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 June 30, 2021
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 August 6, 2021 was 6,532,018.

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ITEM 1. FINANCIAL STATEMENTS
NUWELLIS, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

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

See notes to the condensed consolidated financial statements.

NUWELLIS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except per share amounts)

	Three months ended June 30, 2021	Three months ended June 30, 2020	Six months ended June 30, 2021	Six months ended June 30, 2020
Net sales	$ 2,508	$ 1,863	$ 4,426	$ 3,493
Cost of goods sold	997	664	1,949	1,460
Gross profit	1,511	1,199	2,477	2,033
Operating expenses:				
Selling, general and administrative	5,063	4,234	10,300	8,770
Research and development	1,174	885	2,121	1,749
Total operating expenses	6,237	5,119	12,421	10,519
Loss from operations	(4,726)	(3,920)	(9,944)	(8,486)
Other income (expense), net	(2)	—	(3)	—
Loss before income taxes	(4,728)	(3,920)	(9,947)	(8,486)
Income tax expense	(3)	(2)	(5)	(4)
Net loss	$ (4,731)	$ (3,922)	$ (9,952)	$ (8,490)
Basic and diluted loss per share	$ (0.72)	$ (3.10)	$ (2.04)	$ (11.31)
Weighted average shares outstanding – basic and diluted	6,532	1,264	4,887	906
Other comprehensive loss:				
Foreign currency translation adjustments	$ —	$ (2)	$ (3)	$ (5)
Total comprehensive loss	$ (4,731)	$ (3,924)	$ (9,955)	$ (8,495)

See notes to the condensed consolidated financial statements.

NUWELLIS, INC. AND SUBSIDIARIES
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, 2019	**155,802**	**$ —**	**$ 218,278**	**$ 1,214**	**$ (217,502)**	**$ 1,990**
Net loss	—	—	—	—	(4,568)	(4,568)
Foreign currency translation adjustment	—	—	—	(3)	—	(3)
Stock-based compensation, net	—	—	380	—	—	380
Issuance of common and preferred stock, net	340,261	—	9,616	—	—	9,616
Exercise of warrants	29,933	—	289	—	—	289
Conversion of preferred stock into common stock	378,751	—	—	—	—	—
Balance March 31, 2020	**904,747**	**$ —**	**$ 228,563**	**$ 1,211**	**$ (222,070)**	**$ 7,704**
Net loss	—	—	—	—	(3,922)	(3,922)
Foreign currency translation adjustment	—	—	—	(2)	—	(2)
Stock-based compensation, net	—	—	347	—	—	347
Issuance of common stock, net	290,938	—	3,424	—	—	3,424
Exercise of warrants	227,939	—	2,051	—	—	2,051
Conversion of preferred stock into common stock	16,270	—	—	—	—	—
Balance June 30, 2020	**1,439,894**	**$ —**	**$ 234,385**	**$ 1,209**	**$ (225,992)**	**$ 9,602**

	Outstanding Shares of Common Stock	Common Stock	Additional Paid in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Stockholders' Equity
Balance December 31, 2020	**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 stock, 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**
Net loss	—	—	—	—	(4,731)	(4,731)
Foreign currency translation adjustment	—	—	—	—	—	—
Stock-based compensation, net	—	—	381	—	—	381
Issuance costs related to common stock offerings	—	—	(6)	—	—	(6)
Exercise of warrants	76	—	—	—	—	—
Balance June 30, 2021	**6,532,018**	**$ —**	**$ 269,296**	**$ (10)**	**$ (243,290)**	**$ 25,996**

See notes to the condensed consolidated financial statements

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

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

See notes to the condensed consolidated financial statements.

NUWELLIS, INC. AND SUBSIDIARIES
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., 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 more appropriately reflect the direction of its business.

Principles of Consolidation: The accompanying 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 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 financial statements and during the reporting period. Actual results could materially differ from these estimates.

For further information, refer to the consolidated financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2020.

Going Concern: The Company’s financial statements have been prepared and presented on a basis assuming it continues as a going concern. During the years ended December 31, 2020 and 2019 and through June 30, 2021, 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 June 30, 2021, the Company had an accumulated deficit of $243.3 million and it expects to incur losses for the immediate future. To date, the Company has been funded by debt and 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 effectively training personnel at hospitals 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 2019, 2020 and through March 19, 2021, the Company closed on underwritten public equity offerings for aggregate net proceeds of approximately $57.6 million after deducting the underwriting discounts and commissions and other costs associated with the offerings (see Note 3 –Stockholders’ Equity). The Company will require additional funding to grow the 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 December 31, 2022. However, the Company may seek to raise additional capital to support its growth or other strategic initiatives through debt, equity or a combination thereof.

