

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the quarterly period ended **September 30, 2022**

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 001-35312

**NUWELLIS, INC.**

(Exact Name of Registrant as Specified in its Charter)

Delaware  
(State or Other Jurisdiction of  
Incorporation or Organization)

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer

Non-accelerated Filer

Emerging growth company

Accelerated filer

Smaller reporting 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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

The number of outstanding shares of the registrant's common stock, \$0.0001 par value, as of November 4, 2022 was 31,531,650

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**PART I—FINANCIAL INFORMATION**  
**ITEM 1. FINANCIAL STATEMENTS**  
**NUWELLIS, INC. AND SUBSIDIARY**  
**Condensed Consolidated Balance Sheets**  
(In thousands, except share and per share amounts)

	September 30, 2022 (unaudited)	December 31, 2021
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 12,053	\$ 24,205
Accounts receivable	1,100	750
Inventories	2,919	2,843
Other current assets	368	328
<b>Total current assets</b>	<b>16,440</b>	<b>28,126</b>
Property, plant and equipment, net	1,027	1,188
Operating lease right-of-use asset	949	1,082
Other assets	21	21
<b>TOTAL ASSETS</b>	<b>\$ 18,437</b>	<b>\$ 30,417</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
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
<b>Total current liabilities</b>	<b>3,611</b>	<b>3,307</b>
Operating lease liability	810	956
Finance lease liability	—	28
Other long-term liability	—	179
<b>Total liabilities</b>	<b>4,421</b>	<b>4,470</b>
Commitments and contingencies		
<b>Stockholders' equity</b>		
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)
<b>Total stockholders' equity</b>	<b>14,016</b>	<b>25,947</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 18,437</b>	<b>\$ 30,417</b>

See notes to the condensed consolidated financial statements.

**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
<b>Net sales</b>	\$ 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>
<b>Operating expenses:</b>				
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)
<b>Net loss</b>	<u>\$ (3,870)</u>	<u>\$ (5,272)</u>	<u>\$ (12,629)</u>	<u>\$ (15,224)</u>
<b>Basic and diluted loss per share</b>	<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
<b>Other comprehensive loss:</b>				
Foreign currency translation adjustments	\$ 2	\$ —	\$ 1	\$ (3)
<b>Total comprehensive loss</b>	<u>\$ (3,868)</u>	<u>\$ (5,272)</u>	<u>\$ (12,628)</u>	<u>\$ (15,227)</u>

See notes to the condensed consolidated financial statements.

**NUWELLIS, INC. AND SUBSIDIARY**  
**Condensed Consolidated Statements of Stockholders' Equity**  
**(Unaudited)**  
(In thousands, except share amounts)

	Outstanding Shares of Common Stock	Common Stock	Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Equity
<b>Balance December 31, 2020</b>	2,736,060	\$ —	\$ 249,663	\$ (7)	\$ (233,338)	\$ 16,318
Net loss	—	—	—	—	(5,221)	(5,221)
Foreign currency translation adjustment	—	—	—	(3)	—	(3)
Stock-based compensation, net	—	—	355	—	—	355
Issuance of common, net	3,795,816	—	18,902	—	—	18,902
Exercise of warrants	66	—	1	—	—	1
<b>Balance March 31, 2021</b>	<b>6,531,942</b>	<b>\$ —</b>	<b>\$ 268,921</b>	<b>\$ (10)</b>	<b>\$ (238,559)</b>	<b>\$ 30,352</b>
Net loss	—	—	—	—	(4,731)	(4,731)
Foreign currency translation adjustment	—	—	—	—	—	—
Stock-based compensation, net	—	—	381	—	—	381
Issuance costs related to common stock offering	—	—	(6)	—	—	(6)
Exercise of warrants	76	—	—	—	—	—
<b>Balance June 30, 2021</b>	<b>6,532,018</b>	<b>\$ —</b>	<b>\$ 269,296</b>	<b>\$ (10)</b>	<b>\$ (243,290)</b>	<b>\$ 25,996</b>
Net loss	—	—	—	—	(5,272)	(5,272)
Foreign currency translation adjustment	—	—	—	—	—	—
Stock-based compensation, net	—	—	257	—	—	257
Issuance of common stock, net	4,005,588	1	8,999	—	—	9,000
<b>Balance September 30, 2021</b>	<b>10,537,606</b>	<b>\$ 1</b>	<b>\$ 278,552</b>	<b>\$ (10)</b>	<b>\$ (248,562)</b>	<b>\$ 29,981</b>
	Outstanding Shares of Common Stock	Common Stock	Additional Paid in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Stockholders' Equity
<b>Balance December 31, 2021</b>	10,537,606	\$ 1	\$ 278,873	\$ (11)	\$ (252,916)	\$ 25,947
Net loss	—	—	—	—	(4,473)	(4,473)
Foreign currency translation adjustment	—	—	—	(2)	—	(2)
Stock-based compensation, net	—	—	241	—	—	241
<b>Balance March 31, 2022</b>	<b>10,537,606</b>	<b>\$ 1</b>	<b>\$ 279,114</b>	<b>\$ (13)</b>	<b>\$ (257,389)</b>	<b>\$ 21,713</b>
Net loss	—	—	—	—	(4,286)	(4,286)
Foreign currency translation adjustment	—	—	—	1	—	1
Stock-based compensation, net	—	—	236	—	—	236
<b>Balance June 30, 2022</b>	<b>10,537,606</b>	<b>\$ 1</b>	<b>\$ 279,350</b>	<b>\$ (12)</b>	<b>\$ (261,675)</b>	<b>\$ 17,664</b>
Net loss	—	—	—	—	(3,870)	(3,870)
Foreign currency translation adjustment	—	—	—	2	—	2
Stock-based compensation, net	—	—	220	—	—	220
<b>Balance September 30, 2022</b>	<b>10,537,606</b>	<b>\$ 1</b>	<b>\$ 279,570</b>	<b>\$ (10)</b>	<b>\$ (265,545)</b>	<b>\$ 14,016</b>

See notes to the condensed consolidated financial statements

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

	<b>Nine months ended</b>	
	<b>2022</b>	<b>September 30,</b>
		<b>2021</b>
<b>Operating Activities:</b>		
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
<b>Net cash used in operating activities</b>	<b>(12,022)</b>	<b>(13,688)</b>
<b>Investing Activities:</b>		
Purchases of property and equipment	(103)	(191)
<b>Net cash used in investing activities</b>	<b>(103)</b>	<b>(191)</b>
<b>Financing Activities:</b>		
Proceeds from public stock offerings, net	—	27,896
Proceeds from warrant exercises	—	1
Payments on finance lease liability	(28)	(21)
<b>Net cash (used in) provided by financing activities</b>	<b>(28)</b>	<b>27,876</b>
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
<b>Cash and cash equivalents - end of period</b>	<b>\$ 12,053</b>	<b>\$ 28,431</b>
<b>Supplemental cash flow information</b>		
Inventory transferred to property, plant and equipment	\$ 37	\$ 257

See notes to the condensed consolidated financial statements.

**NUWELLIS, INC. AND SUBSIDIARY**  
**Notes to Condensed Consolidated Financial Statements**  
(Unaudited)

**Note 1 – Nature of Business and Basis of Presentation**

*Nature of Business:* Nuwellis, Inc. (the “Company”) is a medical device company focused on developing, manufacturing and commercializing the Aquadex FlexFlow® and Aquadex SmartFlow® systems (collectively, the “Aquadex System”) for ultrafiltration therapy. The Aquadex System is indicated for temporary (up to eight 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. Nuwellis, Inc. is a Delaware corporation headquartered in Minneapolis with a wholly owned subsidiary in Ireland. The Company’s common stock began trading on the Nasdaq Stock Market in February 2012.

In August 2016, the Company acquired the business associated with the Aquadex System (the “Aquadex Business”) from a subsidiary of Baxter International, Inc. (“Baxter”) and refocused its strategy to fully devote its resources to the Aquadex Business. On April 27, 2021, the Company announced that it was changing its name from CHF Solutions, Inc. to Nuwellis, Inc. to reflect the expansion of its customer base from treating fluid imbalance resulting from congestive heart failure to also include critical care and pediatric applications.

