

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, 2024**

OR

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

For the transition period from _____ to _____

Commission file number 001-35312

NUWELLIS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

No. 68-0533453
(I.R.S. Employer
Identification No.)

12988 Valley View Road, Eden Prairie, MN 55344
(Address of Principal Executive Offices) (Zip Code)

(952) 345-4200
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	NUWE	Nasdaq Capital Market

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

Yes No

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

Yes No

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

Large accelerated filer
Non-accelerated filer
Emerging growth company

Accelerated filer
Smaller reporting company

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

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

Yes No

The number of outstanding shares of the registrant's common stock, \$0.0001 par value, as of August 13, 2024 was 1,383,539.

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

	June 30, 2024	December 31, 2023
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 1,023	\$ 3,800
Accounts receivable	1,292	1,951
Inventories, net	1,967	1,997
Other current assets	544	461
Total current assets	4,826	8,209
Property, plant and equipment, net	630	728
Operating lease right-of-use asset	613	713
Other assets	120	120
TOTAL ASSETS	\$ 6,189	\$ 9,770
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable and accrued liabilities	\$ 3,028	\$ 2,380
Accrued compensation	706	525
Current portion of operating lease liability	226	216
Other current liabilities	56	51
Total current liabilities	4,016	3,172
Common stock warrant liability	8,579	2,843
Operating lease liability	428	544
Total liabilities	13,023	6,559
Commitments and contingencies		
Mezzanine Equity		
Series J Convertible Preferred Stock as of June 30, 2024 and December 31, 2023, par value \$0.0001 per share; authorized 600,000 shares, issued and outstanding 88 and 11,950, respectively	2	221
Stockholders' equity (deficit)		
Series A junior participating preferred stock as of June 30, 2024 and December 31, 2023, par value \$0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Series F convertible preferred stock as of June 30, 2024 and December 31, 2023, par value \$0.0001 per share; authorized 18,000 shares, issued and outstanding 127 shares	—	—
Preferred stock as of June 30, 2024 and December 31, 2023, par value \$0.0001 per share; authorized 39,352,000 shares, none outstanding	—	—
Common stock as of June 30, 2024 and December 31, 2023, par value \$0.0001 per share; authorized 100,000,000 shares, issued and outstanding 515,744 and 162,356, respectively	—	—
Additional paid-in capital	292,887	290,647
Accumulated other comprehensive income:		
Foreign currency translation adjustment	(42)	(31)
Accumulated deficit	(299,681)	(287,626)
Total stockholders' equity (deficit)	(6,836)	2,990
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	\$ 6,189	\$ 9,770

See notes to the condensed consolidated financial statements.

NUWELLIS, INC. AND SUBSIDIARY
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except per share amounts and weighted average shares outstanding)

	Three months ended June 30		Six months ended June 30	
	2024	2023	2024	2023
Net sales	\$ 2,194	\$ 2,075	\$ 4,051	\$ 3,901
Cost of goods sold	720	928	1,386	1,687
Gross profit	<u>1,474</u>	<u>1,147</u>	<u>2,665</u>	<u>2,214</u>
Operating expenses:				
Selling, general and administrative	3,236	4,664	7,842	10,154
Research and development	558	1,505	1,892	2,933
Total operating expenses	<u>3,794</u>	<u>6,169</u>	<u>9,734</u>	<u>13,087</u>
Loss from operations	(2,320)	(5,022)	(7,069)	(10,873)
Other income (expense), net	6	179	(95)	302
Financing Expense	(5,607)	—	(5,607)	—
Change in fair value of warrant liability	198	—	720	(755)
Loss before income taxes	(7,723)	(4,843)	(12,051)	(11,326)
Income tax expense	(2)	(2)	(4)	(4)
Net loss	<u>\$ (7,725)</u>	<u>\$ (4,845)</u>	<u>\$ (12,055)</u>	<u>\$ (11,330)</u>
Deemed dividend attributable to Series J Convertible Preferred Stock	—	—	541	—
Net loss attributable to common shareholders	<u>\$ (7,725)</u>	<u>\$ (4,845)</u>	<u>\$ (11,514)</u>	<u>\$ (11,330)</u>
Basic and diluted loss per share	<u>\$ (18.85)</u>	<u>\$ (127.65)</u>	<u>\$ (40.91)</u>	<u>\$ (323.15)</u>
Weighted average shares outstanding – basic and diluted	409,690	37,949	294,649	35,060
Other comprehensive loss:				
Foreign currency translation adjustments	\$ (2)	\$ 1	\$ (11)	\$ (6)
Total comprehensive loss	<u>\$ (7,727)</u>	<u>\$ (4,844)</u>	<u>\$ (12,066)</u>	<u>\$ (11,336)</u>

See notes to the condensed consolidated financial statements.

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

	Outstanding Shares of Common Stock	Common Stock	Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Equity
Balance December 31, 2022	15,326	\$ —	\$ 279,736	\$ 38	\$ (267,417)	\$ 12,357
Net loss	—	—	—	—	(6,485)	(6,485)
Unrealized foreign currency translation adjustment	—	—	—	(7)	—	(7)
Unrealized gain on marketable securities	—	—	—	6	—	6
Stock-based compensation	—	—	181	—	—	181
Issuance costs related to 2022 common stock offering	—	—	(11)	—	—	(11)
Issuance of common stock from Preferred Series I stock conversions	300	—	—	—	—	—
Reclassification of warrants to equity	—	—	7,623	—	—	7,623
Issuance of common stock from exercise of warrants	18,858	—	—	—	—	—
Balance March 31, 2023	34,484	\$ —	\$ 287,529	\$ 37	\$ (273,902)	\$ 13,664
Net loss	—	—	—	—	(4,845)	(4,845)
Unrealized foreign currency translation adjustment	—	—	—	—	—	(7)
Unrealized gain on marketable securities	—	—	—	(61)	—	(61)
Stock-based compensation	—	—	197	—	—	197
Issuance costs related to ATM offering	—	—	(98)	—	—	(98)
Issuance of common stock from ATM offering	18,781	—	2,217	—	—	2,217
Balance June 30, 2023	53,265	\$ —	\$ 289,845	\$ (24)	\$ (278,747)	\$ 11,074
	Outstanding Shares of Common Stock	Common Stock	Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Equity
Balance December 31, 2023	162,356	\$ —	\$ 290,647	\$ (31)	\$ (287,626)	\$ 2,990
Net loss	—	—	—	—	(4,330)	(4,330)
Unrealized foreign currency translation adjustment	—	—	—	(9)	—	(9)
Stock-based compensation	—	—	158	—	—	158
Issuance of common stock from conversion of Series J Convertible Preferred Stock	31,971	—	1,535	—	—	1,535
Series J Convertible Preferred Stock deemed dividend	—	—	541	—	—	541
Balance March 31, 2024	194,327	\$ —	\$ 292,881	\$ (40)	\$ (291,956)	\$ 885
Net loss	—	—	—	—	(7,725)	(7,725)
Unrealized foreign currency translation adjustment	—	—	—	(2)	—	(2)
Stock-based compensation	—	—	115	—	—	115
Issuance of common stock, net	321,417	—	(109)	—	—	(109)
Balance June 30, 2024	515,744	\$ —	\$ 292,887	\$ (42)	\$ (299,681)	\$ (6,836)

See notes to the condensed consolidated financial statements.

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

	Six months ended	
	June 30	
	2024	2023
Operating Activities:		
Net loss	\$ (12,055)	\$ (11,330)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	151	169
Stock-based compensation expense	273	378
Change in fair value of warrant liability	(720)	755
Warrant financing costs	5,607	—
Net realized gain on marketable securities	—	(65)
Changes in operating assets and liabilities:		
Accounts receivable	659	230
Inventory, net	30	(72)
Other current assets	(395)	(547)
Other assets and liabilities	5	(20)
Accounts payable and accrued expenses	829	(856)
Net cash used in operating activities	(5,616)	(11,358)
Investing Activities:		
Proceeds from sale of marketable securities	—	578
Additions to intangible assets	—	(99)
Purchases of property and equipment	(53)	(64)
Net cash provided by (used in) investing activities	(53)	415
Financing Activities:		
Issuance of common stock from offering	2,403	—
Proceeds from the exercise of Series J Convertible Preferred Warrants	500	—
Proceeds from ATM stock offerings, net	—	2,108
Net cash provided by financing activities	2,903	2,108
Effect of exchange rate changes on cash	(11)	(6)
Net decrease in cash and cash equivalents	(2,777)	(8,841)
Cash and cash equivalents - beginning of period	3,800	17,737
Cash and cash equivalents - end of period	\$ 1,023	\$ 8,896
Supplemental cash flow information		
Issuance of Series J Preferred Stock for exercise of Warrants	\$ 1,857	\$ —
Issuance of Common Stock for conversion of Series J Preferred Stock	\$ 1,535	\$ —
Deemed dividend on Series J Preferred Stock	\$ (541)	\$ —
Common stock offering costs included in prepaids	\$ 306	\$ —

See notes to the condensed consolidated financial statements.

