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 **March 31, 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	**No. 68-0533453**
(State or Other Jurisdiction of Incorporation or Organization)	**(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 ☐	Accelerated filer ☐
Non-accelerated Filer ☒	Smaller reporting company ☒
Emerging growth company ☐	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 May 6, 2022 was 10,537,606

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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)

	March 31, 2022 (unaudited)	December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	$ 19,300	$ 24,205
Accounts receivable	951	750
Inventories	3,294	2,843
Other current assets	350	328
Total current assets	**23,895**	**28,126**
Property, plant and equipment, net	1,153	1,188
Operating lease right-of-use asset	1,038	1,082
Other assets	21	21
TOTAL ASSETS	**$ 26,107**	**$ 30,417**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,797	$ 1,414
Accrued compensation	1,335	1,664
Current portion of operating lease liability	181	167
Current portion of finance lease liability	24	26
Other current liabilities	55	36
Total current liabilities	3,392	**3,307**
Operating lease liability	909	956
Finance lease liability	22	28
Other long-term liability	71	179
Total liabilities	**4,394**	**4,470**
Commitments and contingencies		
Stockholders' equity		
Series A junior participating preferred stock as of March 31, 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 March 31, 2022 and December 31, 2021, par value $0.0001 per share; authorized 127 shares, issued and outstanding 127 shares	—	—
Preferred stock as of both March 31, 2022 and December 31, 2021, par value $0.0001 per share; authorized 39,969,873 shares, none outstanding	—	—
Common stock as of March 31, 2022 and December 31, 2021, par value $0.0001 per share; authorized 100,000,000 shares, issued and outstanding 10,537,606 shares	1	1
Additional paid-in capital	279,114	278,873
Accumulated other comprehensive income:		
Foreign currency translation adjustment	(13)	(11)
Accumulated deficit	(257,389)	(252,916)
Total stockholders' equity	**21,713**	**25,947**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 26,107**	**$ 30,417**

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 March 31, 2022	Three months ended March 31, 2021
Net sales	$ 1,926	$ 1,918
Cost of goods sold	824	952
Gross profit	1,102	966
Operating expenses:		
Selling, general and administrative	4,412	5,237
Research and development	1,106	947
Total operating expenses	5,518	6,184
Loss from operations	(4,416)	(5,218)
Other income (expense), net	(55)	(1)
Loss before income taxes	(4,471)	(5,219)
Income tax expense	(2)	(2)
Net loss	$ (4,473)	$ (5,221)
Basic and diluted loss per share	$ (0.42)	$ (1.62)
Weighted average shares outstanding – basic and diluted	10,538	3,242
Other comprehensive loss:		
Unrealized foreign currency translation adjustments	$ (2)	$ (3)
Total comprehensive loss	$ (4,475)	$ (5,224)

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
Balance December 31, 2020	**2,736,060**	**$ —**	**$ 249,663**	**$ (7)**	**$ (233,338)**	**$ 16,318**
Net loss	—	—	—	—	(5,221)	(5,221)
Unrealized 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
Balance March 31, 2021	**6,531,942**	**$ —**	**$ 268,921**	**$ (10)**	**$ (238,559)**	**$ 30,352**

	Outstanding Shares of Common Stock	Common Stock	Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Equity
Balance December 31, 2021	**10,537,606**	**$ 1**	**$ 278,873**	**$ (11)**	**$ (252,916)**	**$ 25,947**
Net loss	—	—	—	—	(4,473)	(4,473)
Unrealized foreign currency translation adjustment	—	—	—	(2)	—	(2)
Stock-based compensation, net	—	—	241	—	—	241
Balance March 31, 2022	**10,537,606**	$ 1	**$ 279,114**	**$ (13)**	**$ (257,389)**	**$ 21,713**

See notes to the condensed consolidated financial statements

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

	Three months ended March 31, 2022	Three months ended March 31, 2021
Operating Activities:		
Net loss	$ (4,473)	$ (5,221)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	105	126
Stock-based compensation expense, net	241	355
Changes in operating assets and liabilities:		
Accounts receivable	(201)	(14)
Inventory	(451)	(89)
Other current assets	(22)	(132)
Other assets and liabilities	(80)	24
Accounts payable and accrued expenses	54	(431)
Net cash used in operating activities	**(4,827)**	**(5,382)**
Investing Activities:		
Purchases of property and equipment	(70)	(56)
Net cash used in investing activities	**(70)**	**(56)**
Financing Activities:		
Proceeds from public stock offerings, net	—	18,902
Proceeds from warrant exercises	—	1
Payments on finance lease liability	(6)	(6)
Net cash provided (used in) by financing activities	**(6)**	**18,897**
Effect of exchange rate changes on cash	(2)	(3)
Net increase (decrease) in cash and cash equivalents	(4,905)	13,456
Cash and cash equivalents - beginning of period	24,205	14,437
Cash and cash equivalents - end of period	**$ 19,300**	**$ 27,893**
Supplemental cash flow information		
Inventory transferred to property, plant and equipment	$ —	$ 89

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 20kg 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 Capital 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 December 31, 2021, which has been derived from the consolidated audited financial statements and the unaudited condensed consolidated financial statements have 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 materially differ 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 March 31, 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 March 31, 2022, the Company had an accumulated deficit of $257.4 million and it expects to incur losses for 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 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 and through March 31, 2022, 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.