*Principles of Consolidation:* The accompanying condensed consolidated balance sheet as of September 30, 2022, which has been derived from the consolidated audited financial statements and the unaudited condensed consolidated financial statements has been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 8 of Regulation S-X. Certain information and note disclosures normally included in the audited annual consolidated financial statements have been condensed or omitted pursuant to those rules and regulations. Accordingly, they do not include all of the information necessary for a fair presentation of results of operations, comprehensive loss, financial condition, and cash flows in conformity with U.S. GAAP. In the opinion of management, the condensed consolidated financial statements reflect all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the results of the Company for the periods presented. Operating results for interim periods are not necessarily indicative of results that may be expected for the year as a whole. The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and the related disclosures at the date of the consolidated financial statements and during the reporting period. Actual results could differ materially from these estimates.

These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2021.

*Liquidity:* The Company’s consolidated financial statements have been prepared and presented on a basis assuming it continues as a going concern. During the years ended December 31, 2021, and 2020 and through September 30, 2022, the Company incurred losses from operations and net cash outflows from operating activities as disclosed in the consolidated statements of operations and cash flows, respectively. As of September 30, 2022, the Company had an accumulated deficit of \$265.5 million and it expects to incur losses in the immediate future. To date, the Company has been funded by equity financings, and although the Company believes that it will be able to successfully fund its operations, there can be no assurance that it will be able to do so or that it will ever operate profitably.

The Company became a revenue-generating company after acquiring the Aquadex Business in August 2016. The Company expects to incur additional losses in the near term as it grows the Aquadex Business, including investments in expanding its sales and marketing capabilities, purchasing inventory, manufacturing components, and complying with the requirements related to being a U.S. public company. To become and remain profitable, the Company must succeed in expanding the adoption and market acceptance of the Aquadex System. This will require the Company to succeed in training personnel at hospitals and in outpatient care settings and in effectively and efficiently manufacturing, marketing and distributing the Aquadex System and related components. There can be no assurance that the Company will succeed in these activities, and it may never generate revenues sufficient to achieve profitability.

During 2021, the Company closed on underwritten public equity offerings for aggregate net proceeds of approximately \$27.9 million after deducting the underwriting discounts and commissions and other costs associated with the offerings. In addition, during 2021 we received approximately \$1,300 in proceeds from the exercise of investor warrants. See Note 3—Stockholders’ Equity for additional related disclosure. The Company will require additional funding to grow its Aquadex Business, which may not be available on terms favorable to the Company, or at all. The Company may receive those funds from the proceeds from future warrant exercises, issuances of equity securities, or other financing transactions. Should warrant exercises not materialize or future capital raising be unsuccessful, the Company may not be able to continue as a going concern. No adjustments have been made relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company not continue as a going concern.

The Company believes that its existing capital resources will be sufficient to support its operating plan through December 31, 2023. However, the Company may seek to raise additional capital to support its growth or other strategic initiatives through debt, equity or a combination thereof. There can be no assurance the Company will be successful in raising additional capital.

**Revenue Recognition:** The Company recognizes revenue in accordance with Accounting Standards Codification, Topic 606, Revenue from Contracts with Customers. Accordingly, the Company recognizes revenue when its customers obtain control of its products or services, in an amount that reflects the consideration that the Company expects to receive in exchange for those goods and services. See Note 2 – Revenue Recognition below for additional disclosures. For the three months ended September 30, 2022, one customer represented 12% of net sales. For the nine months ended September 30, 2022, two customers each represented 13% and 10% of net sales. For the three months ended September 30, 2021, two customers represented 14% and 12% of net sales. For the nine months ended September 30, 2021, two customers represented 12% and 11% of net sales.

**Accounts Receivable:** Accounts receivable are unsecured, are recorded at net realizable value, and do not bear interest. The Company makes judgments as to its ability to collect outstanding receivables based upon significant patterns of collectability, historical experience, and management’s evaluation of specific accounts and will provide an allowance for credit losses when collection becomes doubtful. The Company performs credit evaluations of its customers’ financial condition on an as-needed basis. Payment is generally due 30 days from the invoice date and accounts past 30 days are individually analyzed for collectability. When all collection efforts have been exhausted, the account is written off against the related allowance. To date the Company has not experienced any write-offs or significant deterioration of the aging of its accounts receivable, and therefore, no allowance for doubtful accounts was considered necessary as of September 30, 2022, or December 31, 2021. As of September 30, 2022, one customer represented 19% of the accounts receivable balance. As of December 31, 2021, two customers represented 12% and 11% of the accounts receivable balance.

**Inventories:** Inventories represent finished goods purchased from the Company’s suppliers and are recorded as the lower of cost or net realizable value using the first-in first-out method. Overhead is allocated to manufactured finished goods inventory based on the normal capacity of the Company’s production facilities. Abnormal amounts of overhead, if any, are expensed as incurred. Inventories consisted of the following:

(in thousands)	September 30, 2022	December 31, 2021
Finished Goods	\$ 1,180	\$ 1,409
Work in Process	223	276
Raw Materials	1,516	1,158
Total	<u>\$ 2,919</u>	<u>\$ 2,843</u>

**Loss per share:** Basic loss per share is computed based on the net loss for each period divided by the weighted average number of common shares outstanding. The net loss allocable to common stockholders for the nine months ended September 30, 2021 includes a deemed dividend of \$33,000 that resulted from the change in the exercise price of warrants as a result of the March 2021 offering. See Note 3 – Stockholders’ Equity below for additional disclosures.

Diluted earnings per share is computed based on the net loss allocable to common stockholders for each period divided by the weighted average number of common shares outstanding, increased by the number of additional shares that would have been outstanding had the potentially dilutive common shares been issued, and reduced by the number of shares the Company could have repurchased from the proceeds from issuance of the potentially dilutive shares. Potentially dilutive shares of common stock include shares underlying outstanding convertible preferred stock, warrants, stock options and other stock-based awards granted under stock-based compensation plans.

The following table sets forth the potential shares of common stock that are not included in the calculation of diluted net loss per share because to do so would be anti-dilutive as of the end of each period presented:

	<b>September 30,</b>	
	<b>2022</b>	<b>2021</b>
Stock options	1,200,259	738,946
Warrants to purchase common stock	1,630,627	1,631,801
Series F convertible preferred stock	50,800	50,800
Total	<u>2,881,686</u>	<u>2,421,547</u>

The following table reconciles reported net loss with reported net loss per share for each of the three and nine months ended September 30:

	<b>Three months ended</b>		<b>Nine months ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2022</b>	<b>2021</b>	<b>2022</b>	<b>2021</b>
<i>(in thousands, except per share amounts)</i>				
Net loss	\$ (3,870)	\$ (5,272)	\$ (12,629)	\$ (15,224)
Deemed dividend to preferred shareholders (see note 3)	—	—	—	(75)
Net loss after deemed dividend	(3,870)	(5,272)	(12,629)	(15,299)
Weighted average shares outstanding	10,538	7,098	10,538	5,624
Basic and diluted loss per share	<u>\$ (0.37)</u>	<u>\$ (0.75)</u>	<u>\$ (1.20)</u>	<u>\$ (2.72)</u>

*Subsequent events:* The Company evaluates events through the date the condensed consolidated financial statements are filed for events requiring adjustment to or disclosure in the condensed consolidated financial statements.

## **Note 2 – Revenue Recognition**

**Net Sales:** The Company sells its products in the United States primarily through a direct sales force. Customers who purchase the Company's products include hospitals and clinics throughout the United States. In countries outside the United States, the Company sells its products through a limited number of specialty healthcare distributors in Austria, Brazil, Colombia, The Czech Republic, Germany, Greece, Hong Kong, India, Israel, Italy, Panama, Romania, Singapore, Slovakia, Spain, Switzerland, Thailand, United Arab Emirates, and the United Kingdom. These distributors resell the Company's products to hospitals and clinics in their respective geographies.

Revenue from product sales is recognized when the customer or distributor obtains control of the product, which occurs at a point in time, most frequently upon shipment of the product or receipt of the product, depending on shipment terms. The Company's standard shipping terms are FOB shipping point unless the customer requests that control and title to the inventory transfer upon delivery.

Revenue is measured as the amount of consideration we expect to receive, adjusted for any applicable estimates of variable consideration and other factors affecting the transaction price, which is based on the invoiced price, in exchange for transferring products. All revenue is recognized when the Company satisfies its performance obligations under the contract. The majority of the Company's contracts have a single performance obligation and are short term in nature. The Company has entered into extended service plans with customers whose related revenue is recognized over time. This revenue represents less than 1% of net sales for the three and nine months ended September 30, 2022, and 2021. The unfulfilled performance obligations related to these extended service plans are included in deferred revenue, which is included in other current liabilities on the consolidated balance sheets. The majority of the deferred revenue is expected to be recognized within one year.