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

Note 1 – Nature of Business and Basis of Presentation

Nature of Business: Nuwellis, Inc. (the “Company”) is a medical technology company focused on developing, manufacturing, and commercializing the Aquadex FlexFlow® and Aquadex SmartFlow® systems (collectively, the “Aquadex System”) for ultrafiltration therapy. The Aquadex System is indicated for temporary (up to eight hours) or extended (longer than 8 hours in patients who require hospitalization) use in adult and pediatric patients weighing 20 kg. or more whose fluid overload is unresponsive to medical management, including diuretics. Nuwellis, Inc. is a Delaware corporation headquartered in Minneapolis with a wholly owned subsidiary in Ireland. The Company’s common stock began trading on the Nasdaq Capital Market in February 2012.

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

Principles of Consolidation: The accompanying condensed consolidated balance sheet as of December 31, 2023, which has been derived from the consolidated audited financial statements, and the unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 8 of Regulation S-X. Certain information and note disclosures normally included in the audited annual consolidated financial statements have been condensed or omitted pursuant to those rules and regulations. Accordingly, they do not include all of the information necessary for a fair presentation of results of operations, comprehensive loss, financial condition, and cash flows in conformity with U.S. GAAP. In the opinion of management, the condensed consolidated financial statements reflect all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the results of the Company for the periods presented. Operating results for interim periods are not necessarily indicative of results that may be expected for the year as a whole. The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and the related disclosures at the date of the consolidated financial statements and during the reporting period. Actual results could differ materially from these estimates.

These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2023.

Going Concern: The Company’s consolidated financial statements have been prepared and presented on a basis assuming it continues as a going concern. During the years ended December 31, 2023 and 2022 and through June 30, 2024, 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. Since the company’s inception and as of June 30, 2024, the Company had an accumulated deficit of \$299.7 million and it expects to incur losses for the immediate future. To date, the Company has been funded by equity financings, and although the Company believes that it will be able to successfully fund its operations, there can be no assurance that it will be able to do so or that it will ever operate profitably. These factors raise substantial doubt about the Company’s ability to continue as a going concern through the next twelve months. 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 its sales and marketing capabilities, product development, purchasing inventory, manufacturing components, generating additional clinical evidence supporting the efficacy of the Aquadex System, and complying with the requirements related to being a U.S. public company. To become and remain profitable, the Company must succeed in expanding the adoption and market acceptance of the Aquadex System. This will require the Company to succeed in training personnel at hospitals and in outpatient care settings, and effectively and efficiently manufacturing, marketing, and distributing the Aquadex System and related components. There can be no assurance that the Company will succeed in these activities, and it may never generate revenues sufficient to achieve profitability.

On April 30, the Company closed on a best efforts public offering of 240,571 shares of its common stock, 80,854 shares of its common stock for pre-funded warrants and warrants to purchase up to an aggregate of 482,146 shares of its common stock at a combined public offering price \$8.40 per share. All pre-funded warrants were exercised on the date of the offering. Each share of common stock (or prefunded warrant in lieu thereof) was sold together with one warrant to purchase one and a half shares of common stock. The warrants have an exercise price of \$14.00 per share, were exercisable immediately upon issuance, and will expire five years following the date of issuance. Each whole common warrant entitles the holder thereof to purchase one share of common stock.

The common warrants contain a reset of the exercise price, effective upon the Warrant Stockholder Approval, to a price equal to the lesser of (i) the then exercise price, (ii) the lowest volume weighted average price for the five trading days immediately following the date we effect a reverse stock split in the future and (iii) if we effect a reverse stock split prior to obtaining the Warrant Stockholder Approval, the lowest volume weighted average price for the five trading days immediately following the date we obtain the Warrant Stockholder Approval. The Company secured the Warrant Stockholder Approval on June 6, 2024. Subsequent to June 30 2024, the number of shares underlying the common warrants were adjusted to 2,710,734 shares and the exercise price was adjusted to \$2.49 per share. In addition, the common warrants provided for, full ratchet anti-dilution adjustment to the exercise price and number of shares underlying the common warrants upon our issuance of our common stock or common stock equivalents at a price per share that is less than the exercise price of the common warrants, subject to certain exemptions. In no event will the exercise price of the common warrants with respect to either adjustment be reduced below a floor price of \$0.06.

The gross proceeds to the Company from the offering, before deducting the placement agent fees and other offering expenses were approximately \$2.7 million.

On July 24, 2024, the Company announced that it had entered into a definitive securities purchase agreement with certain institutional investors for the purchase and sale of 469,340 shares of the Company's common stock at a price of \$4.24 per share of common stock in a registered direct offering priced at-the-market under Nasdaq rules.

In addition, in a concurrent private placement, the Company will issue to the investors warrants to purchase up to 938,680 shares of common stock. The warrants have an exercise price of \$3.99 per share, will be exercisable immediately following the date of issuance and will have a term of five years from the date of issuance.

The closing of the registered direct offering and the concurrent private placement occurred on or about July 25, 2024, subject to the satisfaction of the customary closing conditions.

The gross proceeds to the Company from the registered direct offering and the concurrent private placement, before deducting the placement agent fees and other offering expenses payable by the Company, were approximately \$2.0 million. The Company intends to use the net proceeds from the offering for working capital and for general corporate purposes.

Understanding the near-term need to raise capital, the Company has recently undertaken steps to reduce our monthly cash burn rate by approximately 40%, balanced against our strategic growth initiatives, which will provide more flexibility in anticipation of tougher capital market conditions for microcap companies like Nuwellis. These reductions include, but are not limited to the following: selected job eliminations, a reduction of the salaries for members of senior management, no merit increases to the base salaries of any named executive officer or employee in 2024 for performance provided during the fiscal year ended December 31, 2023, no cash bonuses to any named executive officer or employee in 2024 for performance provided during the fiscal year ended December 31, 2023, a reduction in Board of Director and committee fees, temporary suspension of company 401k match, travel reductions, and reductions to select professional services.

The Company believes that its existing capital resources will be sufficient to support its operating plan through October 31, 2024. However, the Company will seek to raise additional capital to support its growth or other strategic initiatives through debt, equity or a combination thereof. There can be no assurance we will be successful in raising additional capital.

Revenue Recognition: The Company recognizes revenue in accordance with Accounting Standards Codification, Topic 606, Revenue from Contracts with Customers, which the Company adopted effective January 1, 2018. Accordingly, the Company recognizes revenue when its customers obtain control of its products or services, in an amount that reflects the consideration that the Company expects to receive in exchange for those goods and services. See Note 2 – Revenue Recognition below for additional disclosures. For the three months ended June 30, 2024, two customers represented 16% and 12% of net sales. For the six months ended June 30, 2024, two customers each represented 19% and 11% of net sales. For the three months ended June 30, 2023, two customers represented 16% and 13% of net sales. For the six months ended June 30, 2023, two customers each represented 14% and 13% of net sales.

Accounts Receivable: Accounts receivable are unsecured, are recorded at net realizable value, and do not bear interest. The Company makes judgments as to its ability to collect outstanding receivables based upon significant patterns of collectability, historical experience, and management’s evaluation of specific accounts and will provide an allowance for credit losses when collection becomes doubtful. 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, 2024, or December 31, 2023. As of June 30, 2024, one customer represented 27% of the accounts receivable balance. As of December 31, 2023, two customers represented 14% and 15% of the total accounts receivable balance.

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

<i>(in thousands)</i>	June 30, 2024	December 31, 2023
Finished Goods	\$ 470	\$ 393
Work in Process	307	207
Raw Materials	1,234	1,472
Inventory Reserves	(44)	(75)
Total	<u>\$ 1,967</u>	<u>\$ 1,997</u>

Loss per Share: Basic loss per share is computed based on the net loss for each period divided by the weighted average number of common shares outstanding. See Note 3 – Stockholders’ Equity below for additional disclosures.

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

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

	June 30	
	2024	2023
Stock options	3,979	3,164
Warrants to purchase common stock	543,232	37,401
Series F convertible preferred stock	15,240	254
Series J convertible preferred stock	62	—
Total	562,513	40,819

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

	Three months ended June 30		Six months ended June 30	
	2024	2023	2024	2023
<i>(in thousands, except per share amounts)</i>				
Net loss	\$ (7,725)	\$ (4,845)	\$ (12,055)	\$ (11,330)
Deemed dividend attributable to Series J Convertible Preferred Stock	—	—	541	—
Net loss attributable to common shareholders	\$ (7,725)	\$ (4,845)	\$ (11,514)	\$ (11,330)
Weighted average shares outstanding	410	38	295	35
Basic and diluted loss per share	\$ (18.85)	\$ (127.65)	\$ (40.91)	\$ (323.15)

Subsequent Events: The Company evaluates events through the date the condensed consolidated financial statements are filed for events requiring adjustment to or disclosure in the condensed consolidated financial statements. See note 9 – Subsequent Events for additional disclosures.