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 June 30, 2021, no customer represented over 10% of net sales. For the six months ended June 30, 2021, two customers each represented 11% of net sales. For the three months ended June 30, 2020, one customer represented 10% of net sales. For the six months ended June 30, 2020, two customers each represented 10% 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 June 30, 2021 or December 31, 2020. As of June 30, 2021, one customer represented 12% of the accounts receivable balance. As of December 31, 2020, no customer represented over 10% of the accounts receivable balance.

Inventories: Inventories represent finished goods purchased from the Company's supplier 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)	June 30, 2021	December 31, 2020
Finished Goods	$ 1,304	$ 1,343
Work in Process	199	342
Raw Materials	1,153	1,272
Total	$ 2,656	$ 2,957

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 six months ended June 30, 2020, reflects a $1.8 million increase for the net deemed dividend to preferred stockholders provided in connection with the close of the public offering of Series H Convertible Preferred Stock on January 28, 2020. The deemed dividends represent the intrinsic value of the preferred shares at the time of issuance and includes $0.2 million that resulted from the subsequent change in the exercise price of the warrants as a result of the March 2020 offering. See Note 3 – Stockholders' Equity below for additional disclosures. The net loss allocable to common stockholders for the six months ended June 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.

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:

	June 30	
	2021	2020
Warrants to purchase common stock	1,631,806	764,525
Series F convertible preferred stock	23,114	48,720
Stock options	812,561	17,534
Total	2,467,481	830,779

The following table reconciles reported net loss with reported net loss per share for each of the six months ended June 30:

(in thousands, except per share amounts)	2021	2020
Net loss	$ (9,952)	$ (8,490)
Deemed dividend to preferred shareholders (see Note 3)	(33)	(1,757)
Net loss after deemed dividend	(9,985)	(10,247)
Weighted average shares outstanding	4,887	906
Basic and diluted loss per share	$ (2.04)	$ (11.31)

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, Germany, Greece, Hong Kong, India, Israel, Italy, Romania, Singapore, 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 are 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 which are recognized over time. This revenue represents less than 1% of net sales for the three and six months ended June 30, 2021 and 2020. 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 was to expire 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, described below. Effective October 25, 2019, the conversion price of the Series F convertible preferred stock was reduced from $157.50 to $42.30, and 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, described below. 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 offering, described below. 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, described below.

As of June 30, 2021, and December 31, 2020, 127 shares of the Series F convertible preferred stock remained outstanding.

Series G Convertible Preferred Stock and March 2019 Offering: On March 12, 2019, the Company closed on an underwritten public offering of common stock, Series G convertible preferred stock and warrants to purchase shares of common stock for gross proceeds of $12.4 million (“March 2019 Offering”). Net proceeds totaled approximately $11.0 million after deducting the underwriting discounts and commissions and other costs associated with the offering. The Series G convertible preferred stock included a beneficial conversion amount of $4.5 million, representing the intrinsic value of the shares at the time of issuance. This amount was reflected as an increase to the loss per share allocable to common stockholders in the year ended December 31, 2019.

The March 2019 Offering was comprised of 15,173 shares of common stock priced at $157.50 per share and 1,910,536 shares of Series G convertible preferred stock, convertible into common stock at $157.50 per share. Each share of Series G convertible preferred stock and each share of common stock was accompanied by a Series 1 warrant and a Series 2 warrant. The Series 1 warrants are exercisable into 78,863 shares of common stock and the Series 2 warrants are exercisable into 78,863 shares of common stock. Series 1 warrants expire on the fifth anniversary of the date of issuance and are exercisable at $157.50 to purchase one share of common stock. Series 2 warrants expire on the earlier of: (i) the eighteen-month anniversary of the date of issuance and (ii) the 30th trading day following the public announcement of the receipt from the U.S. Food and Drug Administration (FDA) of clearance or approval of a modification to the product label for the Aquadex System to include pediatric patients. Series 2 warrants are exercisable at $157.50 per share of common stock. The Company announced it had received FDA clearance for use of its Aquadex System in pediatric patients on February 26, 2020, effectively setting the date of expiration of these warrants for April 8, 2020. The conversion price of the Series G convertible preferred stock as well as the exercise price of the warrants are fixed and do not contain any variable pricing features, nor any price based anti-dilutive features apart from customary adjustments for splits and reverse splits of common stock. The Series G convertible preferred stock included a beneficial ownership limitation of 4.99% but had no dividend preference (except to extent dividends are also paid on the common stock), liquidation preference or other preferences over common stock. The securities comprising the units were immediately separable and were issued separately.