Sales taxes and value added taxes in foreign jurisdictions that are collected from customers and remitted to governmental authorities are accounted for on a net basis and therefore are excluded from net sales. Revenue includes shipment and handling fees charged to customers. Shipping and handling costs associated with outbound freight after control over a product has transferred to a customer are accounted for as a fulfillment cost and are included in cost of goods sold.

**Product Returns:** The Company offers customers a limited right of return for its product in case of non-conformity or performance issues. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized. The Company currently estimates product return liabilities using available industry data and its own historical sales and returns information. The Company has not received any returns to date and believes that future returns of its products will be minimal. Therefore, revenue recognized is not currently impacted by variable consideration related to product returns.

### **Note 3 – Stockholders’ Equity**

**Series F Convertible Preferred Stock:** On November 27, 2017, the Company closed on an underwritten public offering Series F convertible preferred stock and warrants to purchase shares of common stock for gross proceeds of \$18.0 million. Net proceeds totaled approximately \$16.2 million after deducting the underwriting discounts and commissions and other costs associated with the offering.

The offering was comprised of Series F convertible preferred stock, convertible into shares of the Company’s common stock at an initial conversion price of \$1,890.00 per share. Each share of Series F convertible preferred stock was accompanied by a Series 1 warrant (which expired on the first anniversary of its issuance) to purchase 16 shares of the Company’s common stock at an exercise price of \$1,890.00 per share, and a Series 2 warrant, which expires on the seventh anniversary of its issuance, to purchase 16 shares of the Company’s common stock at an exercise price of \$1,890.00 per share. The Series F convertible preferred stock has full ratchet price based anti-dilution protection, subject to customary carve-outs, in the event of a down-round financing at a price per share below the conversion price of the Series F convertible preferred stock (which protection will expire if, during any 20 of 30 consecutive trading days, the volume weighted average price of the Company’s common stock exceeds 300% of the then-effective conversion price of the Series F convertible preferred stock and the daily dollar trading volume for each trading day during such period exceeds \$200,000). The exercise price of the warrants is fixed and does not contain any variable pricing features, nor any price-based anti-dilutive features, apart from customary adjustments for stock splits, combinations, reclassifications, stock dividends or fundamental transactions. A total of 18,000 shares of Series F convertible preferred stock initially convertible into 9,557 shares of common stock and warrants to purchase 19,122 shares of common stock were issued in the offering.

Effective March 12, 2019, the conversion price of the Series F convertible preferred stock was reduced from \$890.40 to \$157.50, the per share price to the public of the Series G convertible preferred stock issued in the March 2019 Offering. Effective October 25, 2019, the conversion price of the Series F convertible preferred stock was reduced from \$157.50 to \$42.30, and further reduced on November 6, 2019, from \$42.30 to \$29.83, the per share price to the public in the October and November 2019 transactions, respectively. Effective January 28, 2020, the conversion price of the Series F convertible preferred stock was reduced from \$29.83 to \$16.50, the per share price to the public of the Series H convertible preferred stock, which closed in an underwritten public offering on January 28, 2020, described below. Effective March 23, 2020, the conversion price of the Series F convertible preferred stock was reduced from \$16.50 to \$9.00, the per share price to the public in the March 2020 transaction, described below. In connection with the September 2021 offering, the conversion price of the Series F convertible preferred stock was reduced from \$5.50 to \$2.50, the per share price to the public in the September 2021 offering, described below.

As of September 30, 2022, and December 31, 2021, 127 shares of the Series F convertible preferred stock remained outstanding.

**March 2021 Offering:** On March 19, 2021, the Company closed on an underwritten public offering of 3,795,816 shares of common stock, for gross proceeds of approximately \$20.9 million (the “March 2021 Offering”). Net proceeds totaled approximately \$18.9 million after deducting the underwriting discounts and commissions and other costs associated with the offering and after giving effect to the underwriters’ full exercise of their over-allotment option.

In connection with the March 2021 Offering, the conversion price of the Series F convertible preferred stock was reduced from \$9.00 to \$5.50, the per share price to the public in the March 2021 Offering. In addition, the exercise price of the common stock warrants issued in connection with the January 2020 Offering was reduced from \$9.00 to \$5.50, the per share price to the public in the March 2021 Offering.

**September 2021 Offering:** On September 17, 2021, the Company closed on an underwritten public offering of 4,005,588 shares of common stock, for gross proceeds of approximately \$10.0 million (the “September 2021 Offering”). Net proceeds totaled approximately \$9.0 million after deducting the underwriting discounts and commissions and other costs associated with the offering and after giving effect to the underwriters’ full exercise of their over-allotment option.

In connection with the September 2021 Offering, the conversion price of the Series F convertible preferred stock was reduced from \$5.50 to \$2.50, the per share price to the public in the September 2021 Offering. In addition, the exercise price of the common stock warrants issued in connection with the January 2020 Offering was reduced from \$5.50 to \$2.50, the per share price to the public in the September 2021 Offering.

**Placement Agent Fees:** In connection with the offerings described above, the Company paid the placement agent an aggregate cash placement fee equal to 8% of the aggregate gross proceeds raised in each of the offerings.

**Market-Based Warrants:** On May 30, 2019, the Company granted a market-based warrant to a consultant in exchange for investor relations services. The warrant represents the right to acquire up to 3,334 shares of the Company's common stock at an exercise price of \$95.40 per share, the closing stock price of the Company's common shares on May 30, 2019. The warrant is subject to a vesting schedule based on the Company achieving certain market stock prices within a specified period of time. The warrant expires on May 30, 2024. The warrant was valued at \$57.90 per share using the Monte Carlo valuation methodology and was expensed over the term of the consulting engagement, which was twelve months. Significant inputs used for the Monte Carlo valuation were the expected stock price volatility of 136.21%, and management's expectations regarding the timing of regulatory clearance for an expanded label in pediatrics. None of these warrants had vested as of September 30, 2022.

**Reverse Stock Split:** On October 6, 2020, the Company's stockholders approved a reverse split of its outstanding common stock at a ratio in the range of 1-for-5 to 1-for-30 and, on October 9, 2020, the board of directors approved a 1-for-30 reverse split of the Company's outstanding common stock that became effective after trading on October 16, 2020. This reverse stock split did not change the par value of the Company's common stock or the number of common or preferred shares authorized by the Company's Fourth Amended and Restated Certificate of Incorporation, as amended. All share and per-share amounts have been retroactively adjusted to reflect the reverse stock splits for all periods presented.

#### Note 4 - Stock-Based Compensation

Under the fair value recognition provisions of U.S. GAAP for accounting for stock-based compensation, the Company measures stock-based compensation expense at the grant date based on the fair value of the award and recognizes the compensation expense over the requisite service period, which is generally the vesting period.

The following table presents the classification of stock-based compensation expense recognized for the periods below:

(in thousands)	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Selling, general and administrative expense	\$ 199	\$ 216	\$ 624	\$ 894
Research and development expense	21	40	73	99
<b>Total stock-based compensation expense</b>	<b>\$ 220</b>	<b>\$ 256</b>	<b>\$ 697</b>	<b>\$ 993</b>

#### Note 5 – Income Taxes

The Company provides for a valuation allowance when it is more likely than not that it will not realize a portion of its deferred tax assets. The Company has established a full valuation allowance for U.S. and foreign deferred tax assets due to the uncertainty that enough taxable income will be generated in those taxing jurisdictions to utilize the assets. Therefore, the Company has not reflected any benefit of such deferred tax assets in the accompanying condensed consolidated financial statements.

As of September 30, 2022, there were no material changes to what the Company disclosed regarding tax uncertainties or penalties in its Annual Report on Form 10-K for the year ended December 31, 2021.

#### Note 6—Operating Leases

The Company leases a 23,000 square foot facility located in Eden Prairie, Minnesota for office and manufacturing space under a non-cancelable operating lease that expires in March 2027. In November 2021, the Company entered into a fourth amendment to the lease, extending the term of the lease from March 31, 2022 to March 31, 2027. This facility serves as our corporate headquarters and houses substantially all of our functional areas. Monthly rent and common area maintenance charges, including estimated property tax for our headquarters, total approximately \$29,000. The lease contains provisions for annual inflationary adjustments. Rent expense is being recorded on a straight-line basis over the term of the lease. Beginning on April 1, 2022, the annual base rent is \$10.50 per square foot, subject to annual increases of \$0.32 to \$0.34 per square foot.