Note 2 – Revenue Recognition

Net Sales: The Company sells its products in the United States primarily through a direct salesforce. 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, Belarus, Brazil, Colombia, The Czech Republic, Germany, Greece, Hong Kong, India, Indonesia, Israel, Italy, Panama, Romania, Singapore, Slovak Republic, 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. International revenue represents 3% and 5% of net sales for the three months ended June 30, 2024 and 2023, and 4% of net sales for both the six months ended June 30, 2024 and 2023, respectively.

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

Revenue is measured as the amount of consideration we expect to receive, adjusted for any applicable estimates of variable consideration and other factors affecting the transaction price, which is based on the invoiced price, in exchange for transferring products. All revenue is recognized when the Company satisfies its performance obligations under the contract. The majority of the Company’s contracts have a single performance obligation and are short term in nature. The Company has entered into extended service plans with customers whose related revenue is recognized over time. This revenue represents less than 1% of net sales for the three and six months ended June 30, 2024 and 2023. The unfulfilled performance obligations related to these extended service plans are included in deferred revenue, which is included in other current liabilities on the condensed 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 products 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 received minimal 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 of Series F convertible preferred stock and warrants to purchase shares of common stock. 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 \$7,000,000). Effective for every stock offering or reverse stock split, the conversion price of the Series F convertible preferred stock has been recalculated based on the offering price.

As of July 25, 2024 (the most recent stock offering), the conversion price of the Series F convertible preferred stock was recalculated to \$235.85. As of June 30, 2024 and December 31, 2023, 127 shares of the Series F convertible preferred stock remained outstanding.

2023 At-the-Market Program: In March 2023, the Company filed a Prospectus Supplement to its Registration Statement on Form S-3 with the SEC in connection with a proposed At-the-Market Securities offering (the "At-the-Market Program"). During 2023, the Company issued 18,781 shares of common stock under the At-the-Market Program for gross proceeds of approximately \$2.3 million. Net proceeds totaled approximately \$2.1 million after deducting the underwriting discounts and commissions and other costs associated with the offering. The Company terminated its At-the-Market Program in July of 2024.

Supply Agreement Warrants: On June 19, 2023, we entered into a Supply and Collaboration Agreement (the "**Supply Agreement**") with DaVita Inc., a Delaware corporation ("**DaVita**"), pursuant to which DaVita will pilot the Aquadex ultrafiltration therapy system to treat adult patients with congestive heart failure and related conditions within select U.S. markets. The pilot program is expected to launch by the end of fourth quarter 2023 and extend through May 31, 2024 (the "**Pilot**"). On May 31, 2024, DaVita and Nuwellis amended the Supply and Collaboration Agreement extending the Pilot term through August 31, 2024. Through the Pilot, ultrafiltration therapy using Aquadex will be offered at a combination of DaVita's hospital customer and outpatient center locations, with both companies collaborating on the roll-out of the therapy, clinician training, and patient support. At the conclusion of the Pilot, DaVita has the option, in its sole discretion, to extend the Supply Agreement with the Company for continued provision of both inpatient and outpatient ultrafiltration services for up to 10 years ("**Ultrafiltration Services Approval**").

In conjunction with the Supply Agreement, the Company issued DaVita a warrant to purchase up to an aggregate of 36,830 shares of common stock of the Company, par value \$0.0001 per share, at an exercise price of \$115.49 per share (the “*DaVita Warrant*”), provided that at no time can the DaVita Warrant be exercised for an amount of shares that would represent greater than 19.9% ownership in the Company subject to certain vesting milestones. The DaVita Warrant is expected to vest in four tranches as follows: (i) 25% upon receipt of notice to extend the Supply Agreement past the initial pilot-term; (ii) 25% upon the attainment by the Company of a net revenue achievement from DaVita’s efforts pursuant to the Supply Agreement within twelve months of Ultrafiltration Services Approval; (iii) 25% upon the attainment by the Company of a net revenue achievement from DaVita’s efforts pursuant to the Supply Agreement within twenty-four months of Ultrafiltration Services Approval; and (iv) 25% upon the attainment by the Company of a net revenue achievement from DaVita’s efforts pursuant to the Supply Agreement within thirty-six months of Ultrafiltration Services Approval. This warrant had not vested as of June 30, 2024.

The Company evaluated the accounting treatment for the DaVita Warrant pursuant to ASC 718, “Stock Compensation,” and ASC 480, “Distinguishing Liabilities from Equity,” and concluded that the DaVita Warrant should be classified as an equity instrument on the balance sheet as of June 30, 2024. In accordance with this treatment, the Company’s management concluded none of the performance-based vesting conditions of the DaVita warrant were probable of vesting as of June 30, 2024, and therefore, no expense associated with the DaVita Warrant was recognized in the Company’s financial statements as of that date. The Company will continue to evaluate the probability of achieving the performance milestones associated with the DaVita Supply Agreement and will record the related equity-based expense in its financial statements based on the grant date fair value of the DaVita Warrant when management deems it is probable that the performance-based vesting conditions will be achieved.

October 2023 Offering: On October 12, 2023, Nuwellis, Inc. entered into a Placement Agency Agreement with Lake Street Capital Markets, LLC and Maxim Group LLC, pursuant to which the Company issued and sold, in a best efforts registered public offering by the Company, 150,000 units, with each Unit consisting of (A) one share of the Company’s Series J Convertible Redeemable Preferred Stock, par value \$0.0001 per share, and (B) one warrant to purchase one-half of one (0.50) share of Series J Convertible Preferred Stock, at a price to the public of \$15.00 per Unit, less placement agent fees and commissions. The public offering price of \$15.00 per Unit reflects the issuance of the Series J Convertible Preferred Stock with an original issue discount of 40%. The Company also registered under the Registration Statement (as defined below) an additional 362,933 shares of Series J Convertible Preferred Stock that will be issued, if and when the Company’s Board of Directors declares such dividends, as paid in-kind dividends and the shares of Common Stock issuable upon conversion of the Series J Convertible Preferred Stock issued as PIK dividends.

The Units, the shares of Series J Convertible Preferred Stock, the Warrants, the PIK Dividend Shares, the PIK Conversion Shares as well as the shares of Series J Convertible Preferred Stock issuable upon exercise of the Warrants and the shares of the Company’s common stock, par value \$0.0001 per share, issuable upon conversion of the Series J Convertible Preferred Stock, were offered and sold by the Company pursuant to an effective registration statement on Form S-1. The closing of the Offering contemplated by the Placement Agency Agreement occurred on October 17, 2023.

On October 17, 2023, the Company also entered into a warrant agency agreement with the Company’s transfer agent, Equiniti Trust Company, LLC, who will act as warrant agent for the Company, setting forth the terms and conditions of the Warrants sold in this Offering.

Each Warrant has an exercise price of \$262.50 per one-half of one (0.5) share of Series J Convertible Preferred Stock, is immediately exercisable and will expire three (3) years from the date of issuance.

There is no established trading market for the Series J Convertible Preferred Stock or the Warrants and we do not expect a market to develop. In addition, we do not intend to list the Series J Convertible Preferred Stock or the Warrants on The Nasdaq Capital Market or any other national securities exchange or any other nationally recognized trading system.

The gross proceeds to the Company from the October 17, 2023, Offering were \$2.25 million. Net proceeds were approximately \$1.5 million after deducting placement agent fees and commissions and Offering expenses payable by the Company. The Company used the net proceeds from the Offering for working capital and for general corporate purposes.

The Series J Convertible Preferred Stock is classified as mezzanine equity and accreted to reflect its redemption value as of each reporting date. The accretion will be reflected as a deemed dividend adjustment to arrive at net loss attributed to common stockholders for earnings per share calculations.

The Warrants are recorded as a liability and re-measured at fair value as of each reporting date with fair value changes being recorded as non-operating income or expense. The Warrants were valued on day 1 and exceeded the gross proceeds of the offering. This resulted in a day 1 financing expense of \$2.7 million.

