

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

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended **March 31, 2023**

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 May 8, 2023 was 1,206,932

PART I—FINANCIAL INFORMATION

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

| | March 31, 2023 (unaudited) | December 31, 2022 |
|---|----------------------------------|----------------------|
| ASSETS | | |
| Current assets | | |
| Cash and cash equivalents | \$ 11,515 | \$ 17,737 |
| Marketable securities | 575 | 569 |
| Accounts receivable | 1,301 | 1,406 |
| Inventories, net | 2,742 | 2,661 |
| Other current assets | 477 | 396 |
| Total current assets | 16,610 | 22,769 |
| Property, plant and equipment, net | 907 | 980 |
| Operating lease right-of-use asset | 856 | 903 |
| Other assets | 106 | 21 |
| TOTAL ASSETS | \$ 18,479 | \$ 24,673 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities | | |
| Accounts payable and accrued liabilities | \$ 2,524 | \$ 2,245 |
| Accrued compensation | 1,312 | 2,161 |
| Current portion of operating lease liability | 201 | 196 |
| Current portion of finance lease liability | 21 | 28 |
| Other current liabilities | 49 | 58 |
| Total current liabilities | 4,107 | 4,688 |
| Common stock warrant liability | — | 6,868 |
| Operating lease liability | 708 | 760 |
| Total liabilities | 4,815 | 12,316 |
| Commitments and contingencies | — | — |
| Stockholders' equity | | |
| Series A junior participating preferred stock as of March 31, 2023 and December 31, 2022, par value \$0.0001 per share; authorized 30,000 shares, none outstanding | — | — |
| Series F convertible preferred stock as of both March 31, 2023 and December 31, 2022, par value \$0.0001 per share; authorized 127 shares, issued and outstanding 127 shares | — | — |
| Series I convertible preferred stock as of March 31, 2023 and December 31, 2022, par value \$0.0001; authorized 1,049,280, issued and outstanding none and 1,049,280, respectively | — | — |
| Preferred stock as of both March 31, 2023 and December 31, 2022, par value \$0.0001 per share; authorized 39,969,873 shares, none outstanding | — | — |
| Common stock as of March 31, 2023 and December 31, 2022, par value \$0.0001 per share; authorized 100,000,000 shares, issued and outstanding 1,206,932 and 536,394 shares, respectively | — | — |
| Additional paid-in capital | 287,529 | 279,736 |
| Accumulated other comprehensive income: | | |
| Foreign currency translation adjustment | (25) | (18) |
| Unrealized gain on marketable securities | 62 | 56 |
| Accumulated deficit | (273,902) | (267,417) |
| Total stockholders' equity | 13,664 | 12,357 |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | \$ 18,479 | \$ 24,673 |

See notes to the condensed consolidated financial statements.

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

| | Three months ended | |
|---|---------------------------|-------------------|
| | March 31, | |
| | 2023 | 2022 |
| Net sales | \$ 1,826 | \$ 1,926 |
| Cost of goods sold | 759 | 824 |
| Gross profit | <u>1,067</u> | <u>1,102</u> |
| Operating expenses: | | |
| Selling, general and administrative | 5,490 | 4,412 |
| Research and development | 1,428 | 1,106 |
| Total operating expenses | <u>6,918</u> | <u>5,518</u> |
| Loss from operations | (5,851) | (4,416) |
| Other income (expense), net | 123 | (55) |
| Change in fair value of warrant liability | (755) | — |
| Loss before income taxes | (6,483) | (4,471) |
| Income tax expense | (2) | (2) |
| Net loss | <u>\$ (6,485)</u> | <u>\$ (4,473)</u> |
| Basic and diluted loss per share | <u>\$ (5.76)</u> | <u>\$ (42.45)</u> |
| Weighted average shares outstanding – basic and diluted | 1,126 | 105 |
| Other comprehensive loss: | | |
| Unrealized gain on marketable securities | 6 | — |
| Unrealized foreign currency translation adjustments | \$ (7) | \$ (2) |
| Total comprehensive loss | <u>\$ (6,486)</u> | <u>\$ (4,475)</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, 2021 | 105,376 | \$ — | \$ 278,874 | \$ (35) | \$ (252,892) | \$ 25,947 |
| Net loss | — | — | — | — | (4,473) | (4,473) |
| Unrealized foreign currency translation adjustment | — | — | — | (2) | — | (2) |
| Stock-based compensation, net | — | — | 241 | — | — | 241 |
| Balance March 31, 2022 | 105,376 | \$ — | \$ 279,115 | \$ (37) | \$ (257,365) | \$ 21,713 |