As of December 31, 2019, all 63,685 shares of the Series G convertible preferred stock had been converted into common stock and none remained outstanding.

October and November 2019 Offerings: On October 25, 2019, the Company closed on a registered direct offering of 19,195 shares of common stock at a price of $34.50 per share, for gross proceeds of approximately $660,000, prior to deducting commissions and expenses related to the transaction. In a concurrent private placement, the Company agreed to issue to the investors in the registered direct offering unregistered warrants to purchase up to 19,196 shares of its common stock at an exercise price of $42.30 per share, which became exercisable six months from the date of issuance and will expire five years from the initial exercise date. On November 6, 2019, the Company closed on a registered direct offering of 40,637 shares of common stock, or common equivalents, at a price of $33.60 per share, for gross proceeds of approximately $1.36 million prior to deduction of commissions and offering expenses related to the transaction. In a concurrent private placement, the Company agreed to issue to the investors in the registered direct offering warrants to purchase up to 40,638 shares of our common stock at an exercise price of $29.83 per share, which were exercisable upon the date of issuance, and will expire five years from the initial exercise date.

Series H Convertible Preferred Stock and January 2020 Offering: On January 28, 2020, the Company closed on an underwritten public offering of common stock, Series H convertible preferred stock and warrants to purchase shares of common stock for gross proceeds of $9.7 million ("January 2020 Offering"). Net proceeds totaled approximately $8.6 million after deducting the underwriting discounts and commissions and other costs associated with the offering. The Series H convertible preferred stock included a beneficial conversion amount of $1.6 million, representing the intrinsic value of the shares at the time of issuance, and $0.2 million of down-round protection in connection with the re-pricing of the warrants following the March 2020 offering described below. This amount is reflected as an increase to the loss per share allocable to common stockholders in the six months ended June 30, 2020.

The January 2020 Offering was comprised of 201,546 shares of common stock priced at $16.50 per share and 11,517,269 shares of Series H convertible preferred stock, convertible into common stock at $16.50 per share. Each share of Series H convertible preferred stock and each share of common stock was accompanied by a warrant to purchase common stock. The warrants are exercisable into 585,460 shares of common stock. 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. The warrants were exercisable beginning on the closing date and expire on the fifth anniversary of the closing date and had an initial exercise price per share equal to $16.50 per share, subject to appropriate adjustment in the event of subsequent equity sales of common stock or securities convertible into common stock for an exercise price per share less than the exercise price per share of the warrants then in effect (but in no event lower than 10% of the applicable Unit offering price), or in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock. Effective March 23, 2020, the exercise price of these warrants was reduced from $16.50 to $9.00, the per share price to the public in the March 2020 offering described below. Effective with the March 19, 2021 financing, the exercise price for the unexercised warrants from the January 2020 offering were further reduced to $5.50 per share. The net loss allocable to common stockholders for the six months ended June 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.

As of December 31, 2020, all 11,517,269 shares of the Series H convertible preferred stock had been converted into common stock and none remained outstanding. As of June 30, 2021, warrants to purchase 130,170 shares of common stock remain exercisable.

March 2020 Offering: On March 23, 2020, the Company closed on a registered direct offering of 138,715 shares of its common stock at a price to the public of $9.00 per share, for gross proceeds of approximately $1.2 million, or $1.0 million net after deducting commissions and offering expenses. In a concurrent private placement, the Company agreed to issue to the investors in the registered direct offering warrants to purchase up to 138,715 shares of the Company's common stock. The warrants to purchase up to 138,715 shares of common stock have an exercise price of $11.18 per share, were exercisable six months from the date of issuance, and will expire five and a half years from the date of issuance.