April 2024 Offering: On April 30, the Company closed on a best efforts public offering of 240,571 shares of its common stock, 80,854 shares of its common stock for pre-funded warrants and warrants to purchase up to an aggregate of 482,146 shares of its common stock at a combined public offering price \$8.40 per share. All pre-funded warrants were exercised on the date of the offering. Each share of common stock (or prefunded warrant in lieu thereof) was sold together with one warrant to purchase one and a half shares of common stock. The warrants have an exercise price of \$14.00 per share, were exercisable immediately upon issuance, and will expire five years following the date of issuance. Each whole common warrant entitles the holder thereof to purchase one share of common stock.

The common warrants contain a reset of the exercise price, effective upon the Warrant Stockholder Approval, to a price equal to the lesser of (i) the then exercise price, (ii) the lowest volume weighted average price for the five trading days immediately following the date we effect a reverse stock split in the future and (iii) if we effect a reverse stock split prior to obtaining the Warrant Stockholder Approval, the lowest volume weighted average price for the five trading days immediately following the date we obtain the Warrant Stockholder Approval. The Company secured the Warrant Stockholder Approval on June 6, 2024. Subsequent to June 30 2024, the number of shares underlying the common warrants were adjusted to 2,710,734 shares and the exercise price was adjusted to \$2.49 per share. In addition, the common warrants provided for full ratchet anti-dilution adjustment to the exercise price and number of shares underlying the common warrants upon our issuance of our common stock or common stock equivalents at a price per share that is less than the exercise price of the common warrants, subject to certain exemptions. In no event will the exercise price of the common warrants with respect to either adjustment be reduced below a floor price of \$0.06.

The gross proceeds to the Company from the offering, before deducting the placement agent fees and other offering expenses were approximately \$2.7 million.

The warrants offered in this financing are currently classified as a liability on the balance sheet. An independent valuation of the warrants was performed and reviewed with management, and the valuation at issuance was \$7.8 million and at June 30, 2024, was \$8.0 million, representing a warrant liability increase of \$0.2 million from issuance. The \$0.2 million warrant liability increase from issuance has been reported on the Condensed Consolidated Statement of Operations as a “Change in fair value of warrant liability”. The warrant valuation of \$8.0 million exceeded the gross proceeds of \$2.7 million. Accordingly if the warrant valuation exceeds the gross proceeds, the difference will be recorded as ‘Day 1 interest’. You will find this difference, along with other issuance costs (discounts, legal, printing) reported on the Condensed Consolidated Statement of Operations as “Warrant valuation expense”.

Underwriter and Placement Agent Fees: In connection with the offerings described above, the Company paid the underwriter or placement agent, as applicable, an aggregate cash fee of either 7% or 8% of the aggregate gross proceeds raised in each of the offerings, except with respect to the issuances made pursuant to the At-the-Market Program, for which the placement fee was equal to 3% of the aggregate gross proceeds.

At the Company’s annual meeting of stockholders on June 6, 2024, its stockholders approved a proposal to amend the Company’s Fourth Amended and Restated Certificate of Incorporation to effect such a reverse split of the Company’s outstanding Common Stock at a ratio in the range of 1-for-5 to 1-for-70 to be determined at the discretion of our Board of Directors. On June 26, 2024, the Company’s board of directors approved a one-for-thirty-five reverse stock split of the Company’s issued and outstanding shares of common stock (the “*Reverse Stock Split*”). On June 27, 2024, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment to its Certificate of Incorporation (the “*Certificate of Amendment*”) to affect the Reverse Stock Split. The Reverse Stock Split became effective as of 5:00 p.m. Eastern Time on June 27, 2024, and the Company’s common stock began trading on a split-adjusted basis when the market opened on June 28, 2024. All share and per-share amounts have been retroactively adjusted to reflect the reverse stock splits for all periods presented.

Note 4 - Stock-Based Compensation

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

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

	Three months ended		Six months ended	
	June 30		June 30	
(in thousands)	2024	2023	2024	2023
Selling, general and administrative expense	\$ 115	\$ 179	\$ 272	\$ 351
Research and development expense	—	18	1	27
Total stock-based compensation expense	\$ 115	\$ 197	\$ 273	\$ 378

During the three months ended June 30, 2024 and 2023, under the 2017 Equity Incentive Plan, and the 2021 Inducement Plan, the Company granted 1 and 267 stock options, respectively, to its directors, officers and employees. During the six months ended June 30, 2024 and 2023, the Company granted 1,264 and 2,937 stock options, respectively, to its directors, officers and employees. Vesting generally occurs over an immediate to 48-month period based on a time-of-service condition. The weighted-average grant date fair value of the stock-options issued during the three months ended June 30, 2024 and 2023 was \$8.75 and \$103.52 per share, respectively. The weighted-average grant date fair value of the stock options issued during the six months ended June 30, 2024 and 2023 was \$24.14 and \$258.19 per share, respectively.

The total number of stock options outstanding as of June 30, 2024 and June 30, 2023 was 3,979 and 3,164, respectively.

The weighted-average assumptions used in the Black-Scholes option-pricing model are as follows for the stock options granted during the three and six months ended June 30, 2024 and 2023:

	Three months ended		Six months ended	
	June 30		June 30	
	2024	2023	2024	2023
Expected volatility	138.70%	132.13%	138.70%	156.35%
Expected Life of options (years)	5.51	6.08	5.51	6.23
Expected dividend yield	0%	0%	0%	0%
Risk-free interest rate	3.94%	3.75%	3.94%	4.13%

During the three months ended June 30, 2024 and 2023, 472 and 32 stock options vested, respectively, and 91 and 79 stock options were expired or forfeited during these periods, respectively. During the six months ended June 30, 2024 and 2023, 1,347 and 60 stock options vested, respectively, and 363 and 84 stock options were expired or forfeited during these periods, respectively. During the three and six months ended June 30, 2024 and 2023, no options were exercised.

Note 5—Fair Value of Financial Instruments

The Company’s financial instruments consist of cash and cash equivalents and warrants.

Pursuant to the requirements of Accounting Standards Codification (“ASC”) Topic 820 “Fair Value Measurement,” the Company’s financial assets and liabilities measured at fair value on a recurring basis are classified and disclosed in one of the following three categories:

- Level 1 - Financial instruments with unadjusted quoted prices listed on active market exchanges.
- Level 2 - Financial instruments lacking unadjusted, quoted prices from active market exchanges, including over-the-counter traded financial instruments. The prices for the financial instruments are determined using prices for recently traded financial instruments with similar underlying terms as well as directly or indirectly observable inputs, such as interest rates and yield curves that are observable at commonly quoted intervals.
- Level 3 - Financial instruments that are not actively traded on a market exchange. This category includes situations where there is little, if any, market activity for the financial instrument. The prices are determined using significant unobservable inputs or valuation techniques.

The fair value of the Company’s common and preferred stock warrant liabilities related to the investor warrants issued in the October 2023, October 2022 and April 2024 public offerings was calculated using a Monte Carlo valuation model and was classified as Level 3 in the fair value hierarchy.

The following is a roll-forward of the fair value of the Level 3 warrants:

(in thousands)

Balance at December 31, 2022	\$ 6,868
Change in fair value	755
Issuance of Common Stock for exercise of Series I warrants	(7,623)
October 17, 2023, issuance of Series J warrants	4,965
Exercise of Series J warrants	(536)
Change in fair value	(1,586)
Balance at December 31, 2023	2,843
Exercise of Series J warrants	(1,357)
April 30, 2024, issuance of common warrants	7,993
Change in fair value	(900)
Balance at June 30, 2024	\$ 8,579

Note 6 – Income Taxes

The Company provides for a valuation allowance when it is more likely than not that it will not realize a portion of its deferred tax assets. The Company has established a full valuation allowance for its 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, 2024, 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, 2023.

Note 7—Operating Leases

The Company leases a 23,000 square foot facility located in Eden Prairie, Minnesota for office and manufacturing space under a non-cancelable operating lease that expires in March 2027. In November 2021, the Company entered into a fourth amendment to the lease, extending the term of the lease from March 31, 2022 to March 31, 2027. This facility serves as our corporate headquarters and houses substantially all our functional departments. Monthly rent and common area maintenance charges, including estimated property tax for our headquarters, total approximately \$34,000. The lease contains provisions for annual inflationary adjustments. Rent expense is being recorded on a straight-line basis over the term of the lease. Beginning on April 1, 2022, the annual base rent was \$10.50 per square foot, subject to future annual increases of \$0.32 to \$0.34 per square foot.

Note 8—Commitments and Contingencies

Employee Retirement Plan: The Company has a 401(k) retirement plan that provides retirement benefits to all eligible U.S. employees. Eligible employees may contribute a percentage of their annual compensation, subject to Internal Revenue Service limitations, with the Company matching a portion of the employees' contributions at the discretion of the Company.