| | Outstanding Shares of Common Stock | Common Stock | Additional Paid in Capital | Accumulated Other Comprehensive Income | Accumulated Deficit | Stockholders' Equity |
|--|---|-----------------|----------------------------------|---|------------------------|-------------------------|
| Balance December 31, 2022 | 536,394 | \$ — | \$ 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, net | — | — | 181 | — | — | 181 |
| Issuance costs related to 2022 common stock offering | — | — | (11) | — | — | (11) |
| Conversion of preferred stock into common stock | 10,493 | — | — | — | — | — |
| Reclassification of warrants to equity | — | — | 7,623 | — | — | 7,623 |
| Conversion of warrants into common stock | 660,045 | — | — | — | — | — |
| Balance March 31, 2023 | 1,206,932 | \$ — | \$ 287,529 | \$ 37 | \$ (273,902) | \$ 13,664 |

See notes to the condensed consolidated financial statements

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

| | Three months ended | |
|---|--------------------|------------------|
| | March 31, | |
| | 2023 | 2022 |
| Operating Activities: | | |
| Net loss | \$ (6,485) | \$ (4,473) |
| Adjustments to reconcile net loss to cash flows used in operating activities: | | |
| Depreciation and amortization | 86 | 105 |
| Stock-based compensation expense, net | 181 | 241 |
| Change in fair value of warrant liability | 755 | — |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 105 | (201) |
| Inventory, net | (81) | (451) |
| Other current assets | (81) | (22) |
| Other assets and liabilities | (16) | (80) |
| Accounts payable and accrued expenses | (570) | 54 |
| Net cash used in operating activities | (6,106) | (4,827) |
| Investing Activities: | | |
| Additions to intangible assets | (85) | — |
| Purchases of property and equipment | (13) | (70) |
| Net cash used in investing activities | (98) | (70) |
| Financing Activities: | | |
| Issuance costs related to 2022 common stock offering | (11) | — |
| Payments on finance lease liability | — | (6) |
| Net cash used in financing activities | (11) | (6) |
| Effect of exchange rate changes on cash | (7) | (2) |
| Net decrease in cash and cash equivalents | (6,222) | (4,905) |
| Cash and cash equivalents - beginning of period | 17,737 | 24,205 |
| Cash and cash equivalents - end of period | \$ 11,515 | \$ 19,300 |

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, 2022, 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, 2022.

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, 2022, and 2021 and through March 31, 2023, the Company incurred losses from operations and net cash outflows from operating activities as disclosed in the consolidated statements of operations and cash flows, respectively. As of March 31, 2023, the Company had an accumulated deficit of \$273.9 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 expanding its sales and marketing capabilities, purchasing inventory, manufacturing components, and complying with the requirements related to being a U.S. public company. To become and remain profitable, the Company must succeed in expanding the adoption and market acceptance of the Aquadex System. This will require the Company to succeed in training personnel at hospitals and in outpatient care settings, and effectively and efficiently manufacturing, marketing and distributing the Aquadex System and related components. There can be no assurance that the Company will succeed in these activities, and it may never generate revenues sufficient to achieve profitability.

During 2022, the Company closed on underwritten public equity offerings for aggregate net proceeds of approximately \$9.4 million after deducting the underwriting discounts and commissions and other costs associated with the offerings. See Note 3—Stockholders’ Equity for additional related disclosures. The Company will require additional funding to grow its Aquadex Business, which may not be available on terms favorable to the Company, or at all. The Company may receive those funds from the proceeds from future warrant exercises, issuances of equity securities, or other financing transactions.

