

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

**FORM S-1
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933**

Nuwellis, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

3845
(Primary Standard Industrial
Classification Code Number)

68-0533453
(I.R.S. Employer
Identification Number)

**12988 Valley View Road
Eden Prairie, Minnesota 55344
(952) 345-4200**

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant’s Principal Executive Offices)

**Nestor Jaramillo, Jr.
Chief Executive Officer
Nuwellis, Inc.
12988 Valley View Road
Eden Prairie, Minnesota 55344
(952) 345-4200**

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement is declared effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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 | <input type="checkbox"/> | Accelerated filer | <input type="checkbox"/> |
| Non-accelerated filer | <input checked="" type="checkbox"/> | Smaller reporting company | <input checked="" type="checkbox"/> |
| | | Emerging growth company | <input type="checkbox"/> |

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 7(a)(2)(B) of the Securities Act.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. The securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. The preliminary prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED NOVEMBER 15, 2024

PRELIMINARY PROSPECTUS



NUWELLIS, INC.

Up to 3,734,511 Shares of Common Stock Offered by the Selling Securityholders

This prospectus relates to the offer and resale from time to time of up to 3,734,511 shares of our common stock, par value \$0.0001 per share (the “common stock”) issuable upon (i) the exercise of Series I common stock purchase warrants issued on November 6, 2024 (“Series I Warrants”) in a private placement, (ii) the exercise of Series II common stock purchase warrants issued on November 6, 2024 (“Series II Warrants”) in a private placement, (iii) the exercise of common stock purchase warrants issued on November 6, 2024 to the Company’s placement agent (the “November PA Warrants”), and (iv) the exercise of common stock purchase warrants issued to the Company’s placement agent on August 26, 2024 (the “August PA Warrants,” together with the November PA Warrants, the “PA Warrants”). The Series I Warrants and Series II Warrants were issued to investors in consideration for such investors exercising their common stock purchase warrants issued on April 30, 2024 pursuant to the terms of a warrant inducement offer letter (the “Inducement Letters”) with certain investors to immediately exercise their warrants issued on April 30, 2024.

We are registering the 3,734,511 shares of our common stock on behalf of the selling securityholders identified in the “Selling Securityholders” section of this prospectus or their permitted pledgees, assignees and successors-in-interest (the “Selling Securityholders”) pursuant to the Inducement Letters. The Selling Securityholders may offer, sell or distribute the shares of our common stock in a number of different ways and at varying prices. We provide more information about how the Selling Securityholders may offer, sell or distribute the shares of our common stock in the section of this prospectus titled “Plan of Distribution” beginning on page [16](#). We will not receive any of the proceeds from the sale of shares of our common stock by the Selling Securityholders; however, we will receive proceeds from the exercise of any Series I Warrants, Series II Warrants and PA Warrants for cash. We have paid or will pay the fees and expenses incident to the registration of the shares of our common stock for sale by the Selling Securityholders. The Selling Securityholders will bear all commissions, discounts, brokerage fees and similar expenses, if any, attributable to their sales of shares of our common stock.

Our common stock is listed on the Nasdaq Capital Market (“Nasdaq”) under the symbol “NUWE.” On November 14, 2024, the last reported sale price of our common stock on Nasdaq was \$1.78 per share.

We are a “smaller reporting company” as defined under U.S. federal securities laws and, as such, have elected to comply with reduced public company reporting requirements. See “Prospectus Summary — Implications of Being a Smaller Reporting Company.” This prospectus complies with the requirements that apply to an issuer that is a smaller reporting company.

This registration statement (the “Registration Statement”) to which this prospectus relates registers the resale of a substantial number of shares of our common stock by the Selling Securityholders. Sales in the public market of a large number of shares of our common stock, or the perception in the market that holders of a large number of shares of our common stock intend to sell shares, could reduce the market price of our common stock.

An investment in our shares of common stock involves a high degree of risk. Before making any investment decision, you should carefully read the discussion of the material risks of investing in our shares of common stock in “Risk Factors” beginning on page [6](#) of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is _____, 2024

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-1 that we filed with the Securities and Exchange Commission (the “SEC”). The Selling Securityholders named in this prospectus may, from time to time, sell or otherwise distribute the shares of common stock offered by them as described in the section titled “Plan of Distribution” beginning on page 16 of this prospectus. We will not receive any of the proceeds from the sale of shares of our common stock by the Selling Securityholders; however, we will receive proceeds from the exercise of any Series I Warrants, Series II Warrants and PA Warrants for cash. You should read this prospectus together with the more detailed information regarding the Company, our common stock, and our financial statements and notes to those statements that appear elsewhere in this prospectus and any applicable prospectus supplement together with the additional information that we incorporate in this prospectus by reference, which we describe under the heading “Where You Can Find More Information.”

Neither we nor the Selling Securityholders have authorized anyone to provide you with any information or to make any representations other than those contained in this prospectus or any applicable prospectus supplement or any free writing prospectuses prepared by or on behalf of us or to which we have referred you. Neither we nor the Selling Securityholders take responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. The Selling Securityholders are offering to sell, and seeking offers to buy, shares of their common stock only in jurisdictions where it is lawful to do so.

We may also provide a prospectus supplement or post-effective amendment to the Registration Statement to add information to, or update or change information contained in, this prospectus. You should rely only on the information contained in, or incorporated by reference in, this prospectus and in any accompanying prospectus supplement. We have not authorized anyone to provide you with different information from that contained in, or incorporated by reference in, this prospectus. You should not assume that the information in this prospectus or any prospectus supplement is accurate as of any date other than the date on the front of those documents or that any document incorporated by reference is accurate as of any date other than its filing date. You should not consider this prospectus to be an offer or solicitation relating to the shares of common stock in any jurisdiction in which such an offer or solicitation relating to the shares of common stock is not authorized. Furthermore, you should not consider this prospectus to be an offer or solicitation relating to the shares of common stock if the person making the offer or solicitation is not qualified to do so, or if it is unlawful for you to receive such an offer or solicitation.

In this prospectus, we frequently use the terms “we,” “our,” “us,” “Nuwellis,” “Registrant,” and the “Company” to refer to Nuwellis, Inc.

All trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend the use or display of other companies’ trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before deciding to invest in our shares of common stock, you should read this entire prospectus and the documents incorporated by reference herein and therein carefully, including our financial statements and related notes, the information in the section “Risk Factors,” “Where You Can Find More Information,” and “Incorporation of Certain Documents by Reference.”

Company Overview

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

Corporate Information

Nuwellis, Inc. was incorporated in Delaware on August 22, 2002. We began operating our business in November 1999 through Sunshine Heart Company Pty Limited, which dissolved as a wholly owned Australian subsidiary of Nuwellis, Inc in 2020. Our common stock began trading on the Nasdaq on February 16, 2012. Our principal executive offices are located at 12988 Valley View Road, Eden Prairie, Minnesota 55344, and our telephone number is (952) 345-4200. Our website address is www.nuwellis.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) will be made available free of charge on our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. These reports are also available on the SEC’s website, www.sec.gov. The information on, or that may be accessed through, our website is not incorporated by reference into and should not be considered a part of this prospectus supplement or the registration statement of which it forms a part.

Implications of Being a Smaller Reporting Company

We are a “smaller reporting company”, as defined in Rule 12b-2 of the Exchange Act, meaning that the market value of our shares held by non-affiliates is less than \$700 million and our annual revenue was less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our shares held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than \$700 million. As a smaller reporting company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation. Additionally, as a smaller reporting company, we may continue to take advantage of the exception from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended. If investors consider our common stock less attractive as a result of our election to use the scaled-back disclosure permitted for smaller reporting companies, there may be a less active trading market for our common stock and our share price may be more volatile.

| THE OFFERING | |
|--|--|
| Issuer | Nuwellis, Inc. |
| Common stock offered by the Selling Securityholders | Up to 3,734,511 shares of our common stock issuable upon the exercise of the Series I Warrants, Series II Warrants and PA Warrants. |
| Shares of common stock outstanding as of November 8, 2024 | 4,373,968 |
| Terms of the offering | The Selling Securityholders will determine when and how they will dispose of the shares of our common stock registered for under this prospectus for resale. For additional information, see “Plan of Distribution” beginning on page 16 of this prospectus. |
| Use of proceeds | We will not receive any proceeds from the sale of shares of common stock by the Selling Securityholders. We expect to use the net proceeds from the exercise of any Series I Warrants, Series II Warrants, and PA Warrants for working capital and general corporate purposes. |
| Risk Factors | See “Risk Factors” and other information appearing elsewhere in this prospectus for a discussion of risk factors you should carefully consider before deciding whether to invest in our shares of common stock. |
| Market and trading symbol | Our common stock is listed on the Nasdaq Capital Market under the symbol “NUWE.” |

Except as otherwise indicated, all information in this prospectus is based on 4,373,968 shares of common stock outstanding as of November 8, 2024 and excludes the following:

- 3,877 shares of our common stock issuable upon the exercise of outstanding stock options, having a weighted average exercise price of \$518.86 per share;
- 5,303,264 shares of our common stock issuable upon the exercise of outstanding warrants with a weighted-average exercise price of \$12.18 per share;
- 68,961 shares of our common stock issuable upon the conversion of the 127 outstanding shares of our Series F Convertible Redeemable Preferred Stock, par value \$0.0001 per share (the “Series F Convertible Preferred Stock”);
- 67 shares of our common stock issuable upon the conversion of the 95 outstanding shares of our Series J Convertible Redeemable Preferred Stock, par value \$0.0001 per share (the “Series J Convertible Preferred Stock”);
- 23,762 shares of our common stock issuable upon the exercise of 1,920 warrants issued in October 2023 in a best efforts registered public offering; and
- 42,171 shares of our common stock reserved for future issuance under our equity incentive plans.

To the extent that additional shares of common stock are issued upon the exercise of outstanding options or warrants, or the conversion of our outstanding Series F Convertible Preferred Stock, Series J Convertible Preferred Stock, or the vesting of restricted stock units or additional grants are made pursuant to our equity incentive plans, there may be dilution to new investors. All share and per share amounts for all periods presented in this prospectus and the registration statement of which it forms a part have been retroactively adjusted to reflect the reverse stock splits we previously effected, including the most recent reverse stock split effected on June 27, 2024.

SUMMARY OF RISK FACTORS

Our business is subject to a number of risks. The principal factors and uncertainties include, among others:

- We have limited history of operations and limited experience in sales and marketing, and we might be unsuccessful in increasing our sales and cannot assure you that we will ever generate substantial revenue or be profitable.
- We have incurred operating losses since our inception and anticipate that we will continue to incur operating losses in the near-term. To date, we have been funded by equity financings, and although we believe that we will be able to successfully fund our operations, there can be no assurance that we will be able to do so or that we will ever operate profitably. We will need to raise additional capital to fund our operations through May 31, 2025. If additional capital is not available, we will have to delay, reduce or cease operations. These factors raise substantial doubt about the Company's ability to continue as a going concern through the next twelve months.
- Our near-term prospects are highly dependent on revenues from a single product, the Aquadex System. We face significant challenges in expanding market acceptance of the Aquadex System, which could adversely affect our potential sales.
- 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.
- We depend on a limited number of customers, the loss of which, or failure of which to order our products in a particular period, could cause our revenues to decline.
- We have limited commercial manufacturing experience and could experience difficulty in producing commercial volumes of the Aquadex System and related components or may need to depend on third parties for manufacturing.
- We depend upon third-party suppliers, including single source suppliers, making us vulnerable to supply problems and price fluctuations.
- If we cannot develop adequate distribution, customer service and technical support networks, then we may not be able to market and distribute the Aquadex System effectively and our sales will suffer.
- We compete against many companies, some of which have longer operating histories, more established products and greater resources than we do, which may prevent us from achieving further market penetration or improving operating results.
- The competition for qualified personnel is particularly intense in our industry. If we are unable to retain or hire key personnel, we may not be able to sustain or grow our business.
- Significant additional governmental regulation could subject us to unanticipated delays which would adversely affect our sales.
- Product defects, resulting in lawsuits for product liability, could harm our business, results of operations and financial condition.
- We may face significant risks associated with international operations, which could have a material adverse effect on our business, financial condition and results of operations.
- If we are not able to maintain sufficient quality controls, then the approval or clearance of our products by the European Union, the FDA or other relevant authorities could be withdrawn, delayed or denied and our sales will suffer.
- 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.
- If we violate any provisions of the Federal Food, Drug, and Cosmetic Act or any other statutes or regulations, then we could be subject to enforcement actions by the FDA or other governmental agencies.