The Company believes that its existing capital resources will be sufficient to support its operating plan through June 30, 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 we 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, which the Company adopted effective January 1, 2018. 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 March 31, 2022, two customers represented 14% and 10% of net sales. For the three months ended March 31, 2021, three customers represented 16%, 13% and 12% 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 managements' 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 March 31, 2022, or December 31, 2021. As of March 31, 2022, one customer represented 13% 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)	**March 31, 2022**	**December 31, 2021**
Finished Goods	$ 1,331	$ 1,409
Work in Process	313	276
Raw Materials	1,650	1,158
Total	$ 3,294	$ 2,843

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 three months ended March 31, 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:

	March 31	
	2022	**2021**
Stock options	1,174,748	140,471
Warrants to purchase common stock	1,631,698	1,631,882
Series F convertible preferred stock	50,800	23,114
Total	2,857,246	1,795,467

The following table reconciles reported net loss with reported net loss per share for each of the three months ended March 31:

(in thousands, except per share amounts)	2022	2021
Net loss	$ (4,473)	$ (5,221)
Deemed dividend to preferred shareholders (see Note 3)	—	(33)
Net loss after deemed dividend	(4,473)	(5,254)
Weighted average shares outstanding	10,538	3,242
Basic and diluted loss per share	$ (0.42)	$ (1.62)

Subsequent events: The Company evaluates events through the date the consolidated financial statements are filed for events requiring adjustment to or disclosure in the 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, 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 months ended March 31, 2022, and 2021. The unfulfilled performance obligations related to these extended service plans is 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 March 31, 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 overallotment 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 overallotment 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 March 31, 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:

	Three-months ended March 31,	
(in thousands)	**2022**	**2021**
Selling, general and administrative expense	$ 214	$ 327
Research and development expense	27	28
Total stock-based compensation expense	**$ 241**	**$ 355**

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 the 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 March 31, 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)-profit sharing 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 $356,800 included in Current Accounts Payable and $71,360 included in Other Long-term Liabilities. The full amount of $428,160 was expensed and included in the Research and Development Expense line for the year ended December 31, 2021.

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, 2021and 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 changing 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 20kg 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. 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 pediatrics applications.

Impact of COVID-19 Pandemic

During 2021 and the first 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 in 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 effect on our vendors, 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, difficulties or changes to our sales process and customer support.

Several hospitals in the U.S. initially included the Aquadex System into their treatment protocol for fluid management of COVID-19, especially when dialysis equipment and staff were limited, but treatment regimens subsequently evolved so that the need to restore fluid balance became less prevalent. However, we have also seen 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 or guidance 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.

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 receivables generally have terms that require payment within 30 days. We did not establish an allowance for doubtful accounts as of March 31, 2022, as we have not had any write offs or experienced a deterioration in the aging of our receivables, and do not expect to experience 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, if necessary, 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 three months ended March 31, 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.

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 tests indicate 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 amount the fair value of the asset or asset group is exceeded by its carrying amount. 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 three months ended March 31, 2022.

Going Concern: Our financial statements have been prepared and presented on a basis assuming we continue as a going concern. During the years ended December 31, 2021, and 2020 and through March 31, 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 March 31, 2022, we had an accumulated deficit of $257.4 million and we expect to incur losses for the foreseeable future. To date, we have been funded by debt and 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 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 and through March 31, 2022, we closed on 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 2021we received approximately $1,300 in proceeds from the exercise of investor warrants. See Note 4 –Stockholders' Equity, to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K. 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.

We believe that our existing capital resources will be sufficient to support our operating plan through June 30, 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 debt, equity or a combination thereof.

NEW ACCOUNTING PRONOUNCEMENTS

During the fiscal quarter ended March 31, 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 preclinical 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 transferring manufacturing capabilities from Baxter to our facilities in Eden Prairie, Minnesota. As of March 31, 2022, we had an accumulated deficit of $257.4 million and we expect to incur losses for the foreseeable future. To date, we have been funded by public and private equity financings 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 March 31, 2022, to Three Months Ended March 31, 2021

Net Sales
(in thousands)

Three Months Ended March 31, 2022	Three Months Ended March 31, 2021	Increase (Decrease)	% Change
$ 1,926	$ 1,918	$ 8	0.4%

Revenue is generated mainly from the sale of disposable blood filters and catheters used in conjunction with the Aquadex System consoles. 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 slight increase in sales is due to increased utilization and order timing.