On March 3, 2023, we entered into a Sales Agreement with Ladenburg Thalmann & Co. Inc. (“Ladenburg”) to create an at-the-market offering program under which we may offer and sell shares having an aggregate offering price of up to \$10.0 million. Ladenburg is entitled to a commission at a fixed rate equal to 3% of the gross proceeds.

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

Revenue Recognition: The Company recognizes revenue in accordance with Accounting Standards Codification, Topic 606, Revenue from Contracts with Customers, which the Company adopted effective January 1, 2018. Accordingly, the Company recognizes revenue when its customers obtain control of its products or services, in an amount that reflects the consideration that the Company expects to receive in exchange for those goods and services. See Note 2 – Revenue Recognition below for additional disclosures. For the three months ended March 31, 2023, two customers represented 14% and 13% of net sales. For the three months ended March 31, 2022, two customers represented 14% and 10% of net sales.

Accounts Receivable: Accounts receivable are unsecured, are recorded at net realizable value, and do not bear interest. The Company makes judgments as to its ability to collect outstanding receivables based upon significant patterns of collectability, historical experience, and management’s evaluation of specific accounts and will provide an allowance for credit losses when collection becomes doubtful. The Company performs credit evaluations of its customers’ financial condition on an as-needed basis. Payment is generally due 30 days from the invoice date and accounts past 30 days are individually analyzed for collectability. When all collection efforts have been exhausted, the account is written off against the related allowance. To date the Company has not experienced any write-offs or significant deterioration of the aging of its accounts receivable, and therefore, no allowance for doubtful accounts was considered necessary as of March 31, 2023, or December 31, 2022. As of March 31, 2023, three customers represented 17%, 11% and 10% of the accounts receivable balance. As of December 31, 2022, one customer represented 13% of the accounts receivable balance.

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

| (in thousands) | March 31, 2023 | December 31, 2022 |
|--------------------|-------------------|----------------------|
| Finished Goods | \$ 1,185 | \$ 993 |
| Work in Process | 172 | 204 |
| Raw Materials | 1,523 | 1,609 |
| Inventory Reserves | (138) | (145) |
| Total | <u>\$ 2,742</u> | <u>\$ 2,661</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:

| | March 31 | |
|--------------------------------------|-----------------|---------------|
| | 2023 | 2022 |
| Stock options | 105,296 | 11,747 |
| Warrants to purchase common stock | 19,190 | 16,317 |
| Series F convertible preferred stock | 5,080 | 508 |
| Total | <u>129,566</u> | <u>28,572</u> |

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

| <i>(in thousands, except per share amounts)</i> | 2023 | 2022 |
|---|------------------|-------------------|
| Net loss | \$ (6,485) | \$ (4,473) |
| Weighted average shares outstanding | 1,126 | 105 |
| Basic and diluted loss per share | <u>\$ (5.76)</u> | <u>\$ (42.45)</u> |

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

Note 2 – Revenue Recognition

Net Sales: The Company sells its products in the United States primarily through a direct 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, Brazil, Colombia, The Czech Republic, Germany, Greece, Hong Kong, India, Israel, Italy, Panama, Romania, Singapore, Slovakia, Spain, Switzerland, Thailand, United Arab Emirates, and the United Kingdom. These distributors resell the Company's products to hospitals and clinics in their respective geographies.

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

Revenue is measured as the amount of consideration we expect to receive, adjusted for any applicable estimates of variable consideration and other factors affecting the transaction price, which is based on the invoiced price, in exchange for transferring products. All revenue is recognized when the Company satisfies its performance obligations under the contract. The majority of the Company's contracts have a single performance obligation and are short term in nature. The Company has entered into extended service plans with customers whose related revenue is recognized over time. This revenue represents less than 1% of net sales for the three months ended March 31, 2023, and 2022. The unfulfilled performance obligations related to these extended service plans are included in deferred revenue, which is included in other current liabilities on the consolidated balance sheets. The majority of the deferred revenue is expected to be recognized within one year.