### **Note 7—Finance Lease Liability**

In 2020, the Company entered into lease agreements to finance equipment valued at \$98,000. The equipment consisted of computer hardware and audio-visual equipment and is included in Property, Plant and Equipment in the accompanying consolidated financial statements. The principal amount under the lease agreements was \$93,000 at the date the lease commenced, the implied interest rate is 7.5%, and the term of the lease is 39 months.

### **Note 8—Commitments and Contingencies**

*Employee Retirement Plan:* The Company has a 401(k) retirement savings plan that provides retirement benefits to substantially all full-time U.S. employees. Eligible employees may contribute a percentage of their annual compensation, subject to Internal Revenue Service (“IRS”) limitations, with the Company matching a portion of the employees’ contributions at the discretion of the Company.

*Non-refundable Technology License Fee:* On June 24, 2021, the Company entered into a research and development collaboration agreement with Koronis Biomedical Corporation (KBT) to design and develop an integrated continuous renal replacement therapy device. This agreement became effective on August 5, 2021, when KBT received approval of a \$1.7 million grant from the National Institutes of Health (NIH) to support this project. As part of this agreement, the Company pays KBT a non-refundable technology license fee of \$428,160, payable in twelve equal monthly installments commencing on June 1, 2022. The Company has recorded a liability for the non-refundable technology license fee, with \$285,440 included in Accounts Payable. The full amount of \$428,160 was expensed and included in Research and Development Expense for the year ended December 31, 2021.

### **Note 9 – Subsequent Events**

On October 18, 2022, the Company closed on an underwritten public offering of 20,994,044 shares of common stock and 23,157,124 shares of Series I convertible preferred stock, for gross proceeds of approximately \$11.0 million (the “October 2022 Offering”). Net proceeds totaled approximately \$9.8 million after deducting underwriting discounts and commissions and other costs associated with the offering and after giving effect to the underwriters’ full exercise of their overallotment option.

The offering was comprised of (1) 20,994,044 Class A Units, priced at a public offering price of \$0.25 per Class A Unit, with each Class A Unit consisting of one share of common stock and 1.5 warrants to purchase one share of common stock at an exercise price of \$0.25 per share, and (2) 23,157,124 Class B Units, priced at a public offering price of \$0.25 per Class B Unit, with each Class B Unit consisting of one share of Series I convertible preferred stock, convertible into one share of common stock, and 1.5 warrants to purchase one share of common stock with an exercise price of \$0.25 per share.

The warrants will be exercisable beginning on the effective date of a reverse stock split in an amount sufficient to permit the exercise in full of the warrants, contingent upon stockholder approval of such reverse stock split and of the exercisability of the warrants under Nasdaq rules and will expire on the sixth anniversary of the initial exercise date. The stockholder meetings will be held on or before December 9, 2022. The conversion price of the preferred stock issued in the transaction is fixed and does not contain any variable pricing feature or any price-based anti-dilutive feature. The preferred stock issued in this transaction includes a beneficial ownership blocker but has no dividend rights (except to the extent that dividends are also paid on the common stock) or liquidation preference and, subject to limited exceptions, has no voting rights. The securities comprising the units are immediately separable and were issued separately.

In connection with the October 2022 Offering, the conversion price of the Series F convertible preferred stock was reduced from \$2.50 to \$0.25, the per share price to the public in the October 2022 Offering. In addition, the exercise price of the common stock warrants issued in connection with the January 2020 Offering was reduced from \$2.50 to \$1.65, based on “reset” provisions in the Warrant agreement.

On October 28, 2022, the Company filed a preliminary proxy statement seeking stockholder approval for a reverse stock split of our outstanding common stock at a ratio in the range of 1-for-50 to 1-for-100 and approval to increase the aggregate maximum number of shares of Common Stock that may be issued under the 2017 Equity Incentive Plan. The Company filed another preliminary proxy statement seeking stockholder approval to issue up to 66,226,752 shares of our common stock upon the exercise of our warrants issued to investors in the October 2022 Offering that may be equal to or exceed 20% of our common stock outstanding before the October 2022 Offering.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our interim condensed consolidated financial statements and related notes included in Part I, Item 1 of this Quarterly Report on Form 10-Q and the audited consolidated financial statements and related notes and Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the year ended December 31, 2021. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a variety of factors, including those discussed in Part I, Item 1A "Risk Factors," in our Annual Report on Form 10-K for the year ended December 31, 2021 and in our subsequent filings with the Securities and Exchange Commission (the "SEC").*

Unless otherwise specified or indicated by the context, Nuwellis, Company, we, us and our, refer to Nuwellis, Inc. and its subsidiary.

### OVERVIEW

#### About Nuwellis

We are a medical device company dedicated to transforming the lives of patients suffering from fluid overload through science, collaboration, and innovative technology. The Company is focused on developing, manufacturing, and commercializing medical devices used in ultrafiltration therapy, including the Aquadex System. The Aquadex SmartFlow system is indicated for temporary (up to eight 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.

Prior to July 2016, we were focused on developing the C-Pulse System for treatment of Class III and ambulatory Class IV heart failure. In August 2016, we acquired the Aquadex Business from a subsidiary of Baxter, a global leader in the hospital products and dialysis markets. In September 2016, we announced a refocus of our strategy that included halting all clinical evaluations of the C-Pulse System related technology to fully focus our resources on our recently acquired Aquadex Business. On May 23, 2017, we announced that we were changing our name from Sunshine Heart, Inc. to CHF Solutions, Inc. to more appropriately reflect the direction of our business at that time. On April 27, 2021, we announced that we were changing our name from CHF Solutions, Inc. to Nuwellis, Inc. to reflect the expansion of our customer base from treating fluid imbalance resulting from congestive heart failure to also include critical care and pediatrics applications.

#### Impact of COVID-19 Pandemic

During 2021 and through the third quarter of 2022, we continue to be subject to challenging social and economic conditions created as a result of the outbreak of the novel strain of coronavirus, SARS-CoV-2. The resulting impact of the COVID-19 pandemic created disruptions in our operations resulting from rapid and evolving changes implemented to keep our customers, their patients, and our employees safe. These changes included restrictions on hospital access imposed on our field employees by customers dealing on the front lines of COVID-19 and managing the spread of the virus, changes to work practices by requiring employees to work remotely, and increased protocols to ensure the safety of those employees that remained on site. The ongoing impact of the COVID-19 outbreak on our operational and financial performance will depend on certain future developments, including the duration and spread of the outbreak, the ongoing impact on our customers and hospital access restrictions imposed on our field employees, and effects on our vendors and supply chain, all of which remain uncertain and cannot be predicted.

We may experience curtailed customer demand or constrained supply that could materially adversely impact our business, results of operations and overall financial performance in future periods. Specifically, we may experience negative impacts from changes in how we conduct business due to the COVID-19 pandemic, including but not limited to restrictions on travel and in-person meetings, production delays, warehouses and staffing disruptions and shortages, decreases or delays in customer demand and spending, and difficulties or changes to our sales process and customer support.

We have experienced changes to our sales practices due to restrictions on hospital access and believe that revenue in other areas was negatively impacted by these restrictions. In addition, the disruption created by COVID-19 has created significant uncertainty about our ability to access the capital markets in future periods. As of the filing date of this Form 10-Q, the extent to which COVID-19 may continue to impact our financial condition or results of operations is uncertain and cannot be reasonably estimated but could be material and last for an extended period of time. The effect of the COVID-19 pandemic may not be fully reflected in our results of operations and overall financial performance until future periods. See Part 1, Item 1-A "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2021.

## Recent Developments

### *Public Offerings*

On October 18, 2022, the Company closed on the October 2022 Offering, for gross proceeds of approximately \$11.0 million. Net proceeds totaled approximately \$9.8 million after deducting the underwriting discounts and commissions and other costs associated with the offering and after giving effect to the underwriters' full exercise of their overallotment option.