- We cannot assure you that our products will be safe or that there will not be serious injuries or product malfunctions. Further, we are required under applicable law to report any circumstances relating to our medically approved products that could result in deaths or serious injuries. These circumstances could trigger recalls, class action lawsuits and other events that could cause us to incur expenses and may also limit our ability to generate revenues from such products.
- We face significant uncertainty in the industry due to government healthcare reform.
- We are subject, directly or indirectly, to United States federal and state healthcare fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to, or have not fully complied with such laws, we could face substantial penalties.
- Failure to comply with anti-bribery, anti-corruption, and anti-money laundering laws could subject us to penalties and other adverse consequences.
- If we acquire other businesses, products or technologies, we could incur additional impairment charges and will be subject to risks that could hurt our business.
- We may not be able to protect our intellectual property rights effectively, which could have an adverse effect on our business, financial condition or results of operations.
- Intellectual property litigation could be costly and disruptive to us.
- If we were unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and system could be adversely affected.
- Our products could infringe patent rights of others, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages or limit our ability to commercialize our products.
- We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.
- Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.
- The trading price of our common stock price has been, and could continue to be, volatile.
- The rights of holders of our capital stock will be subject to, and could be adversely affected by, the rights of holders of our outstanding preferred stock and stock that may be issued in the future.
- A more active, liquid trading market for our common stock may not develop, and the price of our common stock may fluctuate significantly.
- If we do not comply with certain tax regulations, including VAT, and similar regulations, we may be subject to additional taxes, customs duties, interest, and penalties in material amounts, which could materially harm our financial condition and operating results.
- Our ability to use U.S. net operating loss carryforwards and other tax attributes might be limited.
- We do not intend to pay cash dividends on our common stock in the foreseeable future.
- There may be future sales of our securities or other dilution of our equity, which may adversely affect the market price of our common stock.

RISK FACTORS

An investment in our shares of common stock involves a high degree of risk. Before you invest you should carefully consider the risks and uncertainties described below, the “Risk Factors” section of our most recent Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2024, June 30, 2024, and September 30, 2024, each of which is incorporated by reference herein, and the other information in or incorporated by reference into this prospectus. Any of the risks and uncertainties set forth herein and therein could materially and adversely affect our business, financial condition, results of operations and prospects, which in turn could materially and adversely affect the trading price or value of our shares of common stock. Additional risks not currently known to us or which we consider immaterial based on information currently available to us may also materially adversely affect us. As a result, you could lose all or part of your investment.

Risk Related to our Common Stock

Sales of substantial amounts of our common stock by a Selling Securityholder or an existing securityholder, or the perception that these sales could occur, could adversely affect the price of our common stock.

The sale by the Selling Securityholders or an existing securityholder of a significant number of shares of common stock could have a material adverse effect on the market price of our common stock. In addition, the perception in the public markets that the Selling Securityholders or an existing securityholder may sell all or a portion of their shares of our common stock as a result of the registration of such shares for resale pursuant to this prospectus could also have a material adverse effect on the market price of our common stock. We cannot predict the effect, if any, that market sales of those shares of our common stock or the availability of those shares of common stock for sale will have on the market price of our common stock. To the extent that shares are sold into the market pursuant to the Registration Statement of which this prospectus forms a part, under Rule 144 or otherwise, particularly in substantial quantities, the market price of our common stock could decline.

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 remained listed and eligible for trading on Nasdaq at least pending the ultimate conclusion of the hearing process.

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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 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. On November 12, 2024, we filed our Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 evidencing compliance with the Stockholder's Equity Requirement. We are awaiting correspondence from 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.

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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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, and the documents that we have filed with the SEC that are incorporated by reference, contain “forward-looking statements” within the meaning of the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”) and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking uncertainties. In some cases, you can identify forward-looking statements by the use of words or phrases such as “anticipates,” “could,” “would,” “should,” “will,” “would,” “may,” “might,” “potential,” “contemplates,” “estimates,” “plans,” “seeks,” “projects,” “predicts,” “targets,” “objectives,” “continuing,” “ongoing,” “expects,” “management believes,” “we believe,” “we intend,” or the negative of these terms, or other comparable terminology intended to identify statements about the future. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this prospectus, and in particular those factors included in the sections entitled “Risk Factors” in this prospectus and in our most recent Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q filed for the periods ended March 31, 2024, June 30, 2024, and September 30, 2024 and other filings we make with the SEC from time to time, which are on file with the SEC and incorporated herein by reference.

Forward-looking statements are based on management’s current expectations, estimates, forecasts and projections about our business and the industry in which we operate, and management’s beliefs and assumptions are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. You should refer to the “Risk Factors” sections of our Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q filed for the periods ended March 31, 2024, June 30, 2024, and September 30, 2024 and other filings we make with the SEC from time to time for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

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 this prospectus. Actual results could differ materially from those contained in forward-looking statements. Many factors could cause actual results to differ materially from those in forward-looking statements, including those matters discussed below, as well as those listed in the “Risk Factors” section contained herein, in any prospectus supplement and any related free writing prospectus, and under similar headings in the other documents that are incorporated by reference into this prospectus.

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.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the Registration Statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and achievements may be different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

USE OF PROCEEDS

We are not selling any shares of common stock under this prospectus and we will not receive any proceeds from the sale of the shares of common stock by the Selling Securityholders. All net proceeds from the sale of the shares of common stock covered by this prospectus will go to the Selling Securityholders. We expect that the Selling Securityholders will sell their shares of common stock as described under “Plan of Distribution” beginning on page [16](#) of this prospectus.

We may receive proceeds from the exercise of any Series I Warrants, Series II Warrants and PA Warrants to the extent that the Series I Warrants, Series II Warrants and PA Warrants are exercised for cash by the Selling Securityholders. If all of the Series I Warrants, Series II Warrants, and PA Warrants were exercised for cash in full, the gross proceeds would be approximately \$7.3 million. We expect to use the net proceeds from the exercise of any Series I Warrants, Series II Warrants and PA Warrants for working capital and general corporate purposes. We can make no assurances that any of the Series I Warrants, Series II Warrants and PA Warrants will be exercised, or if exercised, that they will be exercised for cash, the quantity which will be exercised or in the period in which they will be exercised.

SELLING SECURITYHOLDERS

The shares of common stock being offered by the Selling Securityholders are those issuable to the Selling Securityholders, upon exercise of the Series I Warrants, Series II Warrants and PA Warrants.

We are registering the shares of common stock in order to permit the Selling Securityholders to offer the shares for resale from time to time. The Selling Securityholders may sell all, some or none of their shares of common stock in this offering. For additional information, see the section titled “Plan of Distribution” beginning on page 16 of this prospectus.

The table below lists the Selling Securityholders and other information regarding the beneficial ownership of the shares of common stock by each of the Selling Securityholders as of November 8, 2024. The number of shares of our common stock outstanding as of November 8, 2024 was 4,373,968. The second column lists the number of shares of common stock beneficially owned by each Selling Securityholder prior to the offering, based on its respective ownership of the shares of common stock and securities convertible into shares of common stock within 60 days of November 8, 2024. The third column lists the shares of common stock being offered by this prospectus by the Selling Securityholders. The fourth and fifth columns list the number of shares of common stock owned after the offering and the percentage of common stock owned after the offering, assuming in both cases, the exercise of all 1,832,517 Series I Warrants, all 1,832,517 Series II Warrants, and all 69,477 PA Warrants on that date, without regard to any limitations on the exercise of the Series I Warrants, Series II Warrant, and PA Warrants and the sale of all of the shares of common stock offered by that Selling Securityholder pursuant to this prospectus. Except as otherwise indicated below, based on the information provided to us by the Selling Securityholders, and to the best of our knowledge, no Selling Securityholder is a broker-dealer or an affiliate of a broker-dealer.

| Name of Selling Securityholder | Number of shares of common stock beneficially owned prior to the offering | Maximum number of shares of common stock to be sold pursuant to this prospectus | Number of shares of common stock beneficially owned after the offering | Percentage of shares of common stock beneficially owned after the offering (%) |
|--|---|---|--|--|
| (1) Armistice Capital, LLC | 2,162,714 | 1,190,476 | 972,238 | 11.99 |
| (2) Hudson Bay Master Fund Ltd. | 1,152,987 | 847,618 | 305,367 | 3.77 |
| (3) Bigger Capital Fund, LP. | 603,946 | 291,746 | 312,200 | 3.85 |
| (4) District 2 Capital Fund LP | 1,032,535 | 595,238 | 437,297 | 5.39 |
| (5) Alto Opportunity Master Fund, SPC – Segregated Master Fund Portfolio B | 113,444 | 9,670 | 103,774 | 1.27 |
| (6) L1 Capital Global Opportunities Master Fund | 729,855 | 320,000 | 409,855 | 5.05 |
| (7) Intracoastal Capital, LLC | 612,703 | 260,000 | 352,703 | 4.34 |
| (8) Connective Capital Emerging Energy QP LP | 175,179 | 116,786 | 58,393 | * |
| (9) Connective Capital I QP LP | 50,250 | 33,500 | 16,750 | * |
| (10) Ladenburg Thalmann & Co. Inc. | 27,790 | 27,790 | — | * |
| (11) Nicholas Stergis | 31,652 | 31,652 | — | * |
| (12) David Coherd | 4,193 | 4,193 | — | * |
| (13) Marc Weinberger | 2,096 | 2,096 | — | * |
| (14) Andrew Moorefield | 3,746 | 3,746 | — | * |

* Indicates beneficial ownership of less than one percent.

- (1) The shares of common stock registered hereby were acquired in the November 2024 Warrant Inducement (as defined below) and consist of 595,238 shares of common stock issuable upon the exercise of 595,238 of the Series I Warrants and 595,238 shares of common stock issuable upon the exercise of 595,238 of the Series II Warrants. The Series I Warrants and Series II Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the Selling Securityholder and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. The shares of common stock are directly held by Armistice Capital Master Fund Ltd., a Cayman Islands exempted company (“Master Fund”), and may be deemed to be beneficially owned by: (i) Armistice Capital, LLC (“Armistice Capital”), as the investment manager of Master Fund; and (ii) Steven Boyd, as the Managing Member of Armistice Capital. Armistice Capital has sole voting and dispositive control of the shares reported herein. The address of Master Fund is c/o Armistice Capital, LLC, 510 Madison Avenue, 7th Floor, New York, NY 10022.
- (2) The shares of common stock registered hereby were acquired in the November 2024 Warrant Inducement and consist of 423,809 shares of common stock issuable upon the exercise of 423,809 of the Series I Warrants and 423,809 shares of common stock issuable upon the exercise of 423,809 of the Series II Warrants. The Series I Warrants and Series II Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the Selling Securityholder and its affiliates owning, after exercise, a number of