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

Product Returns: The Company offers customers a limited right of return for its 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 not received any returns to date and believes that future returns of its products will be minimal. Therefore, revenue recognized is not currently impacted by variable consideration related to product returns.

Note 3 – Stockholders’ Equity

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

The offering was comprised of Series F convertible preferred stock, convertible into shares of the Company’s common stock at a conversion price of \$189,000 per share. Each share of Series F convertible preferred stock was accompanied by a Series 1 warrant, which was to expire on the first anniversary of its issuance, to purchase 16 shares of the Company’s common stock at an exercise price of \$189,000 per share, and a Series 2 warrant, which expires on the seventh anniversary of its issuance, to purchase 4 shares of the Company’s common stock at an exercise price of \$189,000 per share. The Series F convertible preferred stock has full ratchet price-based anti-dilution protection, subject to customary carve-outs, in the event of a down-round financing at a price per share below the conversion price of the Series F convertible preferred stock (which protection will expire if, during any 20 of 30 consecutive trading days, the volume weighted average price of the Company’s common stock exceeds 300% of the then-effective conversion price of the Series F convertible preferred stock and the daily dollar trading volume for each trading day during such period exceeds \$200,000). The exercise price of the warrants is fixed and does not contain any variable pricing features, nor any price-based anti-dilutive features, apart from customary adjustments for stock splits, combinations, reclassifications, stock dividends or fundamental transactions. A total of 18,000 shares of Series F convertible preferred stock convertible into 96 shares of common stock and warrants to purchase 191 shares of common stock were issued in the offering.

Effective March 12, 2019, the conversion price of the Series F convertible preferred stock was reduced from \$89,040 to \$15,750, the per share price to the public of the Series G convertible preferred stock issued in the March 2019 Offering. Effective October 25, 2019, the conversion price of the Series F convertible preferred stock was reduced from \$15,750 to \$4,230, and on November 6, 2019, from \$4,230 to \$2,983, the per share price to the public in the October and November 2019 transactions, respectively. Effective January 28, 2020, the conversion price of the Series F convertible preferred stock was reduced from \$2,983 to \$1,650, the per share price to the public of the Series H convertible preferred stock which closed in an underwritten public offering on January 28, 2020, described below. Effective March 23, 2020, the conversion price of the Series F convertible preferred stock was reduced from \$1,650 to \$900, the per share price to the public in the March 2020 transaction, described below. In connection with the September 2021 offering, the conversion price of the Series F convertible preferred stock was reduced from \$550 to \$250, the per share price to the public in the September 2021 offering, described below. In connection with the October 2022 offering, the conversion price of the Series F convertible preferred stock was reduced from \$250 to \$25, the per share price to the public in the October 2022 offering, described below.

As of March 31, 2023, and December 31, 2022, 127 shares of the Series F convertible preferred stock remained outstanding.

March 2021 Offering: On March 19, 2021, the Company closed on an underwritten public offering of 37,958 shares of common stock, for gross proceeds of approximately \$20.9 million (the “March 2021 Offering”). Net proceeds totaled approximately \$18.9 million after deducting the underwriting discounts and commissions and other costs associated with the offering and after giving effect to the underwriters’ full exercise of their overallotment option.

In connection with the March 2021 Offering, the conversion price of the Series F convertible preferred stock was reduced from \$900 to \$550, the per share price to the public in the March 2021 Offering. In addition, the exercise price of the common stock warrants issued in connection with the January 2020 Offering was reduced from \$900 to \$550, the per share price to the public in the March 2021 Offering.

September 2021 Offering: On September 17, 2021, the Company closed on an underwritten public offering of 40,056 shares of common stock, for gross proceeds of approximately \$10.0 million (the “September 2021 Offering”). Net proceeds totaled approximately \$9.0 million after deducting the underwriting discounts and commissions and other costs associated with the offering and after giving effect to the underwriters’ full exercise of their overallotment option.

In connection with the September 2021 Offering, the conversion price of the Series F convertible preferred stock was reduced from \$550 to \$250, the per share price to the public in the September 2021 Offering. In addition, the exercise price of the common stock warrants issued in connection with the January 2020 Offering was reduced from \$550 to \$250, the per share price to the public in the September 2021 Offering.