Milestone Payment: On December 27, 2022, the Company entered into a license and distribution agreement with SeaStar Medical Holding Corporation, (Nasdaq: ICU), a medical device company developing proprietary solutions to reduce the consequences of dysregulated immune responses including hyperinflammation on vital organs, is appointing the Company as the exclusive U.S. distributor to promote, advertise, market, distribute and sell certain products. As a part of this agreement, the Company agreed to pay SeaStar, a milestone payment of \$450,000, upon its receipt of a Human Device Exemption (HDE) approval from the U.S. Food and Drug Administration's (FDA). This payment is due on the later to occur of 30 days after achievement of the milestone event or April 1, 2024. As of December 31, 2023, the Company concluded it was probable HDE approval would be obtained and recorded a liability of \$450,000 on the consolidated balance sheet. On February 22, 2024, SeaStar obtained HDE approval. As of June 30, 2024, the milestone payment has been paid.

Note 9- Subsequent Events

Public Offering: On July 24, 2024, the Company announced that it had entered into a definitive securities purchase agreement with certain institutional investors for the purchase and sale of 469,340 shares of the Company's common stock at a price of \$4.24 per share of common stock in a registered direct offering priced at-the-market under Nasdaq rules.

In addition, in a concurrent private placement, the Company will issue to the investors warrants to purchase up to 938,680 shares of common stock. The warrants have an exercise price of \$3.99 per share, will be exercisable immediately following the date of issuance and will have a term of five years from the date of issuance.

The closing of the registered direct offering and the concurrent private placement occurred on or about July 25, 2024, subject to the satisfaction of the customary closing conditions.

The gross proceeds to the Company from the registered direct offering and the concurrent private placement, before deducting the placement agent fees and other offering expenses payable by the Company, were approximately \$2.0 million. The Company intends to use the net proceeds from the offering for working capital and for general corporate purposes.

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, 2023. 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, 2023 and in our subsequent filings with the Securities and Exchange Commission (the "SEC").

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

OVERVIEW

About Nuwellis

We are a medical technology company dedicated to transforming the lives of patients suffering from fluid overload through science, collaboration, and innovation. The Company is focused on commercializing the Aquadex SmartFlow system for ultrafiltration therapy. The Aquadex SmartFlow system is indicated for temporary (up to eight hours) or extended (longer than 8 hours in patients who require hospitalization) use in adult and pediatric patients weighing 20 kg or more whose fluid overload is unresponsive to medical management, including diuretics.

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

Recent Developments

Nasdaq Compliance

As previously disclosed on May 29, 2024 and June 10, 2024, the Company was notified by the Listing Qualifications Department (the “**Staff**”) of The Nasdaq Stock Market LLC (“**Nasdaq**”) that the Company did not satisfy Nasdaq Listing Rules 5550(b)(1) (the “**Stockholder’s Equity Requirement**”) and 5550(a)(2) (the “**Minimum Bid Price Requirement**”), respectively, and was therefore subject to delisting from Nasdaq unless the Company timely requested a hearing before the Nasdaq Hearings Panel (the “**Panel**”).

On July 18, 2024, Nasdaq notified the Company that it had regained compliance with the Minimum Bid Price Requirement. At a hearing before the Panel on July 23, 2024, the Company presented its plan of compliance to regain compliance with the Stockholder’s Equity Requirement.

On August 8, 2024, the Company was notified by Nasdaq that the Panel had granted the Company’s request for continued listing, subject to, among other things, the Company’s filing of its Quarterly Report on Form 10-Q for the period ending September 30, 2024, evidencing compliance with the Stockholder’s Equity Requirement. Although the Company is diligently working to do so, there can be no assurance that the Company will be able to evidence compliance with all applicable listing criteria within the period of time granted by the Panel.

Public Offering

On July 24, 2024, the Company announced that it had entered into a definitive securities purchase agreement with certain institutional investors for the purchase and sale of 469,340 shares of the Company’s common stock at a price of \$4.24 per share of common stock in a registered direct offering priced at-the-market under Nasdaq rules.

In addition, in a concurrent private placement, the Company issued warrants to the investors to purchase up to 938,680 shares of common stock. The warrants have an exercise price of \$3.99 per share, are exercisable immediately following the date of issuance and will have a term of five years from the date of issuance.

The closing of the registered direct offering and the concurrent private placement occurred on or about July 25, 2024.

The gross proceeds to Nuwellis from the registered direct offering and the concurrent private placement, before deducting the placement agent fees and other offering expenses payable by the Company, are expected to be approximately \$2.0 million. Nuwellis intends to use the net proceeds from the offering for working capital and for general corporate purposes.

Reverse Stock Split

At the Company’s annual meeting of stockholders on June 6, 2024, its stockholders approved a proposal to amend the Company’s Fourth Amended and Restated Certificate of Incorporation to effect such a reverse split of the Company’s outstanding Common Stock at a ratio in the range of 1-for-5 to 1-for-70 to be determined at the discretion of our Board of Directors. On June 26, 2024, the Company’s board of directors approved a one-for-thirty-five reverse stock split of the Company’s issued and outstanding shares of common stock (the “**Reverse Stock Split**”). On June 27, 2024, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment to its Certificate of Incorporation (the “**Certificate of Amendment**”) to affect the Reverse Stock Split. The Reverse Stock Split became effective as of 5:00 p.m. Eastern Time on June 27, 2024, and the Company’s common stock began trading on a split-adjusted basis when the market opened on June 28, 2024.

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, 2023.

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, 2023.

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

Accounts Receivable: Our accounts receivables generally have terms that require payment within 30 days. We did not establish an allowance for doubtful accounts as of June 30, 2024, as we have not incurred any write-offs or experienced a deterioration in the aging of our receivables, and we do not expect to experience write-offs in the future.

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

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

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

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

The stock-based compensation expense associated with the DaVita Warrant will be recognized when the Company determines it is probable that the performance-based vesting conditions underlying the warrant are probable of achievement and at that time, expense will be recognized based on the grant-date fair value of the DaVita Warrant.

Accounting for Warrants: We have issued and may continue to issue warrants to purchase shares of common stock through our public and private offerings and in conjunction with the Supply Agreement executed with DaVita in June 2023. We account for such warrants in accordance with ASC 480, *Distinguishing Liabilities from Equity*, which identifies three categories of freestanding financial instruments that are required to be accounted for as a liability. If determined to be classified as a liability, we will remeasure the fair value of the warrants at each balance sheet date. If determined to be classified as equity, the fair value of the warrants will be measured as of the date of issuance and will not be subject to remeasurement at each subsequent balance sheet date.

The fair value of the warrant liability is estimated using a Monte Carlo simulation model using relevant inputs and assumptions based upon the terms of the warrants.

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. See Note 3 – Stockholders' Equity below for additional disclosures.

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

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

The Company continues to report operating losses and negative cash flows from operations, both of which it considers to be indicators of potential impairment. Therefore, the Company evaluates its long-lived assets for potential impairment at each reporting period. The Company has concluded that its cash flows from the various long-lived assets are highly interrelated and, as a result, the Company consists of a single asset group. As the Company expects to continue incurring losses in the foreseeable future, the undiscounted cash flow step was bypassed, and the Company proceeded to measure fair value of the asset group. The Company has determined the fair value of the asset group associated with its loaner units by using expected cash flows estimating future discounted cash flows expected from the rental of these units. For recently acquired assets within the asset group, primarily equipment, the Company determined the fair value based on the replacement cost. There have been no impairment losses recognized for the three and six month periods ended June 30, 2024 or the year ended December 31, 2023.

Going Concern: Our consolidated financial statements have been prepared and presented on a basis assuming we continue as a going concern. During the years ended December 31, 2023 and 2022, and through June 30, 2024, we incurred losses from operations and net cash outflows from operating activities as disclosed in the consolidated statements of operations and cash flows, respectively. Since the company's inception and as of June 30, 2024, we had an accumulated deficit of \$299.7 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 into the future, there can be no assurance that we will be able to do so or that we will ever operate profitably. These factors raise substantial doubt about the Company's ability to continue as a going concern through at least twelve months from the report date.

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 our sales and marketing capabilities, product development, purchasing inventory and manufacturing components, generating additional clinical evidence supporting the efficacy of the Aquadex System, and complying with the requirements related to being a U.S. public company. To become and remain profitable, we must succeed in expanding the adoption and market acceptance of the Aquadex System. This will require us to succeed in training personnel at hospitals and effectively and efficiently manufacturing, marketing, and distributing the Aquadex System and related components. There can be no assurance that we will succeed in these activities, and we may never generate revenues sufficient to achieve profitability.