April 2020 Offering: On April 1, 2020, the Company closed on a registered direct offering of 171,008 shares of its common stock at a price to the public of $13.02 per share, for gross proceeds of approximately $2.2 million, prior to deduction of commissions and offering expenses related to the transaction. In a concurrent private placement, the Company agreed to issue to the investors in the registered direct offering warrants to purchase up to 85,506 shares of the Company's common stock. The warrants have an exercise price of $11.15 per share, were exercisable immediately, and will expire five and a half years from the date of issuance.

May 2020 Offering: On May 5, 2020, the Company closed on a registered direct offering of 119,930 shares of its common stock at a price to the public of $14.18 per share, for gross proceeds of approximately $1.7 million, prior to deduction of commissions and offering expenses related to the transaction. In a concurrent private placement, the Company agreed to issue to the investors in the registered direct offering warrants to purchase up to 59,966 shares of the Company's common stock. The warrants have an exercise price of $12.30 per share, were exercisable immediately, and will expire five and a half years from the date of issuance.

August 2020 Offering: On August 21, 2020, the Company closed on an underwritten public offering of common stock and warrants to purchase shares of common stock for gross proceeds of approximately $14.4 million ("August 2020 Offering"). Net proceeds totaled approximately $13.0 million after deducting the underwriting discounts and commissions and other costs associated with the offering. The August 2020 Offering was comprised of 1,064,678 shares of common stock priced at $13.50 per share. Each share of common stock was accompanied by a warrant to purchase common stock. The warrants are exercisable into 1,064,678 shares of common stock. The securities comprising the units are immediately separable and were issued separately. The warrants were exercisable beginning on the effective date of our stockholders' approval of a reverse stock split in an amount sufficient to permit the exercise in full of the warrants, which occurred on October 6, 2020, and will expire on the five-year anniversary of the closing date.

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.

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 June 30, 2021.

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 June 30,		Six months ended June 30,	
(in thousands)	**2021**	**2020**	**2021**	**2020**
Selling, general and administrative expense	$ 350	$ 321	$ 677	$ 675
Research and development expense	31	26	59	52
Total stock-based compensation expense	**$ 381**	**$ 347**	**$ 736**	**$ 727**

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 June 30, 2021, 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, 2020.

Note 6—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 7—Commitments and Contingencies

Employee Retirement Plan: The Company has a 401(k)-profit sharing plan that provides retirement benefit 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 employee's contributions at the discretion of the Company.

Note 8—Subsequent Events

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 will pay KBT a non-refundable technology license fee of $428,160, payable in twelve equal monthly installments commencing in June 2022.

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, 2020. 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, 2020 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 subsidiaries.

OVERVIEW

About Nuwellis

We are 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 delivers clinically proven therapy using a simple, flexible and smart method of removing excess fluid from patients suffering from hypervolemia (fluid overload). The Aquadex SmartFlow system is indicated for temporary (up to 8 hours) or extended (longer than 8 hours in patients who require hospitalization) use in adult and pediatric patients weighing 20 kg or more whose fluid overload is unresponsive to medical management, including diuretics.

Previously, the Company was focused on developing the C-Pulse® Heart Assist System for treatment of Class III and ambulatory Class IV heart failure. 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.

Impact of COVID-19 Pandemic

During the first six months of 2021, 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, and the resulting coronavirus disease 2019 ("COVID-19") pandemic. The COVID-19 pandemic continues to affect our operations and has required us to continue the changes that were made to keep our customers, their patients, and our employees safe. These changes continue to include 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 employee work practices by continuing to allow employees to work remotely and increased protocols to ensure the safety of those employees who are required to work on site. The ongoing impact of the COVID-19 pandemic 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, and difficulties or changes to our sales process and customer support.

Several hospitals in the U.S. have included the Aquadex System into their treatment protocol for fluid management of COVID-19, especially when dialysis equipment and staff are limited. In March 2020, we increased production of the Aquadex System to meet anticipated demand due to its use in treatment protocols for COVID-19. We estimate that approximately 14% of our U.S. revenue for the year ended December 31, 2020, was driven by hospitals treating patients with COVID-19, but as intensive care patients have declined due to the drop in the infection rate, we have seen little revenue in the six months ended June 30, 2021 for treating patients with COVID-19. 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 Quarterly Report on Form 10-Q, the extent to which the COVID-19 pandemic 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.