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- shares of common stock in excess of the beneficial ownership limitation. The shares of common stock are directly held by Hudson Bay Master Fund Ltd, a Cayman Islands exempted company (“Hudson Bay”). Hudson Bay Capital Management LP, the investment manager of Hudson Bay, has sole voting and dispositive control of the shares reported herein. Sander Gerber is the managing member of Hudson Bay Capital GP LLC, which is the general partner of Hudson Bay Capital Management LP. Each of Hudson Bay and Sander Gerber disclaims beneficial ownership of the shares reported herein. The address of Hudson Bay is c/o Hudson Bay Capital Management LP, 28 Havemeyer Place, 2nd Floor, Greenwich, CT, 06830.
- (3) The shares of common stock registered hereby were acquired in the November 2024 Warrant Inducement and consist of 145,873 shares of common stock issuable upon the exercise of 145,873 of the Series I Warrants and 145,873 shares of common stock issuable upon the exercise of 145,873 of the Series II Warrants. The Series I Warrants and Series II Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the Selling Securityholder and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. The shares of common stock are directly held by Bigger Capital Fund, LP, a Delaware limited partnership (“Bigger Capital”), and may be deemed to be beneficially owned by: (i) Bigger Capital GP, LLC, as the general partner of Bigger Capital and (ii) Michael Bigger, as the Managing Member of Bigger Capital GP, LLC. Bigger Capital GP, LLC has sole voting and dispositive control of the shares reported herein. The address of Bigger Capital is 11700 W. Charleston Blvd. #170-659, Las Vegas, Nevada, 89135.
 - (4) The shares of common stock registered hereby were acquired in the November 2024 Warrant Inducement and consist of 297,619 shares of common stock issuable upon the exercise of 297,619 of the Series I Warrants and 297,619 shares of common stock issuable upon the exercise of 297,619 of the Series II Warrants. The Series I Warrants and Series II Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the Selling Securityholder and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. The shares of common stock are directly held by District 2 Capital Fund, LP, a Delaware limited partnership (“District 2 Capital”), and may be deemed to be beneficially owned by: (i) District 2 GP LLC, as the general partner of District 2 Capital and (ii) Michael Bigger, as the Managing Member of District 2 GP LLC. District 2 GP LLC has sole voting and dispositive control of the shares reported herein. The address of District 2 Capital is 14 Wall Street, 2nd Floor, Huntington, New York, 11743.
 - (5) The shares of common stock registered hereby were acquired in the November 2024 Warrant Inducement and consist of 4,835 shares of common stock issuable upon the exercise of 4,835 of the Series I Warrants and 4,835 shares of common stock issuable upon the exercise of 4,835 of the Series II Warrants. The Series I Warrants and Series II Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the Selling Securityholder and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. The shares of common stock are directly held by Alto Opportunity Master Fund, SPC – Segregated Master Fund Portfolio B, a Cayman Islands exempted company (“Alto Opportunity”), and may be deemed to be beneficially owned by: (i) Ayrton Capital, LLC (“Ayrton Capital”), as the investment manager of the Alto Opportunity; and (ii) Waqas Khatri, as the Managing Member of Ayrton Capital. Ayrton Capital has sole voting and dispositive control of the shares reported herein. The address of Alto Opportunity is c/o Ayrton Capital, 55 Post Road West, 2nd Floor, Westport, Connecticut, 06880.
 - (6) The shares of common stock registered hereby were acquired in the November 2024 Warrant Inducement and consist of 160,000 shares of common stock issuable upon the exercise of 160,000 of the Series I Warrants and 160,000 shares of common stock issuable upon the exercise of 160,000 of the Series II Warrants. The Series I Warrants and Series II Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the Selling Securityholder and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. The shares of common stock are directly held by L1 Capital Global Opportunities Master Fund, a Cayman Islands exempted company (“L1 Capital”), and may be deemed to be beneficially owned by: (i) David Feldman and (ii) Joel Arber, each of whom are directors of L1, and have shared voting and shared dispositive control of the shares reported herein. The address of L1 Capital is 161A Shedden Road, 1 Artillery Court, PO Box 10085, Grand Cayman KY1-1001, Cayman Islands.
 - (7) The shares of common stock registered hereby were acquired in the November 2024 Warrant Inducement and consist of 130,000 shares of common stock issuable upon the exercise of 130,000 of the Series I Warrants and 130,000 shares of common stock issuable upon the exercise of 130,000 of the Series II Warrants. The Series I Warrants and Series II Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the Selling Securityholder and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. The shares of common stock are directly held by Intracoastal Capital, LLC, a Delaware limited liability company (“Intracoastal”). Mitchell P. Kopin (“Mr. Kopin”) and Daniel B. Asher (“Mr. Asher”), each of whom are managers of Intracoastal, have shared voting control and investment discretion over the securities reported herein that are held by Intracoastal. As a result, each of Mr. Kopin and Mr. Asher may be deemed to have beneficial ownership (as determined under Section 13(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”)) of the securities reported herein that are held by Intracoastal.
 - (8) The shares of common stock registered hereby were acquired in the November 2024 Warrant Inducement and consist of 58,393 shares of common stock issuable upon the exercise of 58,393 of the Series I Warrants and 58,393 shares of common stock issuable upon the exercise of 58,393 of the Series II Warrants. The Series I Warrants and Series II Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the Selling Securityholder and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. The shares of common stock are directly held by Connective Capital Emerging Energy QP LP, a Delaware limited partnership (“Connective Emerging Energy”), and may be deemed to be beneficially owned by: Robert Romero (“Mr. Romero”), who is the Chief Executive Officer of Connective Capital I, and has sole voting and dispositive control of the shares reported herein. The address of Connective Capital is 720 University Avenue, Suite 100, Palo Alto, CA 94301.
 - (9) The shares of common stock registered hereby were acquired in the November 2024 Warrant Inducement and consist of 16,750 shares of common stock issuable upon the exercise of 16,750 of the Series I Warrants and 16,750 shares of common stock issuable upon the exercise of 16,750 of the Series II Warrants. The Series I Warrants and Series II Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the Selling Securityholder and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. The shares of common stock are directly held by Connective Capital I QP LP, a Delaware limited partnership (“Connective Capital I”), and may be deemed to be beneficially owned by: Robert Romero (“Mr. Romero”), who is the Chief Executive Officer of Connective Capital I, and has sole voting and dispositive control of the shares reported herein. The address of Connective Capital is 720 University Avenue, Suite 100, Palo Alto, CA 94301.
 - (10) The shares of common stock registered hereby were acquired in the (i) August Private Placement (as defined below) and consist of 5,800 shares of common stock issuable upon the exercise of 5,800 of the August PA Warrants and (ii) November 2024 Warrant

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- Inducement and consist of 21,990 shares of common stock issuable upon the exercise of 21,990 of the November PA Warrants. The August PA Warrants and November PA Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the Selling Securityholder and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Ladenburg Thalmann & Co. Inc. is a registered broker dealer with a registered address 640 Fifth Avenue, 4th Floor, New York, NY 10019, and has sole voting and dispositive power over the securities held.
- (11) The shares of common stock registered hereby were acquired in the (i) August Private Placement (as defined below) and consist of 6,913 shares of common stock issuable upon the exercise of 6,913 of the August PA Warrants and (ii) November 2024 Warrant Inducement and consist of 24,739 shares of common stock issuable upon the exercise of 24,739 of the November PA Warrants. The August PA Warrants and November PA Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the Selling Securityholder and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Mr. Stergis is affiliated with Ladenburg Thalmann & Co. Inc., a registered broker dealer with a registered address 640 Fifth Avenue, 4th Floor, New York, NY 10019, and has sole voting and dispositive power over the securities held. The Selling Stockholder acquired the Placement Agent Warrants in the ordinary course of business and, at the time the Placement Agent Warrants were acquired, the Selling Stockholder had no agreement or understanding, directly or indirectly, with any person to distribute such securities.
- (12) The shares of common stock registered hereby were acquired in the (i) August Private Placement (as defined below) and consist of 894 shares of common stock issuable upon the exercise of 894 of the August PA Warrants and (ii) November 2024 Warrant Inducement and consist of 3,299 shares of common stock issuable upon the exercise of 3,299 of the November PA Warrants. The August PA Warrants and November PA Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the Selling Securityholder and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Mr. Coherd is affiliated with Ladenburg Thalmann & Co. Inc., a registered broker dealer with a registered address 640 Fifth Avenue, 4th Floor, New York, NY 10019, and has sole voting and dispositive power over the securities held. The Selling Stockholder acquired the Placement Agent Warrants in the ordinary course of business and, at the time the Placement Agent Warrants were acquired, the Selling Stockholder had no agreement or understanding, directly or indirectly, with any person to distribute such securities.
- (13) The shares of common stock registered hereby were acquired in the (i) August Private Placement (as defined below) and consist of 447 shares of common stock issuable upon the exercise of 447 of the August PA Warrants and (ii) November 2024 Warrant Inducement and consist of 1,649 shares of common stock issuable upon the exercise of 1,649 of the November PA Warrants. The August PA Warrants and November PA Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the Selling Securityholder and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Mr. Weinberger is affiliated with Ladenburg Thalmann & Co. Inc., a registered broker dealer with a registered address 640 Fifth Avenue, 4th Floor, New York, NY 10019, and has sole voting and dispositive power over the securities held. The Selling Stockholder acquired the Placement Agent Warrants in the ordinary course of business and, at the time the Placement Agent Warrants were acquired, the Selling Stockholder had no agreement or understanding, directly or indirectly, with any person to distribute such securities.
- (14) The shares of common stock registered hereby were acquired in the (i) August Private Placement (as defined below) and consist of 447 shares of common stock issuable upon the exercise of 447 of the August PA Warrants and (ii) November 2024 Warrant Inducement and consist of 3,299 shares of common stock issuable upon the exercise of 3,299 of the November PA Warrants. The August PA Warrants and November PA Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the Selling Securityholder and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Mr. Moorefield is affiliated with Ladenburg Thalmann & Co. Inc., a registered broker dealer with a registered address 640 Fifth Avenue, 4th Floor, New York, NY 10019, and has sole voting and dispositive power over the securities held. The Selling Stockholder acquired the Placement Agent Warrants in the ordinary course of business and, at the time the Placement Agent Warrants were acquired, the Selling Stockholder had no agreement or understanding, directly or indirectly, with any person to distribute such securities.

Material Relationships with Selling Securityholders

Below is a description of material relationships in the past three years between the Company, its predecessors or affiliates and the Selling Securityholders.

August 2024 Offering

On August 23, 2024, we entered into a placement agency agreement with the Placement Agent (as defined below) and a securities purchase agreement, dated as of August 23, 2024, by and among us and the purchasers named therein (the “August Purchase Agreement”) with certain purchasers pursuant to which the Company agreed to sell, in a registered direct offering (the “August Registered Offering”), an aggregate of 483,351 shares (the “August Shares”) of the Company’s common stock at a purchase price of \$1.8450 per August Share. The August Shares were sold pursuant to the Company’s effective shelf registration statement on Form S-3 (File No. 333-280647), including a base prospectus contained therein, which was originally filed with the SEC on July 1, 2024, and was declared effective by the SEC on July 9, 2024, and a related prospectus supplement, dated August 23, 2024, related to the August Registered Offering.

Pursuant to the August Purchase Agreement, in a concurrent private placement (the “August Private Placement” and together with the August Registered Offering, the “August 2024 Offering”), the Company also agreed to sell and issue to the purchasers the common stock purchase warrants issued on August 26, 2024 (the “August Warrants”) to purchase up to 483,351 shares of common stock. The August Warrants have an exercise

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price of \$1.72 per share, were immediately exercisable and expire five years following the date of effectiveness of the registration statement for the purposes of registering the shares of common stock underlying the August Warrants. The August Warrants and August PA Warrants were issued to the purchasers, which are institutional accredited investors, in a private placement pursuant to Section 4(a)(2) and Regulation D promulgated under the Securities Act. The August Warrants were registered for resale on September 6, 2024.

Ladenburg Thalmann & Co. Inc. acted as the exclusive placement agent (the “Placement Agent”) in connection with the August 2024 Offering, and as compensation in connection with the August 2024 Offering, we agreed to (i) pay the Placement Agent a cash fee equal to 8.0% of the gross proceeds of the August 2024 Offering, (ii) pay the Placement Agent up to \$90,000 for its expenses in connection with such offering, and (iii) issue the August PA Warrants to purchase up to 14,501 shares of common stock. The August PA Warrants were immediately exercisable, have an exercise price of \$3.04425 per share, and expire five (5) years following the commencement of the sales pursuant to the offering. The shares underlying the August PA Warrants are being offered for resale in this Registration Statement on Form S-1.

November 2024 Warrant Inducement

On November 5, 2024, the Company entered into Inducement Letters with certain investors (the “November 2024 Warrant Inducement”) to immediately exercise approximately 1.8 million of the common stock purchase warrants issued by the Company on April 30, 2024 (the “April 2024 Warrants”) held by such investors. In consideration for exercising the April 2024 Warrants, pursuant to the terms of the Inducement Letters, the Company issued to the investors a new Series I Warrant and a new Series II Warrant, in each case, to purchase up to a number of shares of common stock equal to 100% of the number of shares of common stock issued pursuant to the immediate exercise of the corresponding April 2024 Warrants.

The Series I Warrant has an exercise price of \$1.94, is exercisable six (6) months from the date of issuance and has a term of five (5) years from the date of initial exercise. The Series II Warrant has an exercise price of \$1.94, is exercisable six (6) months from the date of issuance and has a term of two (2) years from the date of initial exercise.

The Series I Warrants, Series II Warrants, and November PA Warrants were issued to the Selling Securityholders, which are institutional accredited investors, in a private placement pursuant to Section 4(a)(2) and Regulation D promulgated under the Securities Act.

Pursuant to the terms of the Inducement Letters, among other things, the Company is required to prepare and file with the SEC a registration statement to register for resale the shares of common stock issuable upon exercise of the Series I Warrants and Series II Warrants. The Company is required to use commercially reasonable efforts to have such registration statement declared effective as promptly as possible thereafter, and in any event no later than 60 days following November 6, 2024, or 90 days in the event of a review by the SEC.