October 2022 Offering: On October 18, 2022, the Company closed on an underwritten public offering of 209,940 shares of common stock and 23,157,124 shares of Series I convertible preferred stock, for gross proceeds of approximately \$11.0 million (the “October 2022 Offering”). Net proceeds totaled approximately \$9.4 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.

The offering was comprised of (1) 209,940 Class A Units, priced at a public offering price of \$25 per Class A Unit, with each Class A Unit consisting of one share of common stock and 1.5 warrants to purchase one share of common stock at an exercise price of \$25 per share, and (2) 23,157,124 Class B Units, priced at a public offering price of \$0.25 per Class B Unit, with each Class B Unit consisting of one share of Series I convertible preferred stock, convertible into one share of common stock for every one hundred shares of Series I convertible preferred stock, and 1.5 warrants to purchase one share of common stock for every one hundred shares of Series I convertible preferred stock. The warrants included a cashless exercise provision that upon becoming exercisable, the warrant holders could exercise the warrants for common stock at a \$0.00 exercise price.

The warrants became exercisable beginning on the effective date of a reverse stock split in an amount sufficient to permit the exercise in full of the warrants, contingent upon stockholder approval of (i) such reverse stock split and (ii) of the exercisability of the warrants under Nasdaq rules, and they expire on the sixth anniversary of the initial exercise date.

On December 8, 2022, following a special meeting of stockholders, the Company’s board of directors approved a one-for-one hundred reverse stock split of the Company’s issued and outstanding shares of common stock (the “**Reverse Stock Split**”). On December 9, 2022, 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 effect the Reverse Stock Split. The Reverse Stock Split became effective as of 5:00 p.m. Eastern Time on December 9, 2022, and the Company’s common stock began trading on a split-adjusted basis when the market opened on December 12, 2022. The conversion price of the preferred stock issued in the October 2022 transaction was

fixed and does not contain any variable pricing feature or any price-based anti-dilutive feature. The preferred stock issued in this transaction includes a beneficial ownership blocker but has no dividend rights (except to the extent that dividends are also paid on the common stock) or liquidation preference and, subject to limited exceptions, has no voting rights. The securities comprising the units are immediately separable and were issued separately. This reverse stock split did not change the par value of the Company's common stock or the number of common or preferred shares authorized by the Company's Fourth Amended and Restated Certificate of Incorporation, as amended. All share and per-share amounts have been retroactively adjusted to reflect the reverse stock splits for all periods presented.

On January 4, 2023, stockholder approval was secured by the Company for the exercisability of the common stock warrants. Upon stockholder approval, the warrants were determined to be equity-classified warrants. Concurrent with stockholder approval, the warrants were marked to market, then reclassified to the equity section of the balance sheet. Through March 31, 2023, 660,046 common stock warrants had converted into 660,046 shares of common stock at a \$0.00 exercise price, with no proceeds received by the Company.

In connection with the October 2022 Offering, the conversion price of the Series F convertible preferred stock was reduced from \$250 to \$25, the per-share price to the public in the October 2022 Offering. In addition, the exercise price of the common stock warrants issued in connection with the January 2020 Offering was reduced from \$250 to \$25, the per-share price to the public in the October 2022 Offering.

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

Market-Based Warrants: On May 30, 2019, the Company granted a market-based warrant to a consultant in exchange for investor relations services. The warrant represents the right to acquire up to 33 shares of the Company’s common stock at an exercise price of \$9,540 per share, based on the closing stock price of the Company’s common shares on May 30, 2019. The warrant is subject to a vesting schedule based on the Company achieving certain market stock prices within a specified period of time. The warrant expires on May 30, 2024. None of these warrants had vested as of March 31, 2023.

Note 4 - Stock-Based Compensation

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

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

| (in thousands) | Three-months ended March 31, | |
|---|------------------------------|---------------|
| | 2023 | 2022 |
| Selling, general and administrative expense | \$ 172 | \$ 214 |
| Research and development expense | 9 | 27 |
| Total stock-based compensation expense | \$ 181 | \$ 241 |

Note 5—Fair Value of Financial Instruments

The Company’s financial instruments consist of cash and cash equivalents, marketable securities, 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.