Recent Developments

Departure of Claudia Drayton and Appointment of Paul Wotta

On April 1, 2021, Claudia Drayton notified the Company of her decision to resign as the Company’s Chief Financial Officer. On April 5, 2021, the Board of Directors of the Company (the “Board”) appointed Nestor Jaramillo, Jr., the Company’s current President and Chief Executive Officer, as the Company’s interim Chief Financial Officer, and Paul Wotta, the Company’s Corporate Controller, as the Company’s interim Principal Accounting Officer. Mr. Jaramillo has served as the Company’s President and Chief Executive Officer since January 2021. Mr. Wotta has served as the Company’s Corporate Controller since December 2011.

Company Name Change

On April 27, 2021, the Company announced that it was changing its name from CHF Solutions, Inc. to Nuwellis, Inc. to more appropriately reflect the direction of its business.

Appointment of Neil P. Ayotte

Effective June 7, 2021, the Board of the Company appointed Neil P. Ayotte as Senior Vice President, General Counsel, Secretary and Chief Compliance Officer of the Company. Mr. Ayotte was formerly Executive Vice President, General Counsel & Secretary for Bluestem Group, Inc. a $1.8 billion, private equity sponsored, e-commerce and mail order retailer of seven distinct consumer brands. Prior to holding that position, Mr. Ayotte was Chief Legal Counsel for Medtronic’s Americas Region, the largest of Medtronic’s four super regions. During his 16-year tenure at Medtronic, Mr. Ayotte was the Chief Legal Counsel to the Integration Management Office dedicated exclusively to leading Medtronic’s integration of its $49 billion acquisition of Covidien plc, and he also served as Medtronic’s Interim General Counsel in 2013.

Appointment of George Montague

Effective June 28, 2021, the Board of the Company appointed George Montague as the Chief Financial Officer and Treasurer of the Company. Mr. Montague previously served as the Chief Financial Officer and Chief Operating Officer of Smiths Medical, a $1.1 billion device manufacturer where he restored sales growth and improved profitability. He also worked as the Group Financial Controller of the $4.2 billion parent company in London, UK. Earlier in his career, Mr. Montague led finance and strategy for two of Medtronic plc’s four operating groups. He served as the Vice President, Finance and Strategy for Medtronic’s $6.5 billion operating group – Restorative Therapies Group. He also guided finance, strategy and business development for Medtronic’s Diabetes franchise.

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, 2020.

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, 2020.

Revenue Recognition: We recognize revenue in accordance with Accounting Standards Codification ("ASC"), Topic 606, Revenue from Contracts with Customers, which we adopted effective January 1, 2018. Accordingly, we recognize revenue when our customers obtain control of its 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 have terms that require payment in 30 days. We did not establish an allowance for doubtful accounts as of June 30, 2021 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 as 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 and directors, including grants of stock options, warrants 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. Equity instruments issued to non-employees include common stock awards or warrants to purchase shares of our common stock. These common stock awards or warrants either are fully vested and exercisable at the date of grant or vest over a certain period during which services are provided. 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. In accordance with Accounting Standards Update 2018-07, unvested awards are no longer remeasured to fair value until vesting and rather the fair value is established at the grant date consistent with the treatment of employee director awards.

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 restricted stock units and common stock awards.

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 six months ended June 30, 2020, reflects a $1.8 million increase for the deemed dividend to preferred stockholders provided in connection with the close of the public offering of Series H convertible preferred stock on January 28, 2020. This deemed dividend includes $0.2 million that resulted from the subsequent reduction in the exercise of price of the warrants as a result of the March 2020 offering. The net loss allocable to common stockholders for the six months ended June 30, 2021 includes a deemed dividend of $33,000 that resulted from the change in the exercise price of the warrants as a result of the March 2021 offering.

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 units by considering sales prices for similar assets and by estimating future discounted cash flows expected from the units. 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, 2020 or the six months ended June 30, 2021.

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, 2020 and 2019 and through June 30, 2021, 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 June 30, 2021, we had an accumulated deficit of $243.3 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 the Company to succeed in effectively training personnel at hospitals 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 2019, 2020 and through March 19, 2021, we closed on underwritten public and other equity offerings for aggregate net proceeds of approximately $57.6 million after deducting the underwriting discounts and commissions or placement agents' fees and offering expenses, as applicable, and other costs associated with the offerings. In addition, during 2020 we received $4.1 million 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 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 December 31, 2022. However, 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

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 June 30, 2021, we had an accumulated deficit of $243.3 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.