The Placement Agent acted as the exclusive warrant inducement agent in connection with the November 2024 Warrant Inducement, and as compensation in connection with the November 2024 Warrant Inducement, we agreed to (i) pay the Placement Agent a cash fee equal to 8.0% of the gross proceeds of the November 2024 Warrant Inducement, (ii) pay the Placement Agent up to \$90,000 for its expenses in connection with such offering, and (iii) issue the November PA Warrants to purchase up to 54,976 shares of common stock. The November PA Warrants have substantially the same terms as the Series I Warrants described above, except that the November PA Warrants have an exercise price of \$3.465 per share. The shares underlying the November PA Warrants are being offered for resale in this Registration Statement on Form S-1.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of November 8, 2024 by:

- each person, or group of affiliated persons, who we know to beneficially own more than 5% of our common stock;
- each of our named executive officers and directors; and
- all of our executive officers and directors as a group.

The percentage beneficial ownership information shown in the table is based on an aggregate of 4,373,968 shares of our common stock outstanding as of November 8, 2024, assuming no exercise of outstanding options issued under our equity incentive plans and no exercise of warrants, including the Series I Warrants, Series II Warrants and PA Warrants.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to: (i) the exercise of stock options that are either immediately exercisable or exercisable on or before January 7, 2025, which is 60 days after November 8, 2024; (ii) the vesting of restricted stock units on or before January 7, 2025, which is 60 days after November 8, 2024; and (iii) outstanding warrants to purchase common stock held by that person that is either immediately exercisable or exercisable on or before January 7, 2025, which is 60 days after November 8, 2024. These shares are deemed to be outstanding and beneficially owned by the person holding those options, restricted stock units and warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise noted below, the address of each of the individuals and entities named in the table below is c/o Nuwellis, Inc., 12988 Valley View Road, Eden Prairie, MN 55344.

Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

| Name of Beneficial Owner | Number of Shares | Right to Acquire ⁽¹⁾ | Total | Aggregate Percent of Class ⁽²⁾ |
|---|------------------|---------------------------------|--------|---|
| Executive Officers and Directors | | | | |
| John L. Erb | — | 69,028 ⁽³⁾ | 69,028 | 1.6% |
| Michael McCormick | — | 595 | 595 | * |
| Maria Rosa Costanzo, M.D. | — | — | — | — |
| Archelle Georgiou, M.D. | — | 351 | 351 | * |
| Gregory D. Waller | — | 67 | 67 | * |
| David McDonald | — | 351 | 351 | * |
| Robert B. Scott | — | 181 | 181 | * |
| Nestor Jaramillo, Jr. | 117 | 346 | 463 | * |
| Neil P. Ayotte | — | 121 | 121 | * |
| Lynn Blake | 3 | — | 3 | * |
| All current directors and executive officers as a group (9 persons) | 117 | 71,040 | 71,157 | 1.6% |

* Less than one percent.

- (1) Except as otherwise described below, amounts reflect the number of shares that such holder could acquire through (i) the exercise of outstanding stock options, (ii) the vesting/settlement of outstanding RSUs, (iii) the exercise of outstanding warrants to purchase common stock, and (iv) the conversion of outstanding Series F Preferred Stock, in each case within 60 days after November 8, 2024.
- (2) Based on 4,373,968 shares outstanding as of November 8, 2024.
- (3) Consists of (i) 67 shares issuable upon the exercise of outstanding stock options and (ii) 68,961 shares issuable upon conversion of outstanding shares of Series F Convertible Preferred Stock (assuming all 127 shares of Series F Convertible Preferred Stock held by Mr. Erb are converted at once and rounded up to the nearest whole share).

PLAN OF DISTRIBUTION

Each Selling Securityholder and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their shares of common stock covered hereby on the principal trading market or any other stock exchange, market or trading facility on which the shares of common stock are traded or in private transactions. These sales may be at fixed or negotiated prices. A Selling Securityholder may use any one or more of the following methods when selling shares of our common stock:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares of common stock as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- in transactions through broker-dealers that agree with the Selling Securityholders to sell a specified number of such shares of common stock at a stipulated price per share of common stock;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The Selling Securityholders may also sell shares of common stock under Rule 144 or any other exemption from registration under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the Selling Securityholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Securityholders (or, if any broker-dealer acts as agent for the purchaser of shares of our common stock, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2121; and in the case of a principal transaction a markup or markdown in compliance with FINRA Rule 2121.

In connection with the sale of the shares of common stock or interests therein, the Selling Securityholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the shares of common stock in the course of hedging the positions they assume. The Selling Securityholders may also sell shares of common stock short and deliver these shares of common stock to close out their short positions, or loan or pledge the shares of common stock to broker-dealers that in turn may sell these shares of common stock. The Selling Securityholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of the shares of common stock offered by this prospectus, which shares of common stock such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The Selling Securityholders and any broker-dealers or agents that are involved in selling the shares of common stock may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares of common stock purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Securityholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock.

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the shares of common stock. The Company has agreed to indemnify the Selling Securityholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

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The resale shares of common stock will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale of the shares of common stock covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the shares of common stock may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Securityholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the common stock by the Selling Securityholders or any other person. We will make copies of this prospectus available to the Selling Securityholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

DESCRIPTION OF OUR CAPITAL STOCK

The following summary descriptions of our common stock, preferred stock and common warrants are based on the provisions of our certificate of incorporation and bylaws, and the applicable provisions of the Delaware General Corporation Law. This information may not be complete in all respects and is qualified in its entirety by reference to the provisions of our certificate of incorporation, bylaws and the Delaware General Corporation Law. For information on how to obtain copies of our certificate of incorporation and bylaws, see the information below under the heading “Where You Can Find Additional Information.”

Common Stock

Our authorized capital stock consists of 100,000,000 shares of common stock, par value \$0.0001 per share, and 40,000,000 shares of preferred stock, par value \$0.0001 per share, 30,000 of which are designated as Series A Junior Participating Preferred Stock, 18,000 of which are designated Series F Convertible Preferred Stock (the “Series F Preferred Stock”), and 600,000 of which are designated Series J Convertible Preferred Stock (the “Series J Convertible Preferred Stock”) as of September 30, 2024. Once shares of Series F Preferred Stock and Series J Preferred Stock are converted, redeemed or reacquired by us, such shares shall resume the status of authorized but unissued shares of undesignated preferred stock.

As of November 8, 2024, we had (i) 4,373,968 outstanding shares of common stock, (ii) 127 outstanding shares of Series F Preferred Stock, which, at the currently applicable conversion price, would convert into 68,961 shares of common stock, subject to future adjustment, (iii) 95 outstanding shares of Series J Convertible Preferred Stock, which, at the currently applicable conversion price, would convert into 67 shares of common stock, subject to future adjustment, (iv) outstanding options to acquire 3,877 shares of our common stock, (v) outstanding warrants to purchase 5,303,264 shares of our common stock, and (vi) 23,762 shares of common stock underlying the outstanding Series J Convertible Preferred Stock issuable upon the exercise of 1,920 Series J warrants issued in October 2023 in a best efforts registered public offering.

The following description summarizes the most important terms of our capital stock. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description you should refer to our certificate of incorporation, bylaws and certificate of designation of preferences, rights and limitations of Series F Preferred Stock and Series J Preferred Stock, copies of which have been incorporated by reference as exhibits to the registration statement of which this prospectus forms a part, and to the applicable provisions of the DGCL.

Dividends

Holders of our common stock are entitled to receive dividends when and as declared by our board of directors out of funds legally available.

Voting

Holders of our common stock are entitled to one vote for each share on each matter properly submitted to our stockholders for their vote; provided however, that except as otherwise required by law, holders of our common stock will not be entitled to vote on any amendment to our certificate of incorporation (including any certificate of designation filed with respect to any series of preferred stock) that relates solely to the terms of a series of outstanding preferred stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon by law or pursuant to our certificate of incorporation (including any certificate of designation filed with respect to any series of preferred stock).

Subject to the voting restrictions described above, holders of our common stock may adopt, amend or repeal our bylaws and/or alter certain provisions of our certificate of incorporation with the affirmative vote of the holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of our capital stock entitled to vote generally in the election of directors, voting together as a single class, in addition to any vote of the holders of a class or series of our stock required by law or our certificate of incorporation. Those provisions of our certificate of incorporation that may be altered only by the super-majority vote described above relate to:

- the number of directors on our board of directors, the classification of our board of directors and the terms of the members of our board of directors;

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- the limitations on removal of any of our directors described below under “Description of our Capital Stock – Anti-Takeover Effects of Certain Provisions of Our Certificate of Incorporation and Bylaws and Delaware Law;”
- the ability of our directors to fill any vacancy on our board of directors by the affirmative vote of a majority of the directors then in office under certain circumstances;
- the ability of our board of directors to adopt, amend or repeal our bylaws and the super-majority vote of our stockholders required to adopt, amend or repeal our bylaws described above;
- the limitation on action of our stockholders by written action described below under “Description of Capital Stock – Anti-Takeover Effects of Certain Provisions of Our Certificate of Incorporation and Bylaws and Delaware Law;”
- the choice of forum provision described below under “Description of our Capital Stock – Choice of Forum;”
- the limitations on director liability and indemnification described below under the heading “Description of our Capital Stock – Limitation on Liability of Directors and Indemnification;” and
- the super-majority voting requirement to amend our certificate of incorporation described above.

Conversion, Redemption and Preemptive Rights

Holders of our common stock do not have any conversion, redemption or preemptive rights pursuant to our organizational documents.

Liquidation, Dissolution and Winding-up

In the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in any assets remaining after the satisfaction in full of the prior rights of creditors and the aggregate of any liquidation preference pursuant to the terms of any certificate of designations filed with respect to any series of preferred stock, including our outstanding Series F Preferred Stock and Series J Preferred Stock.

Listing

Our common stock is listed on the Nasdaq Capital Market under the symbol “NUWE.”

Preferred Stock

We may issue any class of preferred stock in any series. Our board of directors has the authority to establish and designate series, and to fix the number of shares included in each such series and to determine or alter for each such series, such voting powers, designation, preferences, and relative participating, optional, or other rights and such qualifications, limitations or restrictions thereof. Our board of directors is not restricted in repurchasing or redeeming such stock while there is any arrearage in the payment of dividends or sinking fund installments. Our board of directors is authorized to increase or decrease the number of shares of any series subsequent to the issuance of shares of that series, but not below the number of shares of such series then outstanding. The number of authorized shares of preferred stock may be increased or decreased, but not below the number of shares thereof then outstanding, by the affirmative vote of the holders of a majority of the common stock, without a vote of the holders of the preferred stock, or of any series thereof, unless a vote of any such holders is required pursuant to the terms of any certificate of designation filed with respect to any series of preferred stock.

Prior to issuance of shares of any series of preferred stock, our board of directors is required by Delaware law to adopt resolutions and file a certificate of designation with the Secretary of State of the State of Delaware. The certificate of designation fixes for each class or series the terms, preferences, conversion or other rights, voting powers, restrictions, limitations as to dividends or other distributions, qualifications and terms or conditions of redemption for each class or series. Any shares of preferred stock will, when issued, be fully paid and non-assessable.

Description of Outstanding Warrants

As of November 8, 2024, there were warrants outstanding to purchase a total of 5,303,264 shares of our common stock, which expire between 2024 and 2030. Each of these warrants entitles the holder to purchase one share of common stock at prices ranging from \$1.72 to \$6,615,000 per share. Certain of these warrants have

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a net exercise provision under which its holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of our common stock at the time of exercise of the warrant after deduction of the aggregate exercise price. Each of these warrants also contains provisions for the adjustment of the exercise price and the aggregate number of shares issuable upon the exercise of the warrant in the event of dividends, share splits, reorganizations and reclassifications and consolidations. Certain of these warrants provide that, subject to limited exceptions, a holder will not have the right to exercise any portion of its warrants if the holder, together with its affiliates, would beneficially own over 4.99% of our then outstanding common stock following such exercise; provided, however, that upon prior notice to us, the warrant holder may increase its ownership, provided that in no event will the ownership exceed 9.99%.

November 2024 Private Placement

On November 5, 2024, the Company entered into the November 2024 Warrant Inducement with certain investors to immediately exercise approximately 1.8 million of the April 2024 Warrants held by such investors. In consideration for exercising the April 2024 Warrants, pursuant to the terms of the Inducement Letters, the Company issued to the investors a new Series I Warrant and a new Series II Warrant, in each case, to purchase up to a number of shares of common stock equal to 100% of the number of shares of common stock issued pursuant to the immediate exercise of the corresponding April 2024 Warrants. The Series I Warrants and Series II Warrants were issued to the Selling Securityholders, which are institutional accredited investors, in a private placement pursuant to Section 4(a)(2) and Regulation D promulgated under the Securities Act.