The offering was comprised of (1) 20,994,044 Class A Units, priced at a public offering price of \$0.25 per Class A Unit, with each Class A Unit consisting of one share of common stock and 1.5 warrants to purchase one share of common stock at an exercise price of \$0.25 per share, and (2) 23,157,124 Class B Units, priced at a public offering price of \$0.25 per Class B Unit, with each Class B Unit consisting of one share of Series I convertible preferred stock, convertible into one share of common stock, and 1.5 warrants to purchase one share of common stock with an exercise price of \$0.25 per share.

The warrants will be exercisable beginning on the effective date of a reverse stock split in an amount sufficient to permit the exercise in full of the warrants, contingent upon stockholder approval of such reverse stock split and of the exercisability of the warrants under Nasdaq rules and will expire on the sixth anniversary of the initial exercise date. The stockholder meetings will be held on or before December 9, 2022. The conversion price of the preferred stock issued in the transaction is fixed and does not contain any variable pricing feature or any price-based anti-dilutive feature. The preferred stock issued in this transaction includes a beneficial ownership blocker but has no dividend rights (except to the extent that dividends are also paid on the common stock) or liquidation preference, and, subject to limited exceptions, has no voting rights. The securities comprising the units are immediately separable and were issued separately.

In connection with the October 2022 Offering, the conversion price of the Series F convertible preferred stock was reduced from \$2.50 to \$0.25, the per share price to the public in the October 2022 Offering. In addition, the exercise price of the common stock warrants issued in connection with the January 2020 Offering was reduced from \$2.50 to \$1.65, based on "reset" provisions in the Warrant agreement.

*Placement Agent Fees:* In connection with the offerings described above, the Company paid the placement agent an aggregate cash placement fee equal to 8% of the aggregate gross proceeds raised in each of the offerings.

### *Preliminary Proxy Statement*

On October 28, 2022, the Company filed a preliminary proxy statement seeking stockholder approval for a reverse stock split of our outstanding common stock at a ratio in the range of 1-for-50 to 1-for-100 and approval to increase the aggregate maximum number of shares of Common Stock that may be issued under the 2017 Equity Incentive Plan. The Company filed another preliminary proxy statement seeking stockholder approval to issue up to 66,226,752 shares of our common stock upon the exercise of our warrants issued to investors in the October 2022 Offering that may be equal to or exceed 20% of our common stock outstanding before the October 2022 Underwritten Offering.

### *Nasdaq Notice*

On May 31, 2022, we received a letter (the "Notice") from the Listing Qualifications Department (the "Staff") of the Nasdaq Stock Market ("Nasdaq") informing us that because the closing bid price for our common stock listed on Nasdaq was below \$1.00 for 30 consecutive trading days, we were not in compliance with the minimum bid price requirement for continued listing on the Nasdaq Capital Market, as set forth in Nasdaq Marketplace Rule 5550(a)(2) (the "Minimum Bid Price Requirement").

In accordance with Nasdaq Marketplace Rule 5810(c)(3)(A), the Company has a period of 180 calendar days from May 31, 2022, or until November 28, 2022, to regain compliance with the Minimum Bid Price Requirement. If at any time before November 28, 2022, the closing bid price of the Company's common stock closes at or above \$1.00 per share for a minimum of 10 consecutive trading days (which number of days may be extended by Nasdaq), Nasdaq will provide written notification that the Company has achieved compliance with the Minimum Bid Price Requirement, and the matter would be resolved.

The Notice also disclosed that in the event the Company does not regain compliance with the Minimum Bid Price Requirement by November 28, 2022, the Company may be eligible for additional time to comply. To qualify for additional time, the Company would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for Nasdaq, with the exception of the Minimum Bid Price Requirement, and would need to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. The Company currently intends to make application for this additional remediation period. If the Company meets these requirements, Nasdaq will inform the Company that it has been granted an additional 180 calendar days. However, if it appears to the Staff that the Company will not be able to cure the deficiency, or if the Company is otherwise not eligible, Nasdaq will provide notice that the Company's securities will be subject to delisting.

The Company intends to continue actively monitoring the closing bid price for the Company's common stock between now and November 28, 2022, and it will consider available options to resolve the deficiency and regain compliance with the Minimum Bid Price Requirement. If the Company does not regain compliance within the allotted compliance period, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that the Company's common stock will be subject to delisting. The Company would then be entitled to appeal that determination to a Nasdaq hearings panel. There can be no assurance that the Company will regain compliance with the Minimum Bid Price Requirement during the 180-day compliance period, secure a second period of 180 calendar days to regain compliance, or maintain compliance with the other Nasdaq listing requirements.

#### *Appointment of Lynn L. Blake*

Effective October 19, 2022, Lynn L. Blake was appointed as Chief Financial Officer of the Company. Ms. Blake, age 55, previously served as a Managing Director at Growth Operators Advisory Services LLC since January 2020. Prior to that, she served as the Senior Vice President, Chief Financial Officer of Tactile Systems Technology, Inc. (Nasdaq: TCMD) from 2016 to 2018. Earlier in her career, she served as Senior Vice President, Chief Financial Officer of Taylor-Wharton International LLC and as Senior Vice President, Chief Financial Officer of Analysts International Corporation. Ms. Blake earned her Bachelor of Business Administration degree from the University of Wisconsin-Madison, with majors in Accounting and Finance, and she earned her Master of Business Administration degree from the University of Minnesota, Carlson School of Management, with a dual concentration in Finance and Strategic Management.

### **CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

We have adopted various accounting policies to prepare the condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States (U.S. GAAP). Our most significant accounting policies are disclosed in Note 1 to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2021.

The preparation of the condensed consolidated financial statements, in conformity with U.S. GAAP, requires us to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Our estimates and assumptions, including those related to stock-based compensation, valuation of equity and debt securities, and income tax reserves are updated as appropriate, which in most cases is quarterly. We base our estimates on historical experience, valuations, or various assumptions that are believed to be reasonable under the circumstances. There have been no material changes to our critical accounting policies and estimates from the information provided in Part II, Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations* included in our Annual Report on Form 10-K for the year ended December 31, 2021.

*Revenue Recognition:* We recognize revenue in accordance with Accounting Standards Codification (ASC) Topic 606, *Revenue from Contracts with Customers*. Accordingly, we recognize revenue when our customers obtain control of their products or services, in an amount that reflects the consideration that we expect to receive in exchange for those goods and services. See Note 2 – Revenue Recognition, included in Part I, Item 1 of this Quarterly Report on Form 10-Q, for additional disclosures.

*Accounts Receivable:* Our accounts receivable generally have terms that require payment within 30 days. We did not establish an allowance for doubtful accounts as of September 30, 2022, as we have not experienced any accounts receivable write-offs or experienced a deterioration in the aging of our receivables, and we do not expect to experience write-offs in the future.

*Inventories:* Inventories consist of finished goods, raw materials and subassemblies and are recorded at the lower of cost or net realizable value using the first-in, first-out method.

*Stock-Based Compensation:* We recognize all share-based payments to employees, directors and consultants, including grants of stock options and common stock awards, in the consolidated statement of operations and comprehensive loss as an operating expense based on their fair values as established at the grant date. Other equity instruments issued to non-employees consist of warrants to purchase shares of our common stock. These warrants are either fully vested and exercisable at the date of grant or vest over a certain period during which services are provided.

We compute the estimated fair values of stock options and warrants using the Black-Scholes option pricing model and market-based warrants using a Monte Carlo valuation model. Market price at the date of grant is used to calculate the fair value of any restricted stock units and common stock awards.

We expense the fair market value of fully vested awards at the time of grant, and of unvested awards over the period in which the related services are received. Stock-based compensation expense is based on awards ultimately expected to vest and is reduced for estimated forfeitures except for market-based warrants, which are expensed based on the grant date fair value regardless of whether the award vests. Forfeitures are estimated at the time of grant and revised in subsequent periods if actual forfeitures differ from those estimates.

*Loss per share:* Basic loss per share is computed based on the net loss for each period divided by the weighted average number of common shares outstanding. The net loss allocable to common stockholders for the nine months ended September 30, 2021 includes a deemed dividend of \$33,000 that resulted from the change in the exercise price of warrants as a result of the March 2021 Offering. See Note 3 – Stockholders’ Equity for additional disclosures.

Diluted earnings per share is computed based on the net loss allocable to common stockholders for each period divided by the weighted average number of common shares outstanding, increased by the number of additional shares that would have been outstanding had the potentially dilutive common shares been issued, and reduced by the number of shares the Company could have repurchased from the proceeds from issuance of the potentially dilutive shares. Potentially dilutive shares of common stock include shares underlying outstanding convertible preferred stock, warrants, stock options and other stock-based awards granted under stock-based compensation plans.