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Results of Operations

Comparison of Three Months Ended June 30, 2021 to Three Months Ended June 30, 2020

Net Sales
(in thousands)

Three Months Ended June 30, 2021		Three Months Ended June 30, 2020		Increase (Decrease)		% Change
$	1,918	$	1,863	$	645	34.6%

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 increase in sales is driven by execution of our commercialization strategy which includes continued expansion of our commercial footprint by the hiring of new sales representatives, clinical education specialists, and marketing personnel.

Costs and Expenses
Our costs and expenses were as follows:

(in thousands)	Three Months Ended June 30, 2021		Three Months Ended June 30, 2020		Increase (Decrease)		% Change	
Cost of goods sold	$	997	$	664	$	333	50.	2%
Selling, general and administrative	$	5,063	$	4,234	$	829	19.	6%
Research and development	$	1,174	$	885	$	289	32.	7%

Cost of Goods Sold
The decline in gross margins was primarily due to a production ramp in the second quarter of 2020 to support the launch of the Aquadex SmartFlow system and to meet expected future demand increases.

Selling, General and Administrative
The increase in selling, general and administrative expense reflects our continued investment in sales and marketing activities, along with nonrecurring leadership transition costs.

Research and Development
Research and development ("R&D") expenses in the second quarter of 2021 were $1.2 million, an increase of 33% compared to the prior year period. The increase in R&D expenses was driven primarily by investments in new products and clinical support of our pediatric registry.

Comparison of Six Months Ended June 30, 2021 to Six Months Ended June 30, 2010

Net Sales
(in thousands)

Six Months Ended June 30, 2021		Six Months Ended June 30, 2020		Increase (Decrease)		% Change
$	4,426	$	3,493	$	933	26.7%

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 increase in sales is driven by execution of our commercialization strategy which includes continued expansion of our commercial footprint by the hiring of new sales representatives, clinical education specialists, and marketing personnel.

Costs and Expenses

Our costs and expenses were as follows:

(in thousands)	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020	Increase (Decrease)	% Change
Cost of goods sold	$ 1,949	$ 1,460	$ 489	33.5%
Selling, general and administrative	$ 10,300	$ 8,770	$ 1,530	17.4%
Research and development	$ 2,121	$ 1,749	$ 372	21.3%

Cost of Goods Sold

The decline in gross margins was primarily due to a production ramp in the second quarter of 2020 to support the launch of the Aquadex SmartFlow system and to meet expected future demand increases.

Selling, General and Administrative

The increase in selling, general and administrative expense reflects our continued investment in sales and marketing activities, along with nonrecurring leadership transition costs.

Research and Development

The increase in R&D expenses over the prior year were primarily driven by clinical expenditures related to our pediatric registry.

Liquidity and Capital Resources

Sources of Liquidity

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

On January 28, 2020, we closed on an underwritten public offering of 201,546 shares of common stock, 383,909 shares of Series H Preferred Stock and warrants to purchase 585,460 shares of common stock, for gross proceeds of approximately $9.7 million. Net proceeds totaled approximately $8.6 million after deducting the underwriting discounts and commissions and other costs associated with the offering.

On March 23, 2020, we closed on a registered direct offering of 138,715 shares of common stock for gross proceeds of approximately $1.2 million, prior to deduction of commissions and offering expenses related to the transaction. In a concurrent private placement, we agreed to issue to the investors in the registered direct offering warrants to purchase up to 138,715 shares of the Company’s common stock.

On April 1, 2020, we closed on a registered direct offering of 171,008 shares of common stock for gross proceeds of approximately $2.2 million, prior to deduction of commissions and offering expenses payable related to the transaction. In a concurrent private placement, we agreed to issue to the investors in the registered direct offering warrants to purchase up to 85,506 shares of the Company’s common stock. The warrants are exercisable immediately and expire five and a half years from the date of issuance.

On May 5, 2020, we closed on a registered direct offering of 119,930 shares of common stock for gross proceeds of approximately $1.7 million, prior to deduction of commissions and offering related to the transaction. In a concurrent private placement, we agreed to issue to the investors in the registered direct offering warrants to purchase up to 59,966 shares of the Company’s common stock. The warrants are exercisable immediately and will expire five and a half years from the date of issuance.

On August 21, 2020, we closed on an underwritten public offering of 1,064,678 shares of common stock and warrants to purchase 1,064,678 shares of common stock, for gross proceeds of approximately $14.4 million. Net proceeds totaled approximately $13.0 million after deducting the underwriting discounts and commissions and other costs associated with the offering.

