our operating plan and accelerate revenue growth in our key markets when the healthcare environment normalizes.”

Third Quarter 2021 Financial Results

Revenue for the third quarter of 2021 was \$1.9 million, representing a decline of 3% compared to the prior-year period. This revenue decline was driven primarily by the cancellation of elective procedures and the change in protocol to minimize use of fluid resuscitation when treating critically ill COVID patients.

- Critical Care revenue more than doubled compared to the prior-year period but declined sequentially due to COVID headwinds. The Company continues to see strong utilization from key accounts that rely heavily on the Aquadex System to treat non-COVID critically ill patients.
- Pediatric revenue declined compared to the prior-year period due to a more difficult hospital operating environment. The Company opened three new pediatric accounts in the third quarter, its largest quarterly addition in 2021, a strong sign of the interest to use the therapy among pediatric institutions.
- Heart Failure revenue increased compared to the prior year period but declined sequentially due a spike in COVID cases which negatively impacted patient behavior and access to hospitals.

Gross margin was 60.4% for the third quarter 2021, compared to 46.1% in the prior year period. The increase in gross margin was primarily due to favorable geographic and product mix.

Selling, general and administrative (“SG&A”) expenses for the third quarter of 2021 were \$4.6 million, an increase of 9% compared to the prior-year period. The increase in SG&A was primarily due to our continued investment in sales and marketing activities, plus additional administrative costs. Research and development (“R&D”) expenses in the third quarter of 2021 were \$1.7 million, an increase of 98% compared to the prior year period. The increase in R&D expenses was driven primarily by investments in new products, namely the new pediatric system, along with increased spending on clinical evidence, regulatory and reimbursement activity.

The net loss for the third quarter of 2021 was \$5.3 million, compared to a net loss of \$4.3 million in the prior year period reflecting the new investments made this year in product development and clinical evidence, as mentioned above.

Cash and cash equivalents were approximately \$28.4 million as of September 30, 2021. During the third quarter of 2021, the Company completed an all-common stock capital raise of \$10.0 million in gross proceeds.

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: 1436426. 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 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 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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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,	
	2021	2020	2021	2020
Net sales	\$ 1,853	\$ 1,904	\$ 6,279	\$ 5,397
Cost of goods sold	733	1,026	2,682	2,486
Gross profit	1,120	878	3,597	2,911
Operating expenses:				
Selling, general and administrative	4,645	4,264	14,945	13,034
Research and development	1,726	871	3,847	2,620
Total operating expenses	6,371	5,135	18,792	15,654
Loss from operations	(5,251)	(4,257)	(15,195)	(12,743)
Other income (expense), net	(19)	—	(22)	—
Loss before income taxes	(5,270)	(4,257)	(15,217)	(12,743)
Income tax expense	(2)	(3)	(7)	(7)
Net loss	\$ (5,272)	\$ (4,260)	\$ (15,224)	\$ (12,750)
Basic and diluted loss per share	\$ (0.75)	\$ (2.08)	\$ (2.72)	\$ (11.27)
Weighted average shares outstanding – basic and diluted	7,098	2,049	5,624	1,287
Other comprehensive loss:				
Foreign currency translation adjustments	\$ —	\$ (7)	\$ (3)	\$ (12)
Total comprehensive loss	\$ (5,272)	\$ (4,267)	\$ (15,227)	\$ (12,762)

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

	September 30, 2021	December 31, 2020
	(unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 28,431	\$ 14,437
Accounts receivable	1,069	905
Inventories	2,805	2,957
Other current assets	420	237
Total current assets	32,725	18,536
Property, plant and equipment, net	1,265	1,200
Operating lease right-of-use asset	105	255
Other assets	—	21
TOTAL ASSETS	\$ 34,095	\$ 20,012
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,851	\$ 1,097
Accrued compensation	1,771	2,192
Current portion of operating lease liability	108	206
Current portion of finance lease liability	27	24
Other current liabilities	38	66
Total current liabilities	3,795	3,585
Operating lease liability	—	55
Finance lease liability	33	54
Other Long-term liability	286	—
Total liabilities	4,114	3,694
Commitments and contingencies		
Stockholders' equity		
Series A junior participating preferred stock as of September 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 September 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 September 30, 2021 and December 31, 2020, par value \$0.0001 per share; authorized 39,969,873 shares, none outstanding	—	—
Common stock as of September 30, 2021 and December 31, 2020, par value \$0.0001 per share; authorized 100,000,000 shares, issued and outstanding 10,537,606 and 2,736,060, respectively	1	—
Additional paid-in capital	278,552	249,663
Accumulated other comprehensive loss:		
Foreign currency translation adjustment	(10)	(7)
Accumulated deficit	(248,562)	(233,338)
Total stockholders' equity	29,981	16,318
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 34,095	\$ 20,012

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

	Nine months ended September 30,	
	2021	2020
Operating Activities:		
Net loss	\$ (15,224)	\$ (12,750)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	383	253
Stock-based compensation expense, net	993	1,036
Loss on disposal of property and equipment	—	46
Changes in operating assets and liabilities:		
Accounts receivable	(164)	(249)
Inventory	(105)	(1,371)
Other current assets	(183)	(74)
Other assets and liabilities	279	112
Accounts payable and accrued expenses	333	(166)
Net cash used in operating activities	(13,688)	(13,163)
Investing Activities:		
Purchases of property and equipment	(191)	(207)
Net cash used in investing activities	(191)	(207)
Financing Activities:		
Proceeds from public stock offerings, net	27,896	25,949
Proceeds from warrant exercises	1	4,115
Payments on finance lease liability	(21)	(14)
Net cash provided by financing activities	27,876	30,050
Effect of exchange rate changes on cash	(3)	(12)
Net increase in cash and cash equivalents	13,994	16,668
Cash and cash equivalents - beginning of period	14,437	1,279
Cash and cash equivalents - end of period	\$ 28,431	\$ 17,947
Supplemental cash flow information		
Inventory transferred to property, plant and equipment	\$ 257	\$ 247
Equipment acquired through finance lease liability	\$ —	\$ 98

INVESTOR CONTACTS:

George Montague
Chief Financial Officer, Nuwellis, Inc.
ir@nuwellis.com

Matt Bacso
Gilmartin Group
Matt.Bacso@gilmartinir.com