*Impairment of Long-Lived Assets:* Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. If the impairment test indicates that the carrying value of the asset or asset group is greater than the expected undiscounted cash flows to be generated by such asset or asset group, further analysis is performed to determine the fair value of the asset or asset group. To the extent the fair value of the asset or asset group is less than its carrying value, an impairment loss is recognized equal to the excess amount of the carrying value over the fair value of the asset or asset group. Assets to be disposed of are carried at the lower of their carrying value or fair value less costs to sell. Considerable management judgment is necessary to estimate the fair value of assets or asset groups and accordingly, actual results could vary significantly from such estimates.

The Company continues to report operating losses and negative cash flows from operations, both of which it considers to be indicators of potential impairment. Therefore, the Company evaluates its long-lived assets for potential impairment at each reporting period. The Company has concluded that its cash flows from the various long-lived assets are highly interrelated and, as a result, the Company consists of a single asset group. As the Company expects to continue incurring losses in the foreseeable future, the undiscounted cash flow step was bypassed, and the Company proceeded to fair value the asset group. The Company has determined the fair value of the asset group using expected cash flows associated with its loaner consoles by considering sales prices for similar assets and by estimating future discounted cash flows expected from the consoles. For recently acquired assets within the asset group, primarily equipment, the Company determined the fair value based on the replacement cost. Because the Company consists of one asset group, consideration is also given to the relationship between the Company’s market capitalization and its carrying value to further support the Company’s determination of fair value. There have been no impairment losses recognized for the year ended December 31, 2021, or the nine months ended September 30, 2022.

*Liquidity:* Our financial statements have been prepared and presented on a basis assuming we continue to operate as a going concern. During the years ended December 31, 2021, and 2020 and through September 30, 2022, we incurred losses from operations and net cash outflows from operating activities as disclosed in the consolidated statements of operations and cash flows, respectively. At September 30, 2022, we had an accumulated deficit of \$265.5 million, and we expect to incur losses for the foreseeable future. To date, we have been funded by equity financings, and although we believe that we will be able to successfully fund our operations, there can be no assurance that we will be able to do so or that we will ever operate profitably.

We became a revenue-generating company after acquiring the Aquadex Business in August 2016. We expect to incur additional losses in the near term as we grow the Aquadex Business, including investments in expanding our sales and marketing capabilities, purchasing inventory, manufacturing components, and complying with the requirements related to being a U.S. public company. To become and remain profitable, we must succeed in expanding the adoption and market acceptance of the Aquadex System. This will require us to succeed in training personnel at hospitals and outpatient care settings and in effectively and efficiently manufacturing, marketing and distributing the Aquadex System and related components. There can be no assurance that we will succeed in these activities, and we may never generate revenues sufficient to achieve profitability.

During 2021, we closed an underwritten public and other equity offerings for aggregate net proceeds of approximately \$27.9 million after deducting the underwriting discounts, commissions and offering expenses, as applicable, and other costs associated with the offerings. In addition, during 2021 we received approximately \$1,300 in proceeds from the exercise of investor warrants. See Note 3 – Stockholders’ Equity, to the condensed consolidated financial statements of this Form 10-Q. The Company also recently closed on the October 2022 Offering. See Note 9 – Subsequent Events. The Company will require additional funding to grow its business, which may not be available on terms favorable to the Company, or at all. The Company may receive those funds from the proceeds from future warrant exercises, issuances of equity securities, or other financing transactions. Should warrant exercises not materialize or future capital raising be unsuccessful, the Company may not be able to continue as a going concern. No adjustments have been made relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company not continue as a going concern.

We believe that our existing capital resources will be sufficient to support our operating plan through December 31, 2023, however, there can be no assurance of this. We may seek to raise additional capital to support our growth or other strategic initiatives through equity.

## NEW ACCOUNTING PRONOUNCEMENTS

During the fiscal quarter ended September 30, 2022, there were no new accounting pronouncements that have been issued, but not yet adopted, that the Company expects will have a material impact on the Company’s consolidated financial position, net loss or cash flows.

## FINANCIAL OVERVIEW

We are a medical device company focused on commercializing the Aquadex system for ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy. Activities since inception have consisted principally of raising capital, performing research and development and conducting pre-clinical and clinical studies. During 2016, we acquired the Aquadex Business and announced that we were halting all clinical evaluations of our prior technology, the C-Pulse System. Since then, our activities have consisted mainly of expanding our sales and marketing capabilities and developing additional clinical evidence in support of our therapy. As of September 30, 2022, we had an accumulated deficit of \$265.6 million, and we expect to incur losses for the foreseeable future. To date, we have been funded by public and private equity financing and debt. Although we believe that we will be able to successfully fund our operations, there can be no assurance that we will be able to do so or that we will ever operate profitably.

## Results of Operations

### Comparison of Three Months Ended September 30, 2022, to Three Months Ended September 30, 2021

#### Net Sales

(in thousands)

Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Increase (Decrease)	% Change
\$ 2,065	\$ 1,853	\$ 212	11.4%

Revenue is generated mainly from the sale of disposable blood filters (“circuits”) and catheters used in conjunction with the Aquadex System consoles, in addition to sales of the consoles themselves. We sell primarily in the United States to hospitals and clinics through our direct salesforce. We sell outside of the United States to independent specialty distributors who in turn sell to hospitals and clinics in their geographic regions. The increase in sales is attributable to an increase in console shipments, partially offset by decreased U.S. circuit sales.

#### Costs and Expenses

Our costs and expenses were as follows:

(in thousands)

	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Increase (Decrease)	% Change
Cost of goods sold	\$ 806	\$ 733	\$ 73	10.0%
Selling, general and administrative	\$ 4,251	\$ 4,645	\$ (394)	(8.5)%
Research and development	\$ 928	\$ 1,726	\$ (798)	(46.2)%

#### Cost of Goods Sold

The increase in cost of goods sold for the three months ended September 30, 2022, compared to the three months ended September 30, 2021, was primarily due to higher fixed overhead absorption because of increased console sales in the quarter.

**Selling, General and Administrative Expense**

The decrease in selling, general and administrative expense primarily reflects the Company's ongoing expense reduction efforts. Selling, general and administrative expenses were also lower due to unfilled positions in the current year quarter.

**Research and Development Expense**

The decrease in R&D expense was primarily driven by timing of expenses associated with investments in new products as well as non-recurring license fee expense of \$428,160 in the prior year quarter.

**Comparison of Nine Months Ended September 30, 2022 to Nine Months Ended September 30, 2021****Net Sales**

(in thousands)

<b>Nine Months Ended September 30, 2022</b>	<b>Nine Months Ended September 30, 2021</b>	<b>Increase (Decrease)</b>	<b>% Change</b>
\$ 6,204	\$ 6,279	\$ (75)	(1.2)%

Revenue is generated mainly from the sale of disposable blood filters ("circuits") and catheters used in conjunction with the Aquadex system consoles, in addition to sales of the consoles themselves. We sell primarily in the United States to hospitals and clinics through our direct salesforce. We sell outside of the United States to independent specialty distributors who in turn sell to hospitals and clinics in their geographic regions. The decrease in sales is attributable to decreased sales of circuits partially offset by increased console sales.

**Costs and Expenses**

Our costs and expenses were as follows:

<i>(in thousands)</i>	<b>Nine Months Ended September 30, 2022</b>	<b>Nine Months Ended September 30, 2021</b>	<b>Increase (Decrease)</b>	<b>% Change</b>
Cost of goods sold	\$ 2,780	\$ 2,682	\$ 98	3.7%
Selling, general and administrative	\$ 12,920	\$ 14,945	\$ (2,025)	(13.5)%
Research and development	\$ 3,141	\$ 3,847	\$ (706)	(18.3)%

**Cost of Goods Sold**

The increase in cost of goods sold for the nine months ended September 30, 2022, compared to the nine months ended September 30, 2021, was primarily due to lower fixed overhead absorption because of decreased sales and finished goods inventory, as well as a \$97,000 inventory write-off resulting from the discontinuation of a distribution agreement.

**Selling, General and Administrative Expense**

The decrease in selling, general and administrative expense primarily reflects the Company's ongoing expense reduction efforts. Selling, general and administrative expenses were also lower due to unfilled positions and non-recurring expenses in the prior year period.