During 2021 and through June 30, 2024, we closed on underwritten public and other equity offerings for aggregate net proceeds of approximately \$43.8 million after deducting the underwriting discounts and commissions or placement agents' fees and offering expenses, as applicable, and other costs associated with the offerings. See Note 4 –Stockholders' Equity, to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K. The Company will require additional funding to grow its business, which may not be available on terms favorable to the Company, or at all. The Company may receive those funds from the issuance of equity securities or other financing transactions. Should future capital raising be unsuccessful, the Company may not be able to continue as a going concern. No adjustments have been made relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company not continue as a going concern.

Understanding the near-term need to raise capital, the Company has recently undertaken steps to reduce our monthly cash burn rate by approximately 40%, balanced against our strategic growth initiatives, which will provide more flexibility in anticipation of tougher capital market conditions for microcap companies like Nuwellis. These reductions include, but are not limited to the following: selected job eliminations, a reduction of the salaries for members of senior management, no merit increases to the base salaries of any named executive officer or employee in 2024 for performance provided during the fiscal year ended December 31, 2023, no cash bonuses to any named executive officer or employee in 2024 for performance provided during the fiscal year ended December 31, 2023, a reduction in Board of Director and committee fees, temporary suspension of company 401k match, travel reductions, and reductions to select professional services.

We believe that our existing capital resources will be sufficient to support our operating plan through October 31, 2024; however, there can be no assurance of this. We will likely seek to raise additional capital to support our growth or other strategic initiatives through debt, equity, or a combination thereof. There can be no assurance the Company will be successful in raising additional capital.

NEW ACCOUNTING PRONOUNCEMENTS

The Company has considered all recent accounting pronouncements issued and their potential effects on its financial statements. The Company's management believes that these recent pronouncements will not have a material effect on the Company's condensed financial statements.

FINANCIAL OVERVIEW

We are a medical technology company focused on commercializing the Aquadex System for ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy. Activities since inception have consisted principally of raising capital, performing research and development, and conducting pre-clinical and clinical studies. During 2016, we acquired the Aquadex Business and announced that we were halting all clinical evaluations of our prior technology, the C-Pulse System. Since then, our activities have consisted mainly of expanding our sales and marketing capabilities, performing clinical research, and engaging in new product development. Since the company's inception and as of June 30, 2024, we had an accumulated deficit of \$299.7 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 continue to successfully fund our operations, there can be no assurance that we will be able to do so or that we will ever operate profitably.

Results of Operations

Comparison of three months ended June 30, 2024 to three months ended June 30, 2023

Net Sales

(in thousands)

Three months ended June 30, 2024	Three months ended June 30, 2023	Increase (Decrease)	% Change
\$ 2,194	\$ 2,075	\$ 119	5.7%

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 in the current year period is due to a 9% increase in circuit sales, reflecting continued increases in the number of patients treated with the Aquadex therapy, and an increase in the average selling price of consoles sold in the current quarter.

Costs and Expenses

Our costs and expenses were as follows:

(in thousands)

	Three months ended June 30, 2024	Three months ended June 30, 2023	Increase (Decrease)	% Change
Cost of goods sold	\$ 720	\$ 928	\$ (208)	(22.4)%
Selling, general and administrative	\$ 3,236	\$ 4,664	\$ (1,428)	(30.6)%
Research and development	\$ 558	\$ 1,505	\$ (947)	(62.9)%

Cost of Goods Sold

The decrease in cost of goods sold for the three months ended June 30, 2024, compared to the three months ended June 30, 2023, was due primarily to higher manufacturing volumes of circuits in the current year period and lower fixed overhead manufacturing expenses.

Selling, General and Administrative

The decrease in selling, general and administrative expense was primarily realized through efficiency initiatives enacted in the second half of 2023.

Research and Development

The decrease in R&D expenses was primarily driven by reduced consulting fees and compensation-related expenses.

Comparison of six months ended June 30, 2024 to six months ended June 30, 2023**Net Sales**

(in thousands)

	Six months ended June 30, 2024		Six months ended June 30, 2023		Increase (Decrease)		% Change
\$	4,051	\$	3,901	\$	150		3.8%

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 in the current year period is due to a 10% increase in circuit sales, reflecting continued increases in the number of patients treated with the Aquadex therapy, partially offset by a decrease in console sales.

Costs and Expenses

Our costs and expenses were as follows:

(in thousands)

	Six months ended June 30, 2024		Six months ended June 30, 2023		Increase (Decrease)		% Change
Cost of goods sold	\$ 1,386	\$	1,687	\$	(301)		(17.8)%
Selling, general and administrative	\$ 7,842	\$	10,154	\$	(2,312)		(22.8)%
Research and development	\$ 1,892	\$	2,933	\$	(1,041)		(35.5)%

Cost of Goods Sold

The decrease in cost of goods sold for the six months ended June 30, 2024, compared to the six months ended June 30, 2023, was primarily due to higher manufacturing volumes of circuits in the current year period and lower fixed overhead manufacturing expenses.

Selling, General and Administrative

The decrease in selling, general and administrative expense was primarily realized through efficiency initiatives enacted in the second half of 2023.

Research and Development

The decrease in R&D expense versus the prior year was primarily driven by reduced consulting fees and compensation-related expenses.

Liquidity and Capital Resources**Sources of Liquidity**

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

On October 18, 2022, the Company closed on an underwritten public offering of 5,998 shares of common stock and 661,632 shares of Series I convertible preferred stock, for gross proceeds of approximately \$11.0 million (the “October 2022 Offering”). Net proceeds totaled approximately \$9.4 million after deducting underwriting discounts and commissions and other costs associated with the offering and after giving effect to the underwriters’ full exercise of their overallotment option.

In March 2023, the Company filed a Prospectus Supplement to its Registration Statement on Form S-3 with the SEC in connection with a proposed At-the-Market Securities offering (the “At-the-Market Program”). During 2023, the Company issued 18,781 shares of common stock under the At-the-Market Program for gross proceeds of approximately \$2.3 million. Net proceeds totaled approximately \$2.1 million after deducting the underwriting discounts and commissions and other costs associated with the offering. The Company terminated its At-the-Market Program in of 2024.

On October 17, 2023, the Company closed on a public offering of 4,286 Units, with each Unit consisting of one share of the Company’s Series J Convertible Redeemable Preferred Stock, par value \$0.0001 per share, with a liquidation preference of \$25.00 per share (the “Series J Convertible Preferred Stock”), and one October 2023 Warrant to purchase one-half of one (0.50) share of Series J Convertible Preferred Stock.

The purchase price for one Unit was \$15.00, which reflects the issuance of the Series J Convertible Preferred Stock with an original issue discount. The Series J Convertible Preferred Stock has a term of three (3) years and is convertible at the option of the holder at any time into shares of the Company’s common stock at a conversion price of \$1.01.

If any shares of our Series J Convertible Preferred Stock are outstanding at the end of the three-year term, then the Company will promptly redeem all of such outstanding shares of Series J Convertible Preferred Stock on a *pro rata* basis among all of the holders of Series J Convertible Preferred Stock commencing on the Mandatory Redemption Date in cash, to the extent legally permissible under Delaware law, or, if redemption for cash is not legally permissible in duly authorized, validly issued, fully paid and non-assessable shares of the Company’s common stock equal in number to the quotient obtained by dividing such unpaid amount by the closing price of the Company’s common stock on the Nasdaq on the Mandatory Redemption Date.

Dividends on the Series J Convertible Preferred Stock will be paid, if and when declared by the Company’s board of directors, in-kind (“PIK dividends”) in additional shares of Series J Convertible Preferred Stock based on the stated value of \$25.00 per share at a dividend rate of 5.0%. The PIK dividends will be paid on a quarterly basis for three (3) years following the closing date to holders of the Series J Convertible Preferred Stock of record at the close of business on October 31, January 31, April 30, and July 31 of each year.

The October 2023 Warrants have a term of three (3) years. Each October 2023 Warrant has an exercise price of \$262.50 (50.0% of the public offering price per Unit) per one-half of one share (0.5) of Series J Convertible Preferred Stock and is immediately exercisable.

The gross proceeds before underwriting discounts and commissions and offering expenses, were approximately \$2.25 million. The Company intends to use the net proceeds from the offering for working capital and for general corporate purposes.

On April 30, Nuwellis closed on an underwritten public offering of 321,417 shares of its common stock (or pre-funded warrants in lieu thereof) and warrants to purchase up to an aggregate of 482,146 shares of its common stock at a combined public offering price \$0.24 per share (or pre-funded warrant in lieu thereof) and associated warrant. Each share of common stock (or prefunded warrant in lieu thereof) was sold together with one warrant to purchase one and a half shares of common stock. The warrants have an exercise price of \$14.00 per share, are exercisable immediately upon issuance, and will expire five years following the date of issuance. Each whole common warrant entitles the holder thereof to purchase one share of common stock.