Subject to certain exceptions and pursuant to the terms of the Inducement Letters, for a period of fifteen (15) days following November 5, 2024, the Company agreed not to issue any shares of common stock or securities convertible into or exercisable or exchangeable for, or that would otherwise entitle the holder thereof to receive, common stock. Also, from the date of pricing until February 26, 2025, the Company shall be prohibited from effecting or entering into an agreement to effect any issuance by the Company or any of its subsidiaries of common stock or common stock equivalents (or a combination of units thereof) involving a defined “Variable Rate Transaction,” subject to certain exceptions.

We have agreed to file a registration statement covering the resale of the shares underlying the Series I Warrants and Series II Warrants as soon as practicable (and in any event within 15 days of November 6, 2024). We must use commercially reasonable efforts to cause such registration statement to become effective within 60 days following the closing date of the offering (or, in the event of a review by the SEC, the 90th calendar day following the closing date of the offering) and to keep such registration statement effective at all times until the purchasers no longer own any Series I Warrants, Series II Warrants or November PA Warrants, or the shares underlying such warrants, or the Delegend Date (as defined in the Inducement Letters).

November Series I Warrants and Placement Agent Warrants

Exercisability. The Series I Warrants are exercisable six (6) months from the date of issuance and expire five years following the date of initial exercise. The Series I Warrants are exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the issuance of the common stock underlying the Series I Warrants under the Securities Act is effective and available for the issuance of such shares, or an exemption from registration under the Securities Act is available for the issuance of such shares, by payment in full in immediately available funds for the number of common stock purchased upon such exercise. If at the time of exercise there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the common stock underlying the Series I Warrants, then the Series I Warrants may also be exercised, in whole or in part, at such time by means of a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the Series I Warrant.

Exercise Limitation. A holder will not have the right to exercise any portion of the Series I Warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or 9.99% upon the request of the investor) of the number of shares of common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Series I Warrants. However, any holder may increase or decrease such percentage, provided that any increase will not be effective until the 61st day after such election.

Exercise Price. The Series I Warrants have an exercise price of \$1.94 per share. The exercise price of each warrant is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits,

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stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our shareholders.

Transferability. In accordance with its terms and subject to applicable laws, a Series I Warrant may be transferred at the option of the holder upon surrender of the Series I Warrant to us together with the appropriate instruments of transfer and payment of funds sufficient to pay any transfer taxes (if applicable).

Exchange Listing. There is no established public trading market for the Series I Warrants being issued in the November 2024 Warrant Inducement, and we do not expect a market to develop. We do not intend to apply for listing of the Series I Warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the Series I Warrants will be limited.

Fundamental Transactions. In the event of any fundamental transaction, as described in the Series I Warrants and generally including any merger with or into another entity, sale of all or substantially all of our assets, tender offer or exchange offer, or reclassification of our common stock, then upon any subsequent exercise of a Series I Warrant, the holder will have the right to receive as alternative consideration, for each share of common stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of Common Stock of the successor or acquiring corporation or of our company, if it is the surviving corporation, and any additional consideration receivable upon or as a result of such transaction by a holder of the number of shares of common stock for which the Series I Warrant is exercisable immediately prior to such event. In addition, in the event of a fundamental transaction, we or any successor entity will be required to purchase at a holder's option, exercisable at any time concurrently with or within 30 days after the consummation of the fundamental transaction (or, if later, the date of the public announcement of the applicable fundamental transaction), such holder's Series I Warrants and generally including any merger with or into another entity, sale of all or substantially all of our assets, tender for cash in an amount equal to the value of the remaining unexercised portion of such holder's Series I Warrants, determined in accordance with the Black Scholes option pricing model as more particularly set forth in the Series I Warrants.

Rights as a Shareholder. Except as otherwise provided in the Series I Warrants or by virtue of such holder's ownership of our common stock, the holder of a Series I Warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the Series I Warrant.

Registration Rights. We have agreed to file a registration statement covering the resale of the shares underlying the Series I Warrants as soon as practicable (and in any event within 15 days of November 6, 2024). We must use commercially reasonable efforts to cause such registration statement to become effective within 60 days following the closing date of the offering (or, in the event of a review by the SEC, the 90th calendar day following the closing date of the offering) and to keep such registration statement effective at all times until the purchasers no longer own any Series I Warrants or shares underlying the Series I Warrants.

The November PA Warrants have substantially the same terms as the Series I Warrants described above, except that the November PA Warrants have an exercise price of \$3.465 per share.

Series II Warrants

Exercisability. The Series II Warrants are exercisable six (6) months from the date of issuance and expire two (2) years following the date of initial exercise. The Series II Warrants are exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the issuance of the common stock underlying the Series II Warrants under the Securities Act is effective and available for the issuance of such shares, or an exemption from registration under the Securities Act is available for the issuance of such shares, by payment in full in immediately available funds for the number of common stock purchased upon such exercise. If at the time of exercise there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the common stock underlying the Series II Warrants, then the Series II Warrants may also be exercised, in whole or in part, at such time by means of a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the Series II Warrant.

Exercise Limitation. A holder will not have the right to exercise any portion of the Series II Warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or 9.99% upon the request of the

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investor) of the number of shares of common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Series II Warrants. However, any holder may increase or decrease such percentage, provided that any increase will not be effective until the 61st day after such election.

Exercise Price. The Series II Warrants have an exercise price of \$1.94 per share. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our shareholders.

Transferability. In accordance with its terms and subject to applicable laws, a Series II Warrant may be transferred at the option of the holder upon surrender of the Series II Warrant to us together with the appropriate instruments of transfer and payment of funds sufficient to pay any transfer taxes (if applicable).

Exchange Listing. There is no established public trading market for the Series II Warrants being issued in the November 2024 Warrant Inducement, and we do not expect a market to develop. We do not intend to apply for listing of the Series II Warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the Series II Warrants will be limited.

Fundamental Transactions. In the event of any fundamental transaction, as described in the Series II Warrants and generally including any merger with or into another entity, sale of all or substantially all of our assets, tender offer or exchange offer, or reclassification of our common stock, then upon any subsequent exercise of an Series II Warrant, the holder will have the right to receive as alternative consideration, for each share of common stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of common stock of the successor or acquiring corporation or of our company, if it is the surviving corporation, and any additional consideration receivable upon or as a result of such transaction by a holder of the number of shares of common stock for which the Series II Warrant is exercisable immediately prior to such event. In addition, in the event of a fundamental transaction, we or any successor entity will be required to purchase at a holder's option, exercisable at any time concurrently with or within 30 days after the consummation of the fundamental transaction (or, if later, the date of the public announcement of the applicable fundamental transaction), such holder's Series II Warrants and generally including any merger with or into another entity, sale of all or substantially all of our assets, tender for cash in an amount equal to the value of the remaining unexercised portion of such holder's Series II Warrants, determined in accordance with the Black Scholes option pricing model as more particularly set forth in the Series II Warrants.

Rights as a Shareholder. Except as otherwise provided in the Series II Warrants or by virtue of such holder's ownership of our common stock, the holder of an Series II Warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the Series II Warrant.

Registration Rights. We have agreed to file a registration statement covering the resale of the shares underlying the Series I Warrants and Series II Warrants as soon as practicable (and in any event within 15 days of November 6, 2024). We must use commercially reasonable efforts to cause such registration statement to become effective within 60 days following the closing date of the offering (or, in the event of a review by the SEC, the 90th calendar day following the closing date of the offering) and to keep such registration statement effective at all times until the purchasers no longer own any Series II Warrants or shares underlying the Series II Warrants.

August Placement Agent Warrants

Exercisability. The August PA Warrants were exercisable immediately and expire five (5) years following the commencement of the sales pursuant to the offering. The August PA Warrants are exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the issuance of the common stock underlying the August PA Warrants under the Securities Act is effective and available for the issuance of such shares, or an exemption from registration under the Securities Act is available for the issuance of such shares, by payment in full in immediately available funds for the number of common stock purchased upon such exercise. If at the time of exercise there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the

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common stock underlying the August PA Warrants, then the August PA Warrants may also be exercised, in whole or in part, at such time by means of a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the August PA Warrant.

Exercise Limitation. A holder will not have the right to exercise any portion of the August PA Warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or 9.99% upon the request of the investor) of the number of shares of common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the August PA Warrants. However, any holder may increase or decrease such percentage, provided that any increase will not be effective until the 61st day after such election.

Exercise Price. The August PA Warrants have an exercise price of \$3.04425 per share. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our shareholders.

Transferability. In accordance with its terms and subject to applicable laws, an August PA Warrant may be transferred at the option of the holder upon surrender of the August PA Warrant to us together with the appropriate instruments of transfer and payment of funds sufficient to pay any transfer taxes (if applicable).

Exchange Listing. There is no established public trading market for the August PA Warrants issued in the concurrent private placement, and we do not expect a market to develop. We do not intend to apply for listing of the August PA Warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the August PA Warrants will be limited.

Fundamental Transactions. In the event of any fundamental transaction, as described in the August PA Warrants and generally including any merger with or into another entity, sale of all or substantially all of our assets, tender offer or exchange offer, or reclassification of our common stock, then upon any subsequent exercise of an August PA Warrant, the holder will have the right to receive as alternative consideration, for each share of common stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of common stock of the successor or acquiring corporation or of our company, if it is the surviving corporation, and any additional consideration receivable upon or as a result of such transaction by a holder of the number of shares of common stock for which the August PA Warrant is exercisable immediately prior to such event. In addition, in the event of a fundamental transaction, we or any successor entity will be required to purchase at a holder's option, exercisable at any time concurrently with or within 30 days after the consummation of the fundamental transaction (or, if later, the date of the public announcement of the applicable fundamental transaction), such holder's August PA Warrants and generally including any merger with or into another entity, sale of all or substantially all of our assets, tender for cash in an amount equal to the value of the remaining unexercised portion of such holder's August PA Warrants, determined in accordance with the Black Scholes option pricing model as more particularly set forth in the August PA Warrants.

Rights as a Shareholder. Except as otherwise provided in the August PA Warrants or by virtue of such holder's ownership of our common stock, the holder of an August PA Warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the August PA Warrant.

Registration Rights. We have agreed to file a registration statement covering the resale of the shares underlying the August PA Warrants as soon as practicable.

Anti-Takeover Effects of Certain Provisions of Our Fourth Amended and Restated Certificate of Incorporation and Third Amended and Restated Bylaws and Delaware Law

Certain provisions of our certificate of incorporation and bylaws may be considered to have an anti-takeover effect, such as those provisions:

- providing for our board of directors to be divided into three classes with staggered three-year terms, with only one class of directors being elected at each annual meeting of our stockholders and the other classes continuing for the remainder of their respective three-year terms;

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- authorizing our board of directors to issue from time to time any series of preferred stock and fix the voting powers, designation, powers, preferences and rights of the shares of such series of preferred stock;
- prohibiting stockholders from acting by written consent in lieu of a meeting;
- requiring advance notice of stockholder intention to put forth director nominees or bring up other business at a stockholders' meeting;
- prohibiting stockholders from calling a special meeting of stockholders;
- requiring a 66 $\frac{2}{3}$ % super-majority stockholder approval in order for stockholders to alter, amend or repeal certain provisions of our certificate of incorporation;
- requiring a 66 $\frac{2}{3}$ % super-majority stockholder approval in order for stockholders to adopt, amend or repeal our bylaws;
- providing that, subject to the rights of the holders of any series of preferred stock to elect additional directors under specified circumstances, neither the board of directors nor any individual director may be removed without cause;
- creating the possibility that our board of directors could prevent a coercive takeover of our Company due to the significant amount of authorized, but unissued shares of our common stock and preferred stock;
- providing that, subject to the rights of the holders of any series of preferred stock, the number of directors shall be fixed from time to time exclusively by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- providing that any vacancies on our board of directors under certain circumstances will be filled only by a majority of our board of directors then in office, even if less than a quorum, and not by the stockholders.