All cash equivalents and marketable securities are considered Level 1 measurements for all periods presented.

The available-for-sale marketable securities primarily consist of investment-grade, U.S. dollar-denominated fixed and floating-rate debt, measured at fair value on a recurring basis.

| (in thousands) | March 31, 2023 | | December 31, 2022 | |
|-----------------------|----------------|---------|-------------------|---------|
| | Fair Value | Level 1 | Fair Value | Level 1 |
| Marketable securities | \$ 575 | \$ 575 | \$ 569 | \$ 569 |

The fair value of the Company’s common stock warrant liability related to the investor warrants issued in the October 2022 public offering 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 |
| Balance at January 4, 2023 (revaluation date) | 7,623 |
| Warrants reclassified to equity | (7,623) |
| Balance at March 31, 2023 | \$ — |

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 March 31, 2023, 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, 2022.

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 of our functional departments. Monthly rent and common area maintenance charges, including estimated property tax for our headquarters, total approximately \$31,000. The lease contains provisions for annual inflationary adjustments. Rent expense is being recorded on a straight-line basis over the term of the lease. Beginning on April 1, 2022, the annual base rent is \$10.50 per square foot, subject to annual increases of \$0.32 to \$0.34 per square foot.

Note 8—Finance Lease Liability

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

Note 9—Commitments and Contingencies

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

Non-refundable Technology License Fee: On June 24, 2021, the Company entered into a research and development collaboration agreement with Koronis Biomedical Corporation (“KBT”) to design and develop an integrated continuous renal replacement therapy device. This agreement became effective on August 5, 2021, when KBT received approval of a \$1.7 million grant from the National Institutes of Health (“NIH”) to support this project. As part of this agreement, the Company pays KBT a non-refundable technology license fee of \$428,160, payable in twelve equal monthly installments commencing on June 1, 2022. The Company has recorded a liability for the non-refundable technology license fee of \$71,360 included in Current Accounts Payable at March 31, 2023. The full amount of \$428,160 was expensed and included in Research and Development Expense for the year ended December 31, 2021.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our interim condensed consolidated financial statements and related notes included in Part I, Item 1 of this Quarterly Report on Form 10-Q and the audited consolidated financial statements and related notes and Management’s Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the year ended December 31, 2022. 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, 2022 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.

Impact of COVID-19 Pandemic

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

Several hospitals in the U.S. initially included the Aquadex System in their treatment protocol for fluid management of COVID-19, especially when dialysis equipment and staff were limited, but treatment regimens subsequently evolved so that the need to restore fluid balance became less prevalent. However, we also experienced changes to our sales practices due to restrictions on hospital access and believe that revenue in other areas was negatively impacted by these restrictions. In addition, the disruption created by COVID-19 created significant uncertainty about our ability to access the capital markets in future periods. As of the filing date of this Form 10-Q, while we are not currently experiencing direct effects of the COVID-19 pandemic, the extent to which COVID-19 or a future pandemic outbreak may impact our financial condition or results of operations or guidance is uncertain and cannot be reasonably estimated but could be material and last for an extended period of time. The effect of the COVID-19 pandemic may not be fully reflected in our results of operations and overall financial performance until future periods. See Part 1, Item 1-A “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2022.

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, 2022.

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, 2022.

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 March 31, 2023, 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.

Accounting for Warrants: We have issued and may continue to issue warrants to purchase shares of common stock through our public and private offerings. 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 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 months ended March 31, 2023 or the year ended December 31, 2022.

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, 2022 and 2021, and through March 31, 2023, we incurred losses from operations and net cash outflows from operating activities as disclosed in the consolidated statements of operations and cash flows, respectively. As of March 31, 2023, we had an accumulated deficit of \$273.9 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 expanding our sales and marketing capabilities, purchasing inventory and manufacturing components, investing in clinical research, 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 2022, we closed on an underwritten public offering for aggregate net proceeds of approximately \$9.4 million after deducting the underwriting discounts and commissions and offering expenses. See Note 4 – Stockholders' Equity, to the consolidated financial statements included in Part II, Item 8 of our Annual Report on Form 10-K for the year ended December 31, 2022. 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.