**Research and Development Expense**

The decrease in R&D expense was primarily driven by timing of expenses associated with investments in new products and a non-recurring \$428,160 technology license fee in the prior year period.

**Liquidity and Capital Resources****Sources of Liquidity**

We have funded our operations primarily through cash on hand and a series of equity issuances.

On March 19, 2021, we closed on an underwritten public offering of 3,795,816 shares of common stock, which included the full exercise of the underwriter's over-allotment option, for gross proceeds of approximately \$20.9 million. Net proceeds totaled approximately \$18.9 million after deducting the underwriting discounts and commissions and other costs associated with the offering and after giving effect to the underwriters' full exercise of their over-allotment option.

The offering was comprised of (1) 20,994,044 Class A Units, priced at a public offering price of \$0.25 per Class A Unit, with each Class A Unit consisting of one share of common stock and 1.5 warrants to purchase one share of common stock at an exercise price of \$0.25 per share, and (2) 23,157,124 Class B Units, priced at a public offering price of \$0.25 per Class B Unit, with each Class B Unit consisting of one share of Series I convertible preferred stock, convertible into one share of common stock, and 1.5 warrants to purchase one share of common stock with an exercise price of \$0.25 per share.

The warrants will be exercisable beginning on the effective date of a reverse stock split in an amount sufficient to permit the exercise in full of the warrants, contingent upon stockholder approval of such reverse stock split and of the exercisability of the warrants under Nasdaq rules and will expire on the sixth anniversary of the initial exercise date. The stockholder meetings will be held on or before December 9, 2022. The conversion price of the preferred stock issued in the transaction is fixed and does not contain any variable pricing feature or any price-based anti-dilutive feature. The preferred stock issued in this transaction includes a beneficial ownership blocker but has no dividend rights (except to the extent that dividends are also paid on the common stock) or liquidation preference and, subject to limited exceptions, has no voting rights. The securities comprising the units are immediately separable and were issued separately.

On September 17, 2021, the Company closed on an underwritten public offering of 4,005,588 shares of common stock for gross proceeds of approximately \$10.0 million. Net proceeds totaled approximately \$9.0 million after deducting the underwriting discounts and commissions and other costs associated with the offering and after giving effect to the underwriters' full exercise of their over-allotment option.

As of September 30, 2022 and December 31, 2021, cash and cash equivalents were \$12.1 million and \$24.2 million, respectively. Our business strategy and ability to fund our operations in the future depends in part on our ability to grow the Aquadex Business by expanding our salesforce, selling our products to hospitals, outpatient centers and other healthcare facilities, and controlling costs. While we expect to continue to receive proceeds from the exercise of warrants, we will need to seek additional financing in the future, which, to date, has been through offerings of our equity. The disruption created by COVID-19 in our operations, our sales outlook, and to the capital markets where we would seek such financing has created uncertainty about our ability to access the capital markets in future periods.

On October 18, 2022, the Company closed on the October 2022 Offering for gross proceeds of approximately \$11.0 million. Net proceeds totaled approximately \$9.8 million after deducting the underwriting discounts and commissions and other costs associated with the offering and after giving effect to the underwriters' full exercise of their over-allotment option.

In connection with the October 2022 Offering, the conversion price of the Series F convertible preferred stock was reduced from \$2.50 to \$0.25, the per share price to the public in the October 2022 Offering. In addition, the exercise price of the common stock warrants issued in connection with the January 2020 Offering was reduced from \$2.50 to \$1.65, based on "reset" provisions in the Warrant agreement. See Recent Events.

#### ***Cash Flows from Operating Activities***

Net cash used in operating activities was \$12.0 million and \$13.7 million for the nine months ended September 30, 2022, and 2021, respectively. The net cash used in each of these periods primarily reflects the net loss for those periods, offset in part by non-cash expenses including stock-based compensation, depreciation and amortization and the effects of changes in operating assets and liabilities, including working capital.

#### ***Cash Flows from Investing Activities***

Net cash used in investing activities was \$103,000 and \$191,000 for the nine months ended September 30, 2022, and 2021, respectively. The cash used in investing activities was for the purchase of manufacturing, laboratory and office equipment.

#### ***Cash Flows from Financing Activities***

As described above, net cash (used) provided by financing activities was (\$28,000) and \$27.9 million for the nine months ended September 30, 2022, and 2021, respectively.

#### ***Capital Resource Requirements***

As of September 30, 2022, we did not have any material commitments for capital expenditures.

#### ***Off-Balance Sheet Arrangements***

We have no off-balance sheet transactions, arrangements, obligations (including contingent obligations), or other relationships with unconsolidated entities or other persons that have, or may have, a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

#### ***Forward-Looking Statements and Risk Factors***

Certain statements in this Quarterly Report on Form 10-Q are forward-looking statements within the meaning of the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended ("Exchange Act"), that are based on management's beliefs, assumptions and expectations and information currently available to management. All statements that address future operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation, our expectations regarding the potential impacts of the COVID-19 pandemic on our business operations, cash flow, business development, and employees, our ability to execute on our strategic realignments, 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, the possibility that we may be unable to raise sufficient funds necessary for our anticipated operations, 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. In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. Management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on forward-looking statements because they speak only as of the date when made. We undertake no obligation to revise any forward-looking statements in order to reflect events or circumstances that might subsequently arise. Forward-looking statements are subject to a number of risks and uncertainties that could cause actual events to adversely differ from the expectations indicated in these forward-looking statements, including without limitation, the risks and uncertainties described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, in other reports filed thereafter with the SEC, which risk factors may be updated from time to time, and in this Quarterly Report on Form 10-Q for the quarter ended September 30, 2022. We operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for us to predict all risk factors and uncertainties. We may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including without limitation, the possibility that regulatory authorities do not accept our application or approve the marketing of our products, the possibility we may be unable to raise the funds necessary for the development and commercialization of our products, and those described in our filings with the SEC.

On May 31, 2022, we received the Notice from the Staff of Nasdaq informing us that because the closing bid price for our common stock listed on Nasdaq was below \$1.00 for 30 consecutive trading days, we were not in compliance with the Minimum Bid Price Requirement for continued listing on the Nasdaq Capital Market, as set forth in Nasdaq Marketplace Rule 5550(a)(2).

In accordance with Nasdaq Marketplace Rule 5810(c)(3)(A), the Company has a period of 180 calendar days from May 31, 2022, or until November 28, 2022, to regain compliance with the Minimum Bid Price Requirement. If at any time before November 28, 2022, the closing bid price of the Company's common stock closes at or above \$1.00 per share for a minimum of 10 consecutive trading days (which number of days may be extended by Nasdaq), Nasdaq will provide written notification that the Company has achieved compliance with the Minimum Bid Price Requirement, and the matter would be resolved.

The Notice also disclosed that in the event the Company does not regain compliance with the Minimum Bid Price Requirement by November 28, 2022, the Company may be eligible for additional time to comply. To qualify for additional time, the Company would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for Nasdaq, with the exception of the Minimum Bid Price Requirement, and would need to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. The Company currently intends to make application for this additional remediation period. If the Company meets these requirements, Nasdaq will inform the Company that it has been granted an additional 180 calendar days. However, if it appears to the Staff that the Company will not be able to cure the deficiency, or if the Company is otherwise not eligible, Nasdaq will provide notice that the Company's securities will be subject to delisting.

The Company intends to continue actively monitoring the closing bid price for the Company's common stock between now and November 28, 2022, and it will consider available options to resolve the deficiency and regain compliance with the Minimum Bid Price Requirement. If the Company does not regain compliance within the allotted compliance period, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that the Company's common stock will be subject to delisting. The Company would then be entitled to appeal that determination to a Nasdaq hearings panel. There can be no assurance that the Company will regain compliance with the Minimum Bid Price Requirement during the 180-day compliance period, secure a second period of 180 calendar days to regain compliance, or maintain compliance with the other Nasdaq listing requirements.

If we fail to maintain compliance with the Minimum Bid Price Requirement, or any other of the continued listing requirements of Nasdaq, Nasdaq may take steps to delist our common stock. If such delisting should occur, it would likely have a negative effect on the price of our common stock and would impair an investor's ability to sell or purchase our common stock when desired. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Minimum Bid Price Requirement, or prevent future non-compliance with Nasdaq's listing requirements.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Not applicable.