On March 19, 2021, we closed on an underwritten public offering of 3,795,816 shares of common stock, 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.

As of June 30, 2021 and December 31, 2020, cash and cash equivalents were $24.0 million and $14.4 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 $9.2 and $8.8 million for the six months ended June 30, 2021 and 2020, 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 $137,000 and $69,000 for the six months ended June 30, 2021 and June 31, 2020, respectively. The cash used in investing activities was primarily for the purchase of manufacturing, laboratory and office equipment.

Cash Flows from Financing Activities

As described above, net cash provided by financing activities was $18.9 and $15.4 million for the six months ended June 30, 2021 and 2020, respectively.

Capital Resource Requirements

As of June 30, 2021, 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, 2020, 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 June 30, 2021. 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, Principal Financial Officer and Principal Accounting 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 June 30, 2021, 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, Principal Financial Officer and Principal Accounting Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of June 30, 2021.

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 material 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, 2020, and in other reports filed thereafter with the SEC, before deciding to invest in or retain shares of our common stock.

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

Not applicable.

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 June 30, 2021

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing	Exhibit Number		
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		
3.5	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K/A	001-35312	October 16, 2020	3.1		
3.6	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	January 2, 2019	3.1		
3.7	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	April 27, 2021	3.1		
3.8	Certificate of Designations of Series A Junior Participating Preferred Stock	8-K	001-35312	June 14, 2013	3.1		
3.9	Certificate of Designation of Preferences, Rights and Limitations of Series F Convertible Preferred Stock	S-1/A	333-221010	November 6, 2017	3.7		
3.10	Certificate of Designation of Preferences, Rights and Limitations of Series G Convertible Preferred Stock	8-K	001-35312	March 13, 2019	3.1		
3.11	Certificate of Designation of Preferences, Rights and Limitations of Series H Convertible Preferred Stock	8-K	001-35312	January 29, 2020	3.1		
3.12	Second Amended and Restated Bylaws	8-K	001-35312	April 27, 2021	3.2		
10.1	Nuwellis, Inc. 2021 Inducement Plan	8-K	001-35312	May 20, 2021	10.1		

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing			
10.2	Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the Nuwellis, Inc. 2021 Inducement Plan	8-K	001-35312	May 20, 2021	10.2		
10.3	Offer Letter by and between Nuwellis, Inc. and George Montague, effective as of June 28, 2021	8-K	001-35312	June 22, 2021	10.1		
10.4	Offer Letter by and between Nuwellis, Inc. and Neil P. Ayotte, effective as of June 7, 2021.					X	
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: August 12, 2021	By: /s/ Nestor Jaramillo, Jr. Nestor Jaramillo, Jr. President, Chief Executive Officer (principal executive officer)
Date: August 12, 2021	By: /s/ George Montague George Montague Chief Financial Officer (principal financial officer)

Exhibit 10.4

nuwellis™
Restoring Fluid Balance. Transforming Care.

May 18, 2021

Neil Ayotte
2016 Meeting St.
Wayzata, MN 55391

Re: Employment Terms

Dear Neil:

We are pleased to offer you employment with Nuwellis, Inc., a Delaware corporation (the ***"Company"***). The terms of your offer are as follows:

Your initial position with us will be as SVP, General Counsel & Chief Compliance Officer, reporting to the President & CEO. This is a position exempt from overtime requirements on the basis of Minnesota Statute, Chapter 177. Your annualized salary will be three-hundred thousand dollars ($300,000.00), paid in semi-monthly installments of $12,500.00. The regularly scheduled paydays are the 15th and last day of each month in accordance with our normal payroll procedures. The number of days in the pay period varies from 13 to 16 depending on the month. In addition to the above base salary, you will be eligible to earn a bonus of up to 35% of your base salary, applied on a pro-rata basis in 2021. One condition of receiving a bonus is that you must be employed in good standing with the Company as of the bonus payment date. In addition, the Company is pleased to offer you stock options as detailed in ATTACHMENT 1, ***"Stock Option Grant".***

You are also entitled to a lump sum payment of ten thousand dollars, ($10,000.00) less applicable taxes and withholdings, payable on your first paycheck. This bonus comes with the condition that if you resign or your employment with Nuwellis, Inc. terminates due to cause within one (1) year of effective date of your employment, you shall be obligated to repay the bonus amount on a pro-rata basis, which will be considered a debt that is immediately due and payable, and Nuwellis, Inc. will also have the right to set off the debt against any compensation or reimbursement that Nuwellis, Inc. owes to you.