Delaware Law

We are also subject to Section 203 of the DGCL, which generally prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder, unless:

- prior to that date, our board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of our voting stock outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned by (i) persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to that date, the business combination is approved by our board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 $\frac{2}{3}$ % of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a "business combination" to include the following:

- any merger or consolidation involving the corporation or a direct or indirect majority-owned subsidiary of the corporation and the interested stockholder;
- any sale, lease, mortgage, pledge transfer, or other disposition of the assets of the corporation or direct or indirect majority-owned a subsidiary of the corporation to or with the interested stockholder, which assets have an aggregate value equal to 10% or more of the fair value of the assets on a consolidated basis or the aggregate market value of the outstanding stock of the corporation;

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- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation or a direct or indirect majority-owned subsidiary of the corporation of any stock of the corporation or subsidiary to the interested stockholder;
- any transaction involving the corporation or direct or indirect majority-owned subsidiary of the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation or the subsidiary beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation or direct or indirect majority-owned subsidiary of the corporation.

In general, Section 203 of the DGCL defines an interested stockholder as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by any of these entities or persons.

The above-summarized provisions of our certificate of incorporation and bylaws and the above-summarized provisions of the DGCL could make it more difficult to acquire us by means of a tender offer, a proxy contest or otherwise, or to remove incumbent officers and directors. These provisions are expected to discourage certain types of coercive takeover practices and takeover bids that our board of directors may consider inadequate and to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging takeover or acquisition proposals because, among other things, negotiation of these proposals could result in an improvement of their terms.

Choice of Forum

Our Fourth Amended and Restated Certificate of Incorporation, as amended, provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL; or any action asserting a claim against us that is governed by the internal affairs doctrine. These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. Our Fourth Amended and Restated Certificate of Incorporation, as amended, will further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, subject to applicable law. Any person or entity purchasing or otherwise acquiring any interest in our securities shall be deemed to have notice of and consented to these provisions. Our exclusive forum provision will not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations.

The provisions of the DGCL, our Fourth Amended and Restated Certificate of Incorporation, as amended, and our Third Amended and Restated Bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Limitation on Liability of Directors and Indemnification

Our certificate of incorporation limits the liability of our directors to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for any:

- breach of their duty of loyalty to us or our stockholders;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares as provided in Section 174 of the DGCL; or
- transaction from which the directors derived an improper personal benefit.

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These limitations of liability do not apply to liabilities arising under federal securities laws and do not affect the availability of equitable remedies such as injunctive relief or rescission.

Our bylaws provide that we will indemnify and advance expenses to our directors and officers to the fullest extent permitted by law or, if applicable, pursuant to indemnification agreements. They further provide that we may choose to indemnify our other employees or agents from time to time. Subject to certain exceptions and procedures, our bylaws also require us to advance to any person who was or is a party, or is threatened to be made a party, to any proceeding by reason of the person's service as one of our directors or officers all expenses incurred by the person in connection with such proceeding.

Section 145(g) of the DGCL and our bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to us, regardless of whether our bylaws permit indemnification. We maintain a directors' and officers' liability insurance policy.

We entered into indemnification agreements with each of our directors and executive officers that provide, in general, that we will indemnify them to the fullest extent permitted by law in connection with their service to us or on our behalf and, subject to certain exceptions and procedures, that we will advance to them all expenses that they incur in connection with any proceeding to which they are, or are threatened to be made, a party.

At present, there is no pending litigation or proceeding involving any of our directors or officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Company pursuant to the foregoing provisions, or otherwise, the Company has been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Participation Rights

Pursuant to a securities purchase agreement between the Company and certain investors on July 24, 2024 (the "July 2024 Offering"), the selling securityholders in the July 2024 Offering were granted a right of participation for a period of 12 months following the closing of the July 2024 Offering in any issuance by the Company of common stock or common stock equivalents for cash consideration, indebtedness or a combination of units thereof, of up to an amount equal to 40% of the subsequent financing on the same terms, conditions and price provided for in the subsequent financing.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Equiniti Trust Company, LLC.

LEGAL MATTERS

Honigman LLP, Kalamazoo, Michigan, has issued a legal opinion as to the validity of the shares of common stock offered by this prospectus. Any underwriters or agents will be advised about legal matters relating to any offering by their own counsel to be named in the applicable prospectus supplement.

EXPERTS

Baker Tilly US, LLP, our independent registered public accounting firm, has audited our consolidated financial statements as of and for the years ended December 31, 2023 and 2022 included in this prospectus, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC this Registration Statement under the Securities Act with respect to the shares of our common stock offered hereby. This prospectus, which constitutes a part of this Registration Statement, does not contain all of the information set forth in this Registration Statement, the exhibits filed therewith or the documents incorporated by reference therein. For further information about us and the shares of our common stock offered hereby, reference is made to this Registration Statement, the exhibits filed therewith and the documents incorporated by reference therein. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to this Registration Statement are not necessarily complete, and in each instance, we refer you to the copy of such contract or other document filed as an exhibit to this Registration Statement.

We are subject to the informational requirements of the Exchange Act, and are required to file annual, quarterly and other reports, proxy statements and other information with the SEC. The SEC maintains an Internet site (<http://www.sec.gov>) that contains reports, proxy and information statements, and various other information regarding issuers that file electronically with the SEC. You may access, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after such each such report is electronically filed with, or furnished to, the SEC.

Information about us is also available on our website at www.nuwellis.com. However, the information on our website is not a part of this prospectus and is not incorporated by reference into this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

We “incorporate by reference” certain documents that we have filed with the SEC into this prospectus, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is deemed to be part of this prospectus, except for any information superseded by information contained directly in this prospectus. This prospectus incorporates by reference:

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on [March 11, 2024](#);
- our definitive proxy statement for our 2024 Annual Meeting of Stockholders filed with the SEC on [May 17, 2024](#);
- our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2024, filed with the SEC on [May 8, 2024](#); the quarter ended June 30, 2024, filed with the SEC on [August 13, 2024](#); and the quarter ended September 30, 2024, filed with the SEC on [November 12, 2024](#);
- our Current Reports on Form 8-K filed with the SEC on [February 6, 2024](#), [March 26, 2024](#), [May 1, 2024](#), [May 29, 2024](#), [June 6, 2024](#), [June 10, 2024](#), [June 26, 2024](#), [July 3, 2024](#), [July 17, 2024](#) (as amended on [July 17, 2024](#)), [July 17, 2024](#), [July 25, 2024](#), [August 12, 2024](#), [August 22, 2024](#), [August 26, 2024](#), [October 23, 2024](#), and [November 7, 2024](#); and
- the description of our common stock in our registration statement on Form 10 filed with the SEC on [September 30, 2011](#), including [Exhibit 4.14](#) to our Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

All documents we file with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, except as to any portion of any report or document that is not deemed filed under such provisions, (i) prior to the termination of the offering and (ii) on or after the date of this prospectus supplement until the earlier of the date on which all of the securities registered hereunder have been sold or the registration statement of which this prospectus is a part has been withdrawn, shall be deemed incorporated by reference in this prospectus and to be a part of this prospectus from the date of filing of those documents. Nothing in this prospectus shall be deemed to incorporate information furnished but not filed with the SEC pursuant to Item 2.02 or 7.01 of Form 8-K.

These documents may also be accessed on our website at www.nuwellis.com. Information contained in, or accessible through, our website is not a part of this prospectus. The SEC also maintains a website at www.sec.gov that contains reports, proxy and information statements, and information regarding issuers that file electronically with the SEC.

We will provide without charge to each person, including any beneficial owners, to whom this prospectus is delivered, upon his or her written or oral request, a copy of any or all reports or documents referred to above which have been or may be incorporated by reference into this prospectus but not delivered with this prospectus, excluding exhibits to those reports or documents unless they are specifically incorporated by reference into those documents. You may request a copy of these documents by writing or telephoning us at the following address:

Nuwellis, Inc.
Attention: Nestor Jaramillo, Chief Executive Officer
12988 Valley View Road
Eden Prairie, MN 55344
Tel: (952) 345-4200

Any statements contained in a document incorporated by reference in this prospectus shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus (or in any other subsequently filed document which also is incorporated by reference in this prospectus) modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed to constitute a part of this prospectus except as so modified or superseded.



Up to 3,734,511 Shares of Common Stock Offered by the Selling Securityholders
PROSPECTUS

, 2024

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth estimated expenses in connection with the issuance and distribution of the shares of common stock being registered hereby. Each item listed is estimated, except for the SEC registration fee:

| Item | Amount Paid or to Be Paid |
|----------------------------------|------------------------------|
| SEC registration fee | \$1,029.15 |
| FINRA filing fee | * |
| Printing expenses | * |
| Legal fees and expenses | * |
| Accounting fees and expenses | * |
| Transfer agent fees and expenses | * |
| Miscellaneous fees and expenses | * |
| Total | \$ * |

* Except for the SEC registration fee, estimated expenses are not presently known. The foregoing sets forth the general categories of expenses (other than underwriting discounts and commissions) that we anticipate we will incur in connection with the offering of shares of our common stock under this Registration Statement. To the extent required, any applicable prospectus supplement will set forth the estimated aggregate amount of expenses payable in respect of any offering of shares of our common stock under this Registration Statement.

Item 14. Indemnification of Directors and Officers.

Our certificate of incorporation and bylaws provide that each person who was or is made a party or is threatened to be made a party to or is otherwise involved (including, without limitation, as a witness) in any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he or she is or was a director or an officer of Nuwellis, Inc. or is or was serving at our request as a director, officer, or trustee of another corporation, or of a partnership, joint venture, trust or other enterprise, including service with respect to an employee benefit plan, whether the basis of such proceeding is alleged action in an official capacity as a director, officer or trustee or in any other capacity while serving as a director, officer or trustee, shall be indemnified and held harmless by us to the fullest extent authorized by the Delaware General Corporation Law, as amended (the "DGCL"), against all expense, liability and loss (including attorneys' fees, judgments, fines, ERISA excise taxes or penalties and amounts paid in settlement) reasonably incurred or suffered by such.

Section 145 of the DGCL permits a corporation to indemnify any director or officer of the corporation against expenses (including attorney's fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with any action, suit or proceeding brought by reason of the fact that such person is or was a director or officer of the corporation, if such person acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, and, with respect to any criminal action or proceeding, if he or she had no reason to believe his or her conduct was unlawful. In a derivative action, (i.e., one brought by or on behalf of the corporation), indemnification may be provided only for expenses actually and reasonably incurred by any director or officer in connection with the defense or settlement of such an action or suit if such person acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, except that no indemnification shall be provided if such person shall have been adjudged to be liable to the corporation, unless and only to the extent that the court in which the action or suit was brought shall determine that the defendant is fairly and reasonably entitled to indemnity for such expenses despite such adjudication of liability.

Pursuant to Section 102(b)(7) of the DGCL, our certificate of incorporation eliminates the liability of a director to us or our stockholders for monetary damages for such a breach of fiduciary duty as a director, except for liabilities arising:

- from any breach of the director's duty of loyalty to us or our stockholders;
- from acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;

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- under Section 174 of the DGCL; and
- from any transaction from which the director derived an improper personal benefit.

We carry insurance policies insuring our directors and officers against certain liabilities that they may incur in their capacities as directors and officers.

The Company has entered into indemnification agreements with each of its directors and executive officers. Pursuant to the indemnification agreements, the Company agrees to hold harmless and indemnify its directors and executive officers to the fullest extent authorized or permitted by the provisions of the Company's certificate of incorporation and bylaws and the DGCL, including for any amounts that such director or officer becomes obligated to pay because of any claim to which such director or officer is made or threatened to be made a party, witness or participant, by reason of such director's or officer's service as a director, officer, employee or other agent of the Company.

There are certain exceptions from the Company's obligation to indemnify its directors and executive officers pursuant to the indemnification agreements, including for "short-swing" profit claims under Section 16(b) of the Exchange Act, losses that result from conduct that is established by a final judgment as knowingly fraudulent or deliberately dishonest or that constituted willful misconduct, or that constituted a breach of the duty of loyalty to the Company or resulted in any improper personal profit or advantage, where payment is actually made to a director or officer under an insurance policy, indemnity clause, bylaw or agreement, except in respect of any excess beyond payment under such insurance, clause, bylaw or agreement, for indemnification which is not lawful, or in connection with any proceeding initiated by such director or officer, or any proceeding against the Company or its directors, officers, employees or other agents, unless (i) such indemnification is expressly required to be made by law, (ii) the proceeding was authorized by the board of directors of the Company, (iii) such indemnification is provided by the Company, in its sole discretion, pursuant to the powers vested in the Company under the DGCL, or (iv) the proceeding is initiated to enforce a claim for indemnification pursuant to the indemnification agreement.