Costs and Expenses
Our costs and expenses were as follows:

(in thousands)	Three Months Ended March 31, 2022	Three Months Ended March 31, 2021	Increase (Decrease)	% Change
Cost of goods sold	$ 824	$ 952	$ (128)	(13.4)%
Selling, general and administrative	$ 4,412	$ 5,237	$ (825)	(15.8)%
Research and development	$ 1,106	$ 947	$ 159	16.8%

Cost of Goods Sold
The increase in gross margin percent for the three months ended March 31, 2022, compared to the three months ended March 31, 2021, was due primarily to favorable product mix and reduced inventory revaluation expense.

Selling, General and Administrative
The decrease in selling, general and administrative expense primarily reflects the Company's on-going effort to optimize costs. General and administrative expenses were also lower due to nonrecurring prior-period costs.

Research and Development
The increase in R&D expenses was primarily driven by investments in new products, along with increased regulatory activity.

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 includes 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 overallotment option.

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 overallotment option.

As of March 31, 2022 and December 31, 2021, cash and cash equivalents were $19.3 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 establishing a sales force, selling our products to hospitals and other healthcare facilities, and controlling costs. While we expect to continue to receive proceeds from the exercise of warrants, we will likely 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 the capital markets where we would seek such financing, have created uncertainty about our ability to access the capital markets in future periods.

Cash Flows from Operating Activities

Net cash used in operating activities was $4.8 million and $5.4 million for the three months ended March 31, 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 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 $70,000 and $56,000 for the three months ended March 31, 2022, and March 31, 2021, respectively. The cash used in investing activities was for the purchase of manufacturing, laboratory and office equipment.

Cash Flows from (used in) Financing Activities

As described above, net cash provided by financing activities was ($6,000) and $18.9 million for the three months ended March 31, 2022, and 2021, respectively.

Capital Resource Requirements

As of March 31, 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 by updated from time to time, and in this Quarterly Report on Form 10-Q for the quarter ended March 31, 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.

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 March 31, 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 March 31, 2022.

Changes in Internal Controls over Financial Reporting

There was no change in our internal control over financial reporting during our most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control 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, 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.

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 March 31, 2022

		Incorporated By Reference					
Exhibit Number	Exhibit Description	Form	File Number	Date of First Filing	Exhibit Number	Filed Herewith	Furnished Herewith
3.1	Fourth Amended and Restated Certificate of Incorporation	10	001-35312	February 1, 2012	3.1		
3.2	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	January 13, 2017	3.1		
3.3	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	May 23, 2017	3.1		
3.4	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	October 12, 2017	3.1		
3.6	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K/A	001-35312	October 16, 2020	3.1		
3.7	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	January 2, 2019	3.1		
3.8	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	April 27, 2021	3.1		
3.9	Form of Certificate of Designation of Series A Junior Participating Preferred Stock	8-K	001-35312	June 14, 2013	3.1		
3.10	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		
3.11	Certificate of Designation of Preferences, Rights and Limitations of Series G Convertible Preferred Stock	8-K	001-35312	March 13, 2019	3.1		
3.12	Certificate of Designation of Preferences, Rights and Limitations of Series H Convertible Preferred Stock	8-K	001-35312	January 29, 2020	3.1		
3.13	Third Amended and Restated Bylaws	8-K	001-35312	April 27, 2021	3.2		
10.1	First Amendment to the 2021 Inducement Plan	8-K	001-35312	April 21, 2022	10.1		

Exhibit Number	Exhibit Description	Incorporated By Reference Form	File Number	Date of First Filing	Exhibit Number	Filed Herewith	Furnished Herewith
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X	
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X	
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002						X
32.2	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: May 12, 2022	By:	/s/ Nestor Jaramillo, Jr.
		Nestor Jaramillo, Jr. Chief Executive Officer
Date: May 12, 2022	By:	/s/ George Montague
		George Montague Chief Financial Officer

Exhibit 31.1

CHIEF EXECUTIVE OFFICER'S 302 CERTIFICATION

I, Nestor Jaramillo, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Nuwellis, Inc. for the quarterly period ended March 31, 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:

   a) 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;

   b) 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;

   c) 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

   d) 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):

   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: May 12, 2022

/s/ Nestor Jaramillo
Nestor Jaramillo
Chief Executive Officer

Exhibit 31.2

CHIEF FINANCIAL OFFICER'S 302 CERTIFICATION

I, George Montague, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Nuwellis, Inc. for the quarterly period ended March 31, 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:

    a) 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;

    b) 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;

    c) 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

    d) 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):

    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: May 12, 2022

/s/ George Montague
George Montague
Chief Financial Officer

Exhibit 32.1

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 March 31, 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: May 12, 2022

/s/ Nestor Jaramillo
Nestor Jaramillo
Chief Executive Officer

Exhibit 32.2

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 March 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the ***"Report"***), I, George Montague, 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: May 12, 2022

/s/ George Montague
George Montague
Chief Financial Officer