**ITEM 4. CONTROLS AND PROCEDURES**

**Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Principal Financial Officer (together, the "Certifying Officers"), as appropriate, to allow for timely decisions regarding required disclosure.

In designing and evaluating disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired objectives. Also, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. The design of any system of controls is based, in part, upon certain assumptions about the likelihood of future events and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

As of September 30, 2022, the end of the period covered by this report, we conducted an evaluation, under the supervision and with the participation of management, including the Certifying Officers, of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their stated objectives. Based on their evaluation, our Chief Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2022.

### **Changes in Internal Controls over Financial Reporting**

There were no changes in our internal controls over financial reporting during our most recently completed fiscal quarter that materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

## **PART II—OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

We are not currently subject to any legal proceedings.

### **ITEM 1A. RISK FACTORS**

You should carefully consider the risks and uncertainties we describe in our Annual Report on Form 10-K for the year ended December 31, 2021, in our Quarterly Report on Form 10-Q filed for the quarter ended June 30, 2022, and in other reports filed thereafter with the SEC, before deciding to invest in or retain shares of our common stock. There have been no material changes to the Risk Factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021, except as set forth below.

#### **Risk Related to our Common Stock**

***Nasdaq may delist our common stock from its exchange which could limit your ability to make transactions in our securities and subject us to additional trading restrictions.***

On May 31, 2022, we received the Notice informing us that because the closing bid price for our common stock listed on Nasdaq was below \$1.00 for 30 consecutive trading days, we were not in compliance with the Minimum Bid Price Requirement, as set forth in Nasdaq Marketplace Rule 5550(a)(2).

In accordance with Nasdaq Marketplace Rule 5810(c)(3)(A), the Company has a period of 180 calendar days from May 31, 2022, or until November 28, 2022, to regain compliance with the Minimum Bid Price Requirement. If at any time before November 28, 2022, the closing bid price of the Company's common stock closes at or above \$1.00 per share for a minimum of 10 consecutive trading days (which number of days may be extended by Nasdaq), Nasdaq will provide written notification that the Company has achieved compliance with the Minimum Bid Price Requirement, and the matter would be resolved.

The Notice also disclosed that in the event the Company does not regain compliance with the Minimum Bid Price Requirement by November 28, 2022, the Company may be eligible for additional time to comply. To qualify for additional time, the Company would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for Nasdaq, with the exception of the bid price requirement, and would need to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. The Company currently intends to make application for this additional remediation period. If the Company meets these requirements, Nasdaq will inform the Company that it has been granted an additional 180 calendar days. However, if it appears to the Staff that the Company will not be able to cure the deficiency, or if the Company is otherwise not eligible, Nasdaq will provide notice that the Company's securities will be subject to delisting.

The Company intends to continue actively monitoring the closing bid price for the Company's common stock between now and November 28, 2022, and it will consider available options to resolve the deficiency and regain compliance with the Minimum Bid Price Requirement. If the Company does not regain compliance within the allotted compliance period, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that the Company's common stock will be subject to delisting. The Company would then be entitled to appeal that determination to a Nasdaq hearings panel. There can be no assurance that the Company will regain compliance with the Minimum Bid Price Requirement during the 180-day compliance period, secure a second period of 180 calendar days to regain compliance, or maintain compliance with the other Nasdaq listing requirements.

If our common stock is delisted from Nasdaq, our ability to raise capital through public offerings of our securities and to finance our operations could be adversely affected. We also believe that delisting would likely result in decreased liquidity and/or increased volatility in our common stock and could harm our business and future prospects. In addition, we believe that, if our common stock is delisted, our stockholders would likely find it more difficult to obtain accurate quotations as to the price of the common stock and it may be more difficult for stockholders to buy or sell our common stock at competitive market prices, or at all.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

The exhibits filed as part of this Quarterly Report on Form 10-Q are listed in the Exhibit Index below.

**Exhibit Index**  
**Nuwellis, Inc.**  
**Form 10-Q for the Quarterly Period Ended September 30, 2022**

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing			
<a href="#">3.1</a>	Fourth Amended and Restated Certificate of Incorporation	10	001-35312	February 1, 2012	3.1		
<a href="#">3.2</a>	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	January 13, 2017	3.1		
<a href="#">3.3</a>	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	May 23, 2017	3.1		
<a href="#">3.4</a>	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	October 12, 2017	3.1		
<a href="#">3.5</a>	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K/A	001-35312	October 16, 2020	3.1		
<a href="#">3.6</a>	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	January 2, 2019	3.1		
<a href="#">3.7</a>	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	April 27, 2021	3.1		
<a href="#">3.8</a>	Form of Certificate of Designation of Series A Junior Participating Preferred Stock	8-K	001-35312	June 14, 2013	3.1		
<a href="#">3.9</a>	Form of Certificate of Designation of Preferences, Rights and Limitations of Series F Convertible Preferred Stock	S-1/A	333-221010	November 17, 2017	3.7		
<a href="#">3.10</a>	Certificate of Designation of Preferences, Rights and Limitations of Series G Convertible Preferred Stock	8-K	001-35312	March 13, 2019	3.1		
<a href="#">3.11</a>	Certificate of Designation of Preferences, Rights and Limitations of Series H Convertible Preferred Stock	8-K	001-35312	January 29, 2020	3.1		
<a href="#">3.12</a>	Certificate of Designation of Preferences, Rights and Limitations of Series I Convertible Preferred Stock.	8-K	001-35312	October 18, 2022	3.1		
<a href="#">3.13</a>	Second Amended and Restated Bylaws	8-K	001-35312	April 27, 2021	3.2		

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing			
<a href="#">3.14</a>	Amendment to Second Amended and Restated Bylaws	8-K	001-35312	October 5, 2022	3.1		
<a href="#">4.1</a>	Form of Warrant to Purchase Shares of Common Stock	S-1/A	333-267368	October 13, 2022	4.20		
<a href="#">10.1</a>	Offer Letter by and between Nuwellis, Inc. and Lynn Blake, effective as of October 24, 2022	8-K	001-35312	October 5, 2022	10.1		
<a href="#">10.2</a>	Underwriting Agreement dated as of October 14, 2022, by and between Nuwellis, Inc. and Ladenburg Thalmann & Co. Inc.	8-K	001-35312	October 18, 2022	1.1		
<a href="#">10.3</a>	Warrant Agency Agreement	8-K	001-35312	October 18, 2022	4.2		
<a href="#">10.4</a>	Leak-Out Agreement	S-1/A	333-267368	September 30, 2022	10.70		
<a href="#">31.1</a>	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X	
<a href="#">31.2</a>	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X	
<a href="#">32.1</a>	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002						X
<a href="#">32.2</a>	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002						X
101.INS	Inline XBRL Instance Document					X	
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X	
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X	
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X	
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X	
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X	
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					X	

## 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 thereunto duly authorized.

Nuwellis, Inc.

Date: November 8, 2022

By: /s/ Nestor Jaramillo, Jr.  
Nestor Jaramillo, Jr.  
Chief Executive Officer

Date: November 8, 2022

By: /s/ Lynn L. Blake  
Lynn L. Blake  
Chief Financial Officer

## CHIEF EXECUTIVE OFFICER'S 302 CERTIFICATION

I, Nestor Jaramillo, Jr. certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Nuwellis, Inc. for the quarterly period ended September 30, 2022;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2022

/s/ Nestor Jaramillo, Jr.  
Nestor Jaramillo, Jr.  
Chief Executive Officer

## CHIEF FINANCIAL OFFICER'S 302 CERTIFICATION

I, Lynn L. Blake, certify that:

I have reviewed this Quarterly Report on Form 10-Q of Nuwellis, Inc. for the quarterly period ended September 30, 2022;

Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2022

/s/ Lynn L. Blake  
Lynn L. Blake  
Chief Financial Officer

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**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Nuwellis, Inc. (the "**Company**") on Form 10-Q for the quarterly period ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "**Report**"), I, Nestor Jaramillo, Jr., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 8, 2022

/s/ Nestor Jaramillo, Jr.  
Nestor Jaramillo, Jr.  
Chief Executive Officer

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**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Nuwellis, Inc. (the "**Company**") on Form 10-Q for the quarterly period ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "**Report**"), I, Lynn L. Blake, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 8, 2022

/s/ Lynn L. Blake  
Lynn L. Blake  
Chief Financial Officer

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