All agreements and obligations of the Company contained in the indemnification agreements shall continue during the period when the director or officer who is a party to an indemnification agreement is a director, officer, employee or other agent of the Company (or is or is serving at the request of the Company as a director, officer, employee or other agent of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise) and shall continue thereafter so long as such director or officer shall be subject to any possible claim or threatened, pending or completed action, suit or proceeding, whether civil, criminal, arbitrational, administrative or investigative. In addition, the indemnification agreements provide for partial indemnification and advance of expenses.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers or controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the Securities and Exchange Commission this indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

Item 15. Recent Sales of Unregistered Securities.

The following sets forth information regarding all unregistered securities we sold in the three years preceding the date of this Registration Statement. This information has been retroactively adjusted to reflect the reverse stock splits for all periods presented.

- On June 19, 2023, the registrant granted a warrant to DaVita, Inc. ("DaVita"), pursuant to a Supply and Collaboration Agreement ("Supply Agreement") dated as of June 19, 2023, 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 warrant represents the right 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, provided that at no time can it be exercised for an amount of shares that would represent greater than 19.9% ownership in the Company (the "DaVita Warrant") subject to certain vesting milestones. The DaVita Warrant is expected to vest in four tranches as follows (i): 25% upon the Company's receipt of notice to extend the Supply Agreement past the initial pilot-term (the "Ultrafiltration Services Approval"); (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 the 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 issuance was made in reliance upon the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder. This warrant was terminated, effective August 21, 2024.

- On July 25, 2024, the registrant closed on a private placement of common stock purchase warrants to purchase 200% of the number of shares of common stock purchased by the Selling Securityholders in the offering, equal to up to 938,680 shares of common stock. The common stock purchase warrants have an exercise price of \$3.99 per share, are immediately exercisable and expire five years from the date of issuance. If all of the common stock purchase warrants are exercised for cash in full, the gross proceeds would be approximately \$3.7 million. This issuance was made in reliance upon the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder.
- On August 26, 2024, the registrant closed on a private placement of common stock purchase warrants to purchase 100% of the number of shares of common stock purchased by the Selling Securityholders in the offering, equal to up to 483,351 shares of common stock. The common stock purchase warrants have an exercise price of \$1.72 per share, are immediately exercisable and expire five years following the date of effectiveness of the registration statement for the purposes of registering the shares of common stock underlying such warrants. If all of the common stock purchase warrants are exercised for cash in full, the gross proceeds would be approximately \$0.8 million. The registrant also offered, as part compensation to Ladenburg Thalmann & Co. Inc., the placement agent, in connection with the offering, warrants to purchase up to 14,501 shares of common stock. Such warrants have an exercise price of \$3.04425 per share and will expire five years following the commencement of sales pursuant to the offering. This issuance was made in reliance upon the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder.
- On November 5, 2024, the Company entered into Inducement Letters with the Selling Securityholders to immediately exercise approximately 1.8 million of the common stock purchase warrants issued by the Company on April 30, 2024 (the "April 2024 Warrants") held by such investors. In consideration for exercising the April 2024 Warrants, pursuant to the terms of the Inducement Letters, the Company issued to the investors new Series I Warrants and new Series II Warrants, in each case, to purchase up to an aggregate of 1,832,517 shares of common stock, equal to 100% of the number of shares of common stock issued pursuant to the immediate exercise of the corresponding April 2024 Warrants. The Series I Warrant has an exercise price of \$1.94, is exercisable six (6) months from the date of issuance and has a term of five (5) years from the date of initial exercise. The Series II Warrant has an exercise price of \$1.94, is exercisable six (6) months from the date of issuance and has a term of two (2) years from the date of initial exercise. The registrant also offered, as part compensation to Ladenburg Thalmann & Co. Inc., the placement agent, in connection with the offering, warrants to purchase up to 54,976 shares of common stock. Such warrants have an exercise price of \$3.465 per share and will expire five years following the commencement of sales pursuant to the offering. The Series I Warrants, Series II Warrants, and November PA Warrants were issued to the Selling Securityholders, which are institutional accredited investors, in a private placement in reliance upon the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) and Regulation D promulgated under the Securities Act.

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Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits

EXHIBIT INDEX

| Exhibit Number | Exhibit Description | Incorporated By Reference | | | | Filed Herewith |
|----------------------|---|---------------------------|-------------|----------------------|----------------|----------------|
| | | Form | File Number | Date of First Filing | Exhibit Number | |
| 3.1 | Fourth Amended and Restated Certificate of Incorporation | 10 | 001-35312 | February 1, 2012 | 3.1 | |
| 3.2 | Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation | 8-K | 001-35312 | January 13, 2017 | 3.1 | |
| 3.3 | Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation | 8-K | 001-35312 | May 23, 2017 | 3.1 | |
| 3.4 | Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation | 8-K | 001-35312 | October 12, 2017 | 3.1 | |
| 3.5 | Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation | 8-K | 001-35312 | January 2, 2019 | 3.1 | |
| 3.6 | Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation | 8-K/A | 001-35312 | October 16, 2020 | 3.1 | |
| 3.7 | Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation | 8-K | 001-35312 | April 27, 2021 | 3.1 | |
| 3.8 | Certificate of Amendment to 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 | Third Amended and Restated Bylaws | 10-Q | 001-35312 | November 12, 2024 | 3.13 | |
| 3.11 | Amendment to Third Amended and Restated Bylaws | 10-Q | 001-35312 | November 12, 2024 | 3.14 | |
| 3.12 | Form of Certificate of Designation of Series F Convertible Preferred Stock | S-1/A | 333-221010 | November 17, 2017 | 3.7 | |
| 3.13 | Certificate of Designation of Preferences, Rights and Limitations, filed with the Delaware Secretary of State on October 16, 2023, with respect to the Series J Convertible Preferred Stock | 8-K | 001-35312 | October 17, 2023 | 3.1 | |
| 4.1 | Specimen of Common Stock Certificate | 10 | 001-35312 | September 30, 2011 | 4.1 | |
| 4.2 | Form of Common Warrant | 8-K | 001-35312 | July 25, 2024 | 4.1 | |
| 4.3 | Form of Common Warrant | 8-K | 001-35312 | August 26, 2024 | 4.1 | |
| 4.4 | Form of Placement Agent Warrant | 8-K | 001-35312 | August 26, 2024 | 4.2 | |
| 4.5 | Form of Series I Common Stock Purchase Warrant | 8-K | 001-35312 | November 7, 2024 | 4.1 | |
| 4.6 | Form of Series II Common Stock Purchase Warrant | 8-K | 001-35312 | November 7, 2024 | 4.2 | |
| 4.7 | Form of Placement Agent Warrant | 8-K | 001-35312 | November 7, 2024 | 4.3 | |
| 5.1 | Opinion of Honigman LLP | | | | X | |

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| Exhibit Number | Exhibit Description | Incorporated By Reference | | | | Filed Herewith |
|-----------------------|--|---------------------------|-------------|----------------------|----------------|----------------|
| | | Form | File Number | Date of First Filing | Exhibit Number | |
| 10.1 | Patent License Agreement between Sunshine Heart, Inc. and Gambro UF Solutions, Inc. dated August 5, 2016 | 8-K | 001-35312 | August 8, 2016 | 10.1 | |
| 10.2 | 2013 Non-Employee Directors' Equity Incentive Plan | 14A | 001-35312 | April 5, 2013 | App. A | |
| 10.3 | Form of Stock Option Grant Notice and Option Agreement for 2013 Non-Employee Directors' Equity Incentive Plan | 10-K | 001-35312 | May 29, 2013 | 10.2 | |
| 10.4 | Form of Restricted Stock Unit Award Grant Notice and Agreement for 2013 Non-Employee Directors' Equity Incentive Plan | 10-K | 001-35312 | March 20, 2015 | 10.11 | |
| 10.5 | New-Hire Equity Incentive Plan | 10-Q | 001-35312 | August 8, 2013 | 10.1 | |
| 10.6 | First Amendment to New-Hire Equity Incentive Plan | 10-Q | 001-35312 | November 12, 2013 | 10.1 | |
| 10.7 | Second Amendment to New-Hire Equity Incentive Plan | S-8 | 333-202904 | March 20, 2015 | 99.12 | |
| 10.8 | Third Amendment to New-Hire Equity Incentive Plan | S-8 | 333-210215 | March 15, 2016 | 99.13 | |
| 10.9 | Fourth Amendment to New-Hire Equity Incentive Plan | 8-K | 001-35312 | May 30, 2017 | 10.4 | |
| 10.10 | Fifth Amendment to New-Hire Equity Incentive Plan | 8-K | 001-35312 | January 18, 2018 | 10.1 | |
| 10.11 | Sixth Amendment to New-Hire Equity Incentive Plan | 10-Q | 001-35312 | August 8, 2019 | 10.2 | |
| 10.12 | Seventh Amendment to New-Hire Equity Incentive Plan | 8-K | 001-35312 | December 6, 2019 | 10.1 | |
| 10.13 | Eighth Amendment to New-Hire Equity Incentive Plan | 8-K/A | 001-35312 | February 25, 2021 | 10.1 | |
| 10.14 | Form of Stock Option Grant Notice and Option Agreement for New-Hire Equity Incentive Plan | 10-Q | 001-35312 | November 12, 2013 | 10.2 | |
| 10.15 | 2017 Equity Incentive Plan | 8-K | 001-35312 | May 30, 2017 | 10.1 | |
| 10.16 | First Amendment to the 2017 Equity Incentive Plan | 14A | 001-35312 | September 11, 2020 | App. A | |
| 10.17 | Second Amendment to the 2017 Equity Incentive Plan | 10-K | 001-35312 | March 3, 2023 | 10.17 | |
| 10.18 | Form of Stock Option Grant Notice and Option Agreement for 2017 Equity Incentive Plan | 8-K | 001-35312 | May 30, 2017 | 10.2 | |
| 10.19 | Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement for 2017 Equity Incentive Plan | 8-K | 001-35312 | May 30, 2017 | 10.3 | |
| 10.20 | Nuwellis, Inc. 2021 Inducement Plan | 8-K | 001-35312 | May 20, 2021 | 10.1 | |
| 10.21 | First Amendment to the 2021 Inducement Plan | 8-K | 001-35312 | April 21, 2022 | 10.1 | |
| 10.22 | Second Amendment to the 2021 Inducement Plan | 8-K | 001-35312 | March 1, 2023 | 10.1 | |
| 10.23 | Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the Nuwellis, Inc. 2021 Inducement Plan | 8-K | 001-35312 | May 20, 2021 | 10.2 | |
| 10.24 | Form of Indemnity Agreement for the Company's executive officers and directors | 10 | 001-35312 | September 30, 2011 | 10.1 | |

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| Exhibit Number | Exhibit Description | Incorporated By Reference | | | | Filed Herewith |
|-----------------------|---|----------------------------------|--------------------|-----------------------------|-----------------------|-----------------------|
| | | Form | File Number | Date of First Filing | Exhibit Number | |
| 10.25 | Form of Change in Control Agreement for the Company's executive officers | 10-K | 001-35312 | March 20, 2015 | 10.16 | |
| 10.26 | Non-Employee Director Compensation Policy (effective January 1, 2023) | 10-K | 001-35312 | March 3, 2023 | 10.27 | |
| 10.27 | Lease Agreement dated October 21, 2011 by and between the Company and Silver Prairie Crossroads, LLC | 10 | 001-35312 | December 16, 2011 | 10.18 | |
| 10.28 | Second Amendment to Lease, dated as of April 20, 2015, by and between the Company and Capital Partners Industrial Fund I, LLLP dba Prairie Crossroads Business Center | 8-K | 001-35312 | April 23, 2015 | 10.1 | |
| 10.29 | Third Amendment to Lease, dated as of August 3, 2018, by and between the Company and Capital Partners Industrial Fund I, LLLP | 10-Q | 001-35312 | November 7, 2018 | 10.2 | |
| 10.30 | Fourth Amendment to Lease, dated as of November 18, 2021, by and between the Company and Capital Partners Industrial Fund I, LLLP | 8-K | 001-35312 | November 23, 2021 | 10.1 | |
| 10.31 | Executive Employment Agreement between Sunshine Heart, Inc. and John L. Erb, dated March 1, 2016 | 8-K | 001-35312 | March 2, 2016 | 10.1 | |
| 10.32 | Letter Agreement dated February 15, 2017 among the Company, Sabby Volatility Warrant Master Fund, Ltd. and Sabby Healthcare Master Fund, Ltd. | 8-K | 003-35312 | February 16, 2017 | 10.1 | |
| 10.33 | Warrant Agency Agreement between the Company and American Stock Transfer & Trust Company, LLC dated April 24, 2017 | 8-K | 001-35312 | April 25, 2017 | 10.1 | |
| 10.34 | Form of Warrant Reprice Agreement | 8-K | 001-35312 | June 29, 2018 | 10.1 | |
| 10.35 | Warrant Agency Agreement, dated as of March 12, 2019, between the Company and American Stock Transfer & Trust Company, LLC | 8-K | 001-35312 | March 13, 2019 | 4.2 | |
| 10.36 | Underwriting Agreement, dated as of March 8, 2019, by and between the Company and Ladenburg Thalmann & Co. Inc. | 8-K | 001-35312 | March 13, 2019 | 1.1 | |
| 10.37 | Form of Employee Proprietary Information, Inventions Assignment and Non-Competition Agreement for the Company's employees, including executive officers | 10-Q | 001-35312 | May, 9, 2019 | 10.3 | |
| 10.38 | Offer Letter, by and between the Company and Nestor Jaramillo, dated April 12, 2019 | 10-Q | 001-35312 | May 9, 2019 | 10.5 | |
| 10.39 | Placement Agency Agreement, dated as of October 23, 2019, by and between the Company and Ladenburg Thalmann & Co. Inc. | 8-K | 001-35312 | October 23, 2019 | 1.1 | |
| 10.40 | Form of Securities Purchase Agreement, dated as of October 23, 2019, by and among the Company and the purchasers identified on the signature pages thereto | 8-K | 001-35312 | October 23, 2019 | 10.1 | |