We believe that our existing capital resources will be sufficient to support our operating plan through December 31, 2023; however, there can be no assurance of this. We 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

In June 2016, the FASB issued Accounting Standards Update (ASU) 2016-13, "Financial Instruments – Credit Losses." This ASU added a new impairment model (known as the current expected credit loss ("CECL") model) that is based on expected losses rather than incurred losses. Under the new guidance, an entity recognizes as an allowance its estimate of expected credit losses. The CECL model applies to most debt instruments, trade receivables, lease receivables, financial guarantee contracts, and other loan commitments. The CECL model does not have a minimum threshold for recognition of impairment losses, and entities will need to measure expected credit losses on assets that have a low risk of loss. As a smaller reporting company pursuant to Rule 12b-2 of the Securities Exchange Act of 1934, as amended, these changes became effective for the Company on January 1, 2023. The adoption of ASU 2016-13 did not have any impact on the Company's consolidated 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. As of March 31, 2023, we had an accumulated deficit of \$273.9 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 March 31, 2023, to Three Months Ended March 31, 2022****Net Sales***(in thousands)*

| Three Months Ended March 31, 2023 | Three Months Ended March 31, 2022 | Increase (Decrease) | % Change |
|--------------------------------------|--------------------------------------|---------------------|----------|
| \$ 1,826 | \$ 1,926 | \$ (100) | (5.2)% |

Revenue is generated mainly from the sale of disposable blood filters and catheters used in conjunction with the Aquadex System consoles. We sell primarily in the United States to hospitals and clinics through our direct salesforce. We sell outside of the United States to independent specialty distributors, who in turn sell to hospitals and clinics in their geographic regions. The slight decrease in sales in the current year period is due to decreased utilization in our top accounts and lower order volume from our Pediatrics customers.

Costs and Expenses

Our costs and expenses were as follows:

(in thousands)

| | Three Months Ended March 31, 2023 | Three Months Ended March 31, 2022 | Increase (Decrease) | % Change |
|-------------------------------------|--|--|------------------------|----------|
| Cost of goods sold | \$ 759 | \$ 824 | \$ (65) | (7.9)% |
| Selling, general and administrative | \$ 5,490 | \$ 4,412 | \$ 1,078 | 24.4% |
| Research and development | \$ 1,428 | \$ 1,106 | \$ 322 | 29.1% |

Cost of Goods Sold

The increase in gross margin percent for the three months ended March 31, 2023, compared to the three months ended March 31, 2022, was due primarily to increased selling prices and, to a lesser extent, favorable product and geographic mix.

Selling, General and Administrative

The increase in selling, general and administrative expense primarily reflects increased staffing expenses and increased professional fees related to consulting, marketing initiatives, and accounting and legal expenses associated with the Company's year-end audit and at-the-market offering filed in March 2023.

Research and Development

The increase in R&D expenses was primarily driven by increased spending on new product development associated with our pediatric dedicated device.

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 209,940 shares of common stock and 23,157,124 shares of Series I convertible preferred stock, for gross proceeds of approximately \$11.0 million (the "October 2022 Offering"). Net proceeds totaled approximately \$9.4 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.

As of March 31, 2023 and December 31, 2022, cash and cash equivalents were \$11.5 million and \$17.7 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 \$6.1 million and \$4.8 million for the three months ended March 31, 2023, and 2022, 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 (in the current year period), and the effects of changes in operating assets and liabilities, including working capital.

Cash Flows used in Investing Activities

Net cash used in investing activities was \$98,000 and \$70,000 for the three months ended March 31, 2023, and March 31, 2022, respectively. The cash used in investing activities was for legal costs related to new patent applications and for the purchase of manufacturing, laboratory, and office equipment, respectively, in those periods.

Cash Flows used in Financing Activities

Net cash used in financing activities was \$11,000 and \$6,000 for the three months ended March 31, 2023, and 2022, respectively. The use of cash in the current year period related to public offering financing costs. The use of cash in the prior year period related to lease payment expense.