During your employment, you will be eligible to participate in the employee stock options program, benefit programs and arrangements that we make available to our employees, including contributory and non-contributory welfare and benefit plans. You will be eligible for an annual accrual of 152 hours of Personal Time Off which will be earned/accrued on a semi-monthly basis. You may also participate in the Company's 401(k) Plan.

Your job duties, title, responsibility and reporting level, compensation and benefits, as well as personnel policies and procedures, are subject to change.

Your employment is effective June 7, 2021 or other mutually agreed upon date. Based on this start date, the first payment of wages earned will be on June 15, 2021. By signing this letter agreement, you acknowledge and agree that your employment with the Company is "at will," meaning that either you or the Company are entitled to terminate your employment at any time for any reason, with or without cause. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at will" nature of your employment may only be changed in an express writing signed by you and a duly authorized officer of the Company.

This offer of employment is contingent upon the satisfactory completion of a drug screen, background check/consumer report, which may include verification of job required licensure, and the truthfulness of the information presented in your job application, résumé, and interview, as well as you providing us with proof of your eligibility to work in the United States within three (3) days of your start date.

Also, you are required as a condition to your employment with the Company to; 1) sign the Company's standard Employee Proprietary Information, Inventions Assignment and Non-Competition Agreement attached hereto as EXHIBIT A, and 2) read the attached Nuwellis Code of Business Conduct and Ethics.

This letter agreement and its attachments contain all of the terms of your employment with the Company and supersede any prior understandings or agreements, whether oral or written, between you and the Company.

Nuwellis complies with all mandated payroll deductions such as federal and state income taxes, social security taxes and any other deductions required by law. In addition, we comply with any deductions required by court order such as wage garnishments or child support orders. Employee benefit deductions may also be made for group health, dental, vision, retirement savings, HSA/FSA accounts and other benefits elected by the employee.

This letter agreement may not be amended or modified except by an express written agreement signed by you and a duly authorized officer of the Company. The terms of this Agreement shall be governed by and construed in accordance with the internal laws of the State of Minnesota, without regard to its principles of conflicts of laws. By signing this Agreement, you irrevocably submit to the exclusive jurisdiction of the courts of the State of Minnesota for the purpose of any suit, action, proceeding or judgment relating to or arising out of this Agreement and the transactions contemplated hereby. By signing this Agreement, you also waive any right to request a trial by jury in any litigation with respect to this letter agreement and represent that counsel has been consulted specifically as to this waiver. Please notify Human Resources if you require this document in another language.

We hope that you find the foregoing terms acceptable. **You may indicate your agreement with these terms and accept this offer by signing and dating this letter agreement and the enclosed Employee Proprietary Information, Inventions Assignment and Non-Competition Agreement and returning them to** me by May 20, 2021.

Sincerely,

Sandra Eayrs

Sandra Eayrs
Sr. Vice President, Human Resources

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I have read and accept the employment offer as set forth in this Agreement. By signing this Agreement, I represent and warrant to the Company that I am under no contractual commitments inconsistent with my obligations to the Company. I hereby acknowledge that I have received and read the Company's Code of Business Conduct and Ethics, and that I understand the Code and its application to my performance of services to the Company.

Neil Ayotte　　　　　　　　　　Date

/s/ Neil Ayotte
Neil Ayotte

5/21/21
Date

ATTACHMENT 1

Stock Option Grant

Stock Options for 41,690 shares under the New Hire Plan will be granted subject to approval by the Board of Directors.

One-fourth of the shares vest on the one-year anniversary of the Vesting Commencement Date; the balance of the shares vest in a series of thirty-six (36) successive equal monthly installments measured from the first anniversary of the Vesting Commencement Date.

ATTACHMENT 1-1

Exhibit 31.1

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 June 30, 2021;

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: August 12, 2021

/s/ Nestor Jaramillo
Nestor Jaramillo
President, 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 June 30, 2021.

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: August 12, 2021

/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 June 30, 2021, 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: August 12, 2021

/s/ Nestor Jaramillo
Nestor Jaramillo
President, 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 June 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the ***"Report"***), I, Paul Wotta, Principal Accounting 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: August 12, 2021

/s/ George Montague
George Montague
Chief Financial Officer