The common warrants contain a reset of the exercise price, to a price equal to the lesser of (i) the then exercise price, (ii) the lowest volume weighted average price for the five trading days immediately following the date we effect a reverse stock split in the future and (iii) if we effect a reverse stock split prior to obtaining the Warrant Stockholder Approval, the lowest volume weighted average price for the five trading days immediately following the date we obtain the Warrant Stockholder Approval. The Company secured the Warrant Stockholder Approval on June 6, 2024. Upon such a reset, there will be a proportionate adjustment to the number of shares underlying the common warrants. In addition, the common warrants will provide for full ratchet anti-dilution adjustment to the exercise price and number of shares underlying the common warrants upon our issuance of our common stock or common stock equivalents at a price per share that is less than the exercise price of the common warrants, subject to certain exemptions. In no event will the exercise price of the common warrants with respect to either adjustment be reduced below a floor price of \$0.06.

The gross proceeds to the Company from the offering, before deducting the placement agent fees and other offering expenses were approximately \$2.7 million.

The warrants offered in this financing are currently carried as a liability on the balance sheet. An independent valuation of the warrants was performed and reviewed with management, and the valuation at issuance was \$7.8 million and at June 30, 2024, was \$8.0 million, representing a warrant liability increase of \$0.2 million from issuance. The \$0.2 million warrant liability increase from issuance has been reported on the Income Statement as a “Change in fair value of warrant liability”. The warrant valuation of \$8.0 million exceeded the gross proceeds of \$2.7 million. Accordingly if the warrant valuation exceeds the gross proceeds, the difference will be recorded as ‘Day 1 interest’. You will find this difference, along with other issuance costs (discounts, legal, printing) reported on the Income Statement as “Warrant valuation expense”.

As of June 30, 2024 and December 31, 2023, cash and cash equivalents were \$1.0 million and \$3.8 million, respectively. Our business strategy and ability to fund our operations in the future depend in part on our ability to grow the Aquadex Business by expanding our salesforce, selling our products to hospitals and other healthcare facilities, and controlling costs. We will need to seek additional financing in the future, which, to date, has been primarily through offerings of our equity securities.

Cash Flows used in Operating Activities

Net cash used in operating activities was \$5.6 million and \$11.4 million for the six months ended June 30, 2024, and June 30, 2023, respectively. The net cash used in each of these periods primarily reflects the net loss for those periods, partially offset by non-cash charges for stock-based compensation, depreciation and amortization, and revaluation of the warrant liability, and the effects of changes in operating assets and liabilities, including working capital.

Cash Flows provided by (used in) Investing Activities

Net cash provided by (used in) investing activities was (\$53,000) and \$415,000 for the six months ended June 30, 2024, and 2023, respectively. The cash used in investing activities was for legal costs related to new patent applications in the prior year and for the purchase of manufacturing, laboratory, and office equipment, respectively, in those periods.

Cash Flows provided by Financing Activities

Net cash provided by financing activities was \$2.9 million and \$2.1 million for the six months ended June 30, 2024, and 2023, respectively. The cash provided by financing activities in the current year period was the result of proceeds received from the April 2024 financing and from the exercise of warrants from the October 2023 financing. The cash provided by financing activities in the prior year period was the result of proceeds received from our 2023 At-The-Market program.

Capital Resource Requirements

As of June 30, 2024, we did not have any material commitments for capital expenditures.

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, 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, 2022, in other reports filed thereafter with the SEC, which risk factors may be updated from time to time, and in this Quarterly Report on Form 10-Q for the quarter ended June 30, 2024. We operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for us to predict all risk factors and uncertainties. We may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including without limitation, the possibility that regulatory authorities do not accept our application or approve the marketing of our products, the possibility we may be unable to raise the funds necessary for the development and commercialization of our products, and those described in our filings with the SEC.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

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

As of June 30, 2024, the end of the period covered by this report, we conducted an evaluation, under the supervision and with the participation of management, including the Certifying Officers, of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their stated objectives. Based on their evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective at a reasonable assurance level as of June 30, 2024. The Certifying Officers based their conclusion on the fact that the Company has identified two material weaknesses in controls over financial reporting, as detailed in the 2023 Annual Report on Form 10-K. In light of this fact, management expects to perform additional analyses, reconciliations, and remediations.

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. However, as a result of the identified material weaknesses, changes in our internal control over financial reporting will occur.

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

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, 2023, and in other reports filed thereafter with the SEC, before deciding to invest in or retain shares of our common stock. There have been no material changes to the Risk Factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023.

Risk Related to our Common Stock

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

Our common stock is listed on the Nasdaq Capital Market under the symbol “NUWE”. In order to maintain that listing, we must satisfy minimum financial and other requirements including, without limitation, the minimum stockholders’ equity requirement and the minimum bid price requirement. There can be no assurances that we will be successful in maintaining, or if we fall out of compliance, in regaining compliance with the continued listing requirements and maintaining the listing of our common stock on the NASDAQ Capital Market. On December 7, 2023, we received a notice from Nasdaq (the “Notice”) informing us that because the closing bid price for our Common Stock was below \$1.00 for 30 consecutive trading days, we were not in compliance with the minimum bid price requirement for continued listing on Nasdaq, as set forth in Nasdaq Marketplace Rule 5550(a)(2) (the “Minimum Bid Price Requirement”).

In accordance with Nasdaq Marketplace Rule 5810(c)(3)(A), we were granted a period of 180 calendar days from December 7, 2023, or until June 4, 2024, to regain compliance with the Minimum Bid Price Requirement. Subsequently, on May 23, 2024, we received a letter from the Listing Qualifications Staff (the “Staff”) informing the Company that it was not in compliance with the minimum stockholders’ equity requirement for continued listing on Nasdaq, under Listing Rule 5550(b)(1) (the “Stockholder’s Equity Requirement”), because the Company’s stockholders’ equity of \$885,000, as reported in the Company’s Quarterly Report on Form 10-Q for the period ended March 31, 2024, was below the required minimum of \$2.5 million, and because, as of May 23, 2024, the Company did not meet the alternative compliance standards, relating to the market value of listed securities of \$35 million or net income from continuing operations of \$500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years.

As a result, on June 5, 2024, we received a letter from Nasdaq indicating the Company’s continued non-compliance with Nasdaq Marketplace Rule 5550(a)(2) (the “Letter”). The Letter further informed the Company that the Common Stock would be delisted from Nasdaq unless the Company appeals the Staff’s delisting determination by requesting a hearing before the Nasdaq Hearings Panel (the “Panel”). The Company’s requested a hearing to request additional time to meeting the Stockholder Equity Requirement which stayed any further delisting action by the Staff pending the ultimate outcome of the hearing. The Common Stock will remain listed and eligible for trading on Nasdaq at least pending the ultimate conclusion of the hearing process.

On June 27, 2024, we effected a 1-for-35 reverse stock split of our outstanding Common Stock. Additionally, in 2020, the SEC approved a Nasdaq rule change to expedite delisting of securities of companies that have had one or more reverse stock splits with a cumulative ratio of one for 250 or more shares over the prior two-year period. Under the new rules, if a company falls out of compliance with the \$1.00 minimum bid price after completing reverse stock splits over the immediately preceding two years that cumulatively result in a ratio one for 250 shares, the company will not be able to avail itself of any compliance periods and Nasdaq will instead require the issuance of a Staff delisting determination, which is appealable to a hearings panel. Our ability to remain listed on Nasdaq may be negatively impacted by this Nasdaq rule.

On July 18, 2024, the Company received a letter from the Staff informing the Company that it had regained compliance with the Minimum Bid Price Requirement, but that because it was still non-compliant with the Stockholder’s Equity Requirement the hearing would continue as scheduled as to the matter of the Stockholder’s Equity Requirement.

On July 23, 2024, the Company addressed the Panel and presented its plan of compliance for the Stockholder’s Equity Requirement to the Panel and is currently awaiting the Panel’s decision. There can be no assurance the Panel will grant any request for continued listing or that the Company will be able to regain compliance with the applicable listing criteria within the period of time that may be granted by the Panel.

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

If our Common Stock is delisted, our Common Stock would likely then trade only in the over-the-counter market. If our Common Stock were to trade on the over-the-counter market, selling our Common Stock could be more difficult because smaller quantities of shares would likely be bought and sold, transactions could be delayed, and we could face significant material adverse consequences, including: a limited availability of market quotations for our securities; reduced liquidity with respect to our securities; a determination that our shares are a “penny stock,” which will require brokers trading in our securities to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our securities; a reduced amount of news and analyst coverage for us; and a decreased ability to issue additional securities or obtain additional financing in the future. These factors could result in lower prices and larger spreads in the bid and ask prices for our Common Stock and would substantially impair our ability to raise additional funds and could result in a loss of institutional investor interest and fewer development opportunities for us.