Capital Resource Requirements

As of March 31, 2023, we did not have any material commitments for capital expenditures.

Off-Balance Sheet Arrangements

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

Forward-Looking Statements and Risk Factors

Certain statements in this Quarterly Report on Form 10-Q are forward-looking statements within the meaning of the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (“Exchange Act”), that are based on management’s beliefs, assumptions and expectations and information currently available to management. All statements that address future operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation, our expectations regarding the potential impacts of the COVID-19 pandemic on our business operations, cash flow, business development, and employees, our ability to execute on our strategic realignments, our post-market clinical data collection activities, benefits of our products to patients, our expectations with respect to product development and commercialization efforts, our ability to increase market and physician acceptance of our products, potentially competitive product offerings, the possibility that we may be unable to raise sufficient funds necessary for our anticipated operations, intellectual property protection, our ability to integrate acquired businesses, our expectations regarding anticipated synergies with and benefits from acquired businesses and other risks and uncertainties described in our filings with the SEC. In some cases, you can identify forward-looking statements by the following words: “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “ongoing,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. Management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on forward-looking statements because they speak only as of the date when made. We undertake no obligation to revise any forward-looking statements in order to reflect events or circumstances that might subsequently arise. Forward-looking statements are subject to a number of risks and uncertainties that could cause actual events to adversely differ from the expectations indicated in these forward-looking statements, including without limitation, the risks and uncertainties described in our Annual Report on Form 10-K for the fiscal year ended December 31, 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 March 31, 2023. We operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for us to predict all risk factors and uncertainties. We may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including without limitation, the possibility that regulatory authorities do not accept our application or approve the marketing of our products, the possibility we may be unable to raise the funds necessary for the development and commercialization of our products, and those described in our filings with the SEC.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

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

As of March 31, 2023, the end of the period covered by this report, we conducted an evaluation, under the supervision and with the participation of management, including the Certifying Officers, of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their stated objectives. Based on their evaluation, our Chief Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2023.

Changes in Internal Controls over Financial Reporting

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

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently subject to any legal proceedings.

ITEM 1A. RISK FACTORS

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

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

Exhibit Index
Nuwellis, Inc.
Form 10-Q for the Quarterly Period Ended March 31, 2023

| 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 | Form of Certificate of Designation of Series A Junior Participating Preferred Stock | 8-K | 001-35312 | June 14, 2013 | 3.1 | | |
| 3.10 | Form of Certificate of Designation of Preferences, Rights and Limitations of Series F Convertible Preferred Stock | S-1/A | 333-221010 | November 17, 2017 | 3.7 | | |
| 3.11 | Form of Certificate of Designation of Preferences, Rights and Limitations of Series I Convertible Preferred Stock | 8-K | 001-35312 | October 18, 2022 | 3.1 | | |
| 3.12 | Third 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 Third Amended and Restated Bylaws | 8-K | 001-35312 | October 5, 2022 | 3.1 | | |
| 10.1 | Second Amendment to 2021 Inducement Plan | 8-K | 000-35312 | March 1, 2023 | 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 | |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document | | | | | X | |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document | | | | | X | |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document | | | | | X | |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document | | | | | X | |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101) | | | | | X | |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Nuwellis, Inc.

Date: May 9, 2023

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

Date: May 9, 2023

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

CHIEF EXECUTIVE OFFICER'S 302 CERTIFICATION

I, Nestor Jaramillo, Jr., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Nuwellis, Inc. for the quarterly period ended March 31, 2023;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2023

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

CHIEF FINANCIAL OFFICER'S 302 CERTIFICATION

I, Lynn Blake, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Nuwellis, Inc. for the quarterly period ended March 31, 2023.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2023

/s/ Lynn Blake
Lynn Blake
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 March 31, 2023, 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: May 9, 2023

/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 March 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "**Report**"), I, Lynn Blake, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: May 9, 2023

/s/ Lynn Blake
Lynn Blake
Chief Financial Officer