In addition to the foregoing, if our Common Stock is delisted from Nasdaq and it trades on the over-the-counter market, the application of the “penny stock” rules could adversely affect the market price of our Common Stock and increase the transaction costs to sell those shares. The SEC has adopted regulations which generally define a “penny stock” as an equity security that has a market price of less than \$5.00 per share, subject to specific exemptions. If our Common Stock is delisted from Nasdaq and it trades on the over-the-counter market at a price of less than \$5.00 per share, our Common Stock would be considered a penny stock. The SEC’s penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document that provides information about penny stocks and the risks in the penny stock market. The broker-dealer must also provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and the salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer’s account. In addition, the penny stock rules generally require that before a transaction in a penny stock occurs, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser’s agreement to the transaction. If applicable in the future, these rules may restrict the ability of brokers-dealers to sell our Common Stock and may affect the ability of investors to sell their shares, until our Common Stock no longer is considered a penny stock.

We continue to actively monitor our performance with respect to the listing standards and will consider available options to resolve any deficiency and maintain compliance with the Nasdaq rules. There can be no assurance that we will be able to maintain compliance or, if we fall out of compliance, regain compliance with any deficiency, or if we implement an option that regains our compliance, maintain compliance thereafter.

If we fail to comply with federal and state laws regarding off-label use of our products, we could face substantial civil and criminal penalties and our business, financial condition, results of operations, and prospects could be adversely affected.

Healthcare professionals may choose to use and prescribe medical devices for uses that are not described in the product’s labeling and for uses that differ from those tested in clinical trials and approved or authorized by the regulatory authorities. Medical device companies, however, are prohibited from marketing and promoting products for indications and uses that are not specifically approved or authorized by FDA. Such “off-label” uses are common on the medical world and often are appropriate treatments for some patients. Regulatory authorities in the U.S. generally do not restrict or regulate the treatment choices of healthcare professionals. Regulatory authorities do, however, restrict communications by companies concerning off-label uses of their products. Any FDA approval or marketing authorization that we have or may obtain in the future permits us to promote the subject medical device only for the specific use(s) cleared, approved, certified or otherwise authorized. We are prohibited from marketing or promoting any medical devices for off-label use.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional speech concerning their products. Accordingly, we engage in medical education activities and communicate with healthcare professionals about many aspects of our products and clinical trials. In addition, we are aware that the Aquadex System, which is cleared by FDA solely for use in adults and pediatric patients weighing 20 kg or more, is being used off-label uses to treat patients who weigh under 20 kg, including being modified by children’s hospitals so that it can provide dialysis to neonates and other premature infants who were born either without kidneys or without normal kidney function. These patients typically have very few other treatment options given the large extracorporeal blood volume required by standard dialysis machines, the need for blood priming of the dialysis circuit and the use of large catheters.

Although we believe that all of our communications regarding off-label uses are in compliance with the relevant regulatory requirements, the FDA or another regulatory authority may disagree, and characterize such communications as marketing and promotion of an off-label use.

If the FDA determines that we have marketed or promoted our products for off-label use by us or our commercial partners, it could request that we or our commercial partners modify those promotional materials. We also could be subject to regulatory or enforcement actions, including the issuance of an untitled letters or warning letters, injunctions, seizures, civil fines and criminal penalties.

In addition to FDA, we may be subject to significant enforcement actions from other federal and state enforcement authorities, such as the Department of Justice and the Office of the Inspector General of the Department of Health and Human Services, if they consider our communications, including promotional and training materials, to constitute promotion of an uncleared, uncertified or unapproved use of a medical device. In the U.S., engaging in the impermissible promotion of our products, following approval, for off-label uses can also subject us to false claims and other litigation under federal and state statutes, including fraud and abuse and consumer protection laws, which can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which we promote or distribute therapeutic products and do business through, for example, corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, and debarment from government contracts and refusal of future orders under existing contracts. These laws include the federal False Claims Act, which allows any individual to bring a lawsuit against a company on behalf of the federal government alleging submission of false or fraudulent claims or causing others to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. Many False Claims Act lawsuits against, and preceding investigations of, manufacturers of healthcare products are brought every year, leading to several substantial civil and criminal settlements related to off-label uses. In addition, False Claims Act lawsuits may expose manufacturers to follow-on claims by private payors based on fraudulent marketing practices. This growth in litigation has increased the risk that a company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If we or our collaborators do not lawfully promote our approved products, we may become subject to such investigations and litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations and prospects.

Additionally, we must have adequate substantiation for the claims we make for our products and services. If any of our claims are determined to be false, misleading or deceptive, our products and services could be considered misbranded under the FDCA or in violation of the Federal Trade Commission Act. We could also face lawsuits from our competitors under the Lanham Act alleging that our marketing materials are false or misleading.

Foreign jurisdictions have their own laws and regulations concerning medical devices, including marketing authorizations and certifications, communications about off-label uses, and substantiation of advertising and promotional claims. Failure to comply with those laws and regulations could result in actions against us, including fines, penalties and exclusion from the market. Any such actions could adversely affect our ability to market new products and services or continue to market existing products and services in those jurisdictions.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES, USE OF PROCEEDS AND ISSUER PURCHASES OF EQUITY SECURITIES

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

Exhibit Index
Nuwellis, Inc.
Form 10-Q for the Quarterly Period Ended June 30, 2024

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing			
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 the Fourth Amended and Restated Certificate of Incorporation	8-K/A	001-35312	October 16, 2020	3.1		
3.6	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	January 2, 2019	3.1		
3.7	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	April 27, 2021	3.1		
3.8	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	December 9, 2022	3.1		
3.9	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	June 26, 2024	3.1		
3.10	Form of Certificate of Designation of Preferences, Rights and Limitations of Series F Convertible Preferred Stock	S-1/A	333-221010	November 17, 2017	3.7		
3.11	Certificate of Designation of Preferences, Rights and Limitations of Series J Convertible Preferred Stock	8-K	001-35312	October 17, 2023	3.1		
3.12	Second Amended and Restated Bylaws	8-K	001-35312	April 27, 2021	3.2		

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing			
3.13	Amendment to Second Amended and Restated Bylaws	8-K	001-35312	October 5, 2022	3.1		
4.1	Form of Warrant to Purchase Shares of Common Stock	8-K	001-35312	May 1, 2024	4.1		
4.2	Form of Pre-Funded Warrant to Purchase Shares of Common Stock	8-K	001-35312	May 1, 2024	4.2		
4.3	Form of Common Warrant	8-K	001-35312	July 25, 2024	4.1		
10.1	Form of Warrant Agency Agreement	8-K	001-35312	May 1, 2024	4.3		
10.2	Form of Securities Purchase Agreement, dated as of April 26, 2024, by and among Nuwellis, Inc. and the purchasers identified on the signature pages thereto	8-K	001-35312	May 1, 2024	10.1		
10.3	Placement Agency Agreement dated as of April 26, 2024, by and between Nuwellis, Inc. and Roth Capital Partners, LLC	8-K	001-35312	May 1, 2024	1.1		
10.4	First Amendment to Supply and Collaboration Agreement dated as of May 31, 2024 by and between the Company and DaVita Inc.	8-K	001-35312	June 6, 2024	10.1		
10.5	Form of Securities Purchase Agreement	8-K	001-35312	July 25, 2024	10.2		
10.6	Placement Agency Agreement dated July 24, 2024 between Nuwellis, Inc. and Roth Capital Partners LLC	8-K	001-35312	July 25, 2024	10.1		
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

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing			
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 13, 2024

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

Date: August 13, 2024

By: /s/ Robert Scott
Robert Scott
Chief Financial Officer

CHIEF EXECUTIVE OFFICER'S 302 CERTIFICATION

I, Nestor Jaramillo, Jr., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Nuwellis, Inc. for the quarterly period ended June 30, 2024;
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 13, 2024

/s/ Nestor Jaramillo, Jr.

Nestor Jaramillo, Jr.

President and Chief Executive Officer

CHIEF FINANCIAL OFFICER'S 302 CERTIFICATION

I, Robert Scott, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Nuwellis, Inc. for the quarterly period ended June 30, 2024.
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 13, 2024

/s/ Robert Scott
Robert Scott
Chief Financial Officer

**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, 2024, as filed with the Securities and Exchange Commission on the date hereof (the *“Report”*), I, Nestor Jaramillo, Jr., President and 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 13, 2024

/s/ Nestor Jaramillo, Jr.

Nestor Jaramillo, Jr.

President and Chief Executive Officer

**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, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "*Report*"), I, Robert Scott, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: August 13, 2024

/s/ Robert Scott

Robert Scott
Chief Financial Officer