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| Exhibit Number | Exhibit Description | Incorporated By Reference | | | | Filed Herewith |
|-----------------------|--|----------------------------------|--------------------|-----------------------------|-----------------------|-----------------------|
| | | Form | File Number | Date of First Filing | Exhibit Number | |
| 10.41 | Placement Agency Agreement, dated as of November 4, 2019, by and between the Company and Ladenburg Thalmann & Co. Inc. | 8-K | 001-35312 | November 4, 2019 | 1.1 | |
| 10.42 | Form of Securities Purchase Agreement, dated as of November 4, 2019, by and among the Company and the purchasers identified on the signature pages thereto | 8-K | 001-35312 | November 4, 2019 | 10.1 | |
| 10.43 | Underwriting Agreement dated as of January 24, 2020, by and between the Company and Ladenburg Thalmann & Co. Inc. | 8-K | 001-35312 | January 29, 2020 | 1.1 | |
| 10.44 | Warrant Agency Agreement, dated as of January 28, 2020, between the Company and American Stock Transfer & Trust Company, LLC. | 8-K | 001-35312 | January 29, 2020 | 4.2 | |
| 10.45 | Placement Agency Agreement, dated as of March 19, 2020, by and between the Company and Ladenburg Thalmann & Co. Inc. | 8-K | 001-35312 | March 20, 2020 | 1.1 | |
| 10.46 | Form of Securities Purchase Agreement, dated as of March 19, 2020, by and among the Company and the purchasers identified on the signature pages thereto | 8-K | 001-35312 | March 20, 2020 | 10.1 | |
| 10.47 | Placement Agency Agreement, dated as of March 30, 2020, by and between the Company and Ladenburg Thalmann & Co. Inc. | 8-K | 001-35312 | March 30, 2020 | 1.1 | |
| 10.48 | Form of Securities Purchase Agreement, dated as of March 30, 2020, by and among the Company and the purchasers identified on the signature pages thereto | 8-K | 001-35312 | March 30, 2020 | 10.1 | |
| 10.49 | Form of Securities Purchase Agreement, dated as of May 1, 2020, by and among the Company and the purchasers identified on the signature pages thereto | 8-K | 001-35312 | May 4, 2020 | 10.1 | |
| 10.50 | Underwriting Agreement, dated as of August 19, 2020, by and between the Company and Ladenburg Thalmann & Co. Inc. | 8-K | 001-35312 | August 21, 2020 | 1.1 | |
| 10.51 | Warrant Agency Agreement, dated as of August 21, 2020, between the Company and American Stock Transfer & Trust Company, LLC | 8-K | 001-35312 | August 21, 2020 | 4.2 | |
| 10.52 | Executive Employment Agreement, dated January 16, 2021, by and between the Company and Nestor Jaramillo, Jr. | 8-K | 001-35312 | January 19, 2021 | 10.1 | |
| 10.53 | Executive Employment Agreement, dated January 16, 2021, by and between the Company and John L. Erb | 8-K | 001-35312 | January 19, 2021 | 10.2 | |
| 10.54 | Offer letter by and between the Company and Neil P. Ayotte, effective as of June 7, 2021 | 10-Q | 001-35312 | August 12, 2021 | 10.4 | |

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| Exhibit Number | Exhibit Description | Incorporated By Reference | | | | Filed Herewith |
|-----------------------|--|----------------------------------|--------------------|-----------------------------|-----------------------|-----------------------|
| | | Form | File Number | Date of First Filing | Exhibit Number | |
| 10.55 | Underwriting Agreement dated September 15, 2021, between the Company and Ladenburg Thalmann & Co. Inc., as the Representative of the several underwriters named in Schedule I thereto. | 8-K | 001-35312 | September 17, 2021 | 1.1 | |
| 10.56 | Warrant Agency Agreement, dated as of October 18, 2022, between the Company and American Stock Transfer & Trust Company, LLC | 8-K | 001-35312 | October 18, 2022 | 4.2 | |
| 10.57 | Leak-Out Agreement | S-1/A | 333-267368 | September 30, 2022 | 10.70 | |
| 10.58 | Offer Letter by and between the Company and Lynn Blake, effective as of October 19, 2022 | 8-K | 001-35312 | October 5, 2022 | 10.1 | |
| 10.59 | First Amendment to Offer Letter between the Company and Lynn Blake | 8-K | 001-35312 | December 9, 2022 | 10.1 | |
| 10.60 | Underwriting Agreement dated as of October 14, 2022, by and between Nuwellis, Inc. and Ladenburg Thalmann & Co. Inc. | 8-K | 001-35312 | October 18, 2022 | 1.1 | |
| 10.61 | Transition Agreement dated August 4, 2023 by and between Nuwellis, Inc. and Lynn Blake | 8-K | 001-35312 | August 8, 2023 | 10.1 | |
| 10.62 | Offer Letter by and between Nuwellis, Inc. and Robert B. Scott, effective as of September 2, 2023 | 8-K | 001-35312 | August 18, 2023 | 10.1 | |
| 10.63 | Placement Agency Agreement dated as of October 12, 2023, by and between Nuwellis, Inc., Lake Street Capital Markets, LLC and Maxim Group LLC | 8-K | 001-35312 | October 17, 2023 | 1.1 | |
| 10.64 | Form of Securities Purchase Agreement | S-1/A | 333-274610 | September 29, 2023 | 10.69 | |
| 10.65 | Form of Warrant Agency Agreement | 8-K | 001-35312 | October 17, 2023 | 4.2 | |
| 10.66 | Consulting Agreement dated August 4, 2023 by and between Nuwellis, Inc. and Lynn Blake | 8-K | 001-35312 | August 8, 2023 | 10.2 | |
| 10.67 | Form of Securities Purchase Agreement | 8-K | 001-35312 | May 1, 2024 | 10.1 | |
| 10.68 | Form of Warrant Agency Agreement | 8-K | 001-35312 | May 1, 2024 | 4.3 | |
| 10.69 | 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 | |
| 10.70 | Placement Agency Agreement dated as of July 24, 2024, by and between Nuwellis, Inc., and Roth Capital Partners, LLC | 8-K | 001-35312 | July 25, 2024 | 10.1 | |
| 10.71 | Form of Securities Purchase Agreement | 8-K | 001-35312 | July 25, 2024 | 10.2 | |
| 10.72 | Termination Agreement to the Supply and Collaboration Agreement, dated August 21, 2024 | 8-K | 001-35312 | August 22, 2024 | 10.1 | |
| 10.73 | Placement Agency Agreement dated as of August 23, 2024, by and between Nuwellis, Inc., and Ladenburg Thalmann & Co. Inc. | 8-K | 001-35312 | August 26, 2024 | 10.1 | |

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| Exhibit Number | Exhibit Description | Incorporated By Reference | | | | Filed Herewith |
|-----------------------|--|---------------------------|-------------|----------------------|----------------------------|----------------|
| | | Form | File Number | Date of First Filing | Exhibit Number | |
| 10.74 | Form of Securities Purchase Agreement | 8-K | 001-35312 | August 26, 2024 | 10.2 | |
| 10.75 | Confidential Settlement Agreement & Release with SeaStar Medical Holding Corporation, dated October 20, 2024 | 8-K | 001-35312 | October 23, 2024 | 10.1 | |
| 10.76 | Form of Warrant Inducement Offer Letter | 8-K | 001-35312 | November 7, 2024 | 10.1 | |
| 21 | List of Subsidiaries | 10-K | 001-35312 | March 11, 2024 | 21 | |
| 23.1 | Consent of Baker Tilly US, LLP | | | | X | |
| 23.2 | Consent of Honigman LLP | | | | Included in Exhibit 5.1 | |
| 24.1 | Power of Attorney | | | | Included on Signature Page | |
| 107 | Filing Fee Table | | | | X | |

(b) Financial Statement Schedules.

All financial statement schedules are omitted because the information required to be set forth therein is not applicable or is included in the consolidated financial statements or related notes incorporated herein by reference.

Item 17. Undertakings.

(a) The undersigned Registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:
 - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act;
 - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Filing Fee Tables" table in the effective registration statement; and
 - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;
provided, however, that paragraphs (a)(1)(i), (ii) and (iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the Registrant pursuant to Section 13 or Section 15(d) of the Exchange Act, that are incorporated by reference in the registration statement.
- (2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

- (4) That, for the purpose of determining liability under the Securities Act to any purchaser,
- (i) each prospectus filed by the Registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and
 - (ii) each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof; *provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.
- (b) The undersigned Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the Registrant's annual report pursuant to Section 13(a) or 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.
- (c) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Eden Prairie, State of Minnesota, on this 15th day of November, 2024.

NUWELLIS, INC.

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

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below, hereby constitutes and appoints Nestor Jaramillo, Jr. and Robert B. Scott, or either of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to the registration statement, including post-effective amendments, and to sign any registration statements filed for the same offering covered by this registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, and does hereby grant unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the foregoing, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

| <u>Signature</u> | <u>Title</u> | <u>Date</u> |
|---|--|-------------------|
| <u>/s/ John L. Erb</u> John L. Erb | Chairman of the Board | November 15, 2024 |
| <u>/s/ Nestor Jaramillo, Jr.</u> Nestor Jaramillo, Jr. | President, Chief Executive Officer and Director (principal executive officer) | November 15, 2024 |
| <u>/s/ Robert B. Scott</u> Robert B. Scott | Chief Financial Officer (principal financial officer and principal accounting officer) | November 15, 2024 |
| <u>/s/ Maria Rosa Costanzo, M.D.</u> Maria Rosa Costanzo, M.D. | Director | November 15, 2024 |
| <u>/s/ Michael McCormick</u> Michael McCormick | Director | November 15, 2024 |
| <u>/s/ Archelle Georgiou, M.D.</u> Archelle Georgiou, M.D. | Director | November 15, 2024 |
| <u>/s/ Gregory Waller</u> Gregory Waller | Director | November 15, 2024 |
| <u>/s/ David McDonald</u> David McDonald | Director | November 15, 2024 |

November 15, 2024

Nuwellis, Inc.
12988 Valley View Road
Eden Prairie, Minnesota 55344**Re: Registration Statement on Form S-1**

Ladies and Gentlemen:

We have acted as counsel to Nuwellis, Inc., a Delaware corporation (the "**Company**"), in connection with the preparation and filing with the Securities and Exchange Commission (the "**Commission**") pursuant to the Securities Act of 1933, as amended (the "**Securities Act**"), of a Registration Statement on Form S-1 (the "**Registration Statement**") and related prospectus relating to the offer and resale from time to time of up to an aggregate of 3,734,511 shares of the Company's common stock, par value \$0.0001 per share (the "**Common Stock**") consisting of: (i) 3,665,034 shares of Common Stock (the "**November Warrant Shares**") issuable upon exercise of certain outstanding warrants to purchase shares of Common Stock issued pursuant to warrant inducement offer letters with certain investors, dated November 5, 2024 (the "**November Warrants**"), (ii) 54,976 shares of Common Stock ("**November PA Warrant Shares**") issuable upon the exercise of certain outstanding warrants to purchase shares of Common Stock issued to the Company's placement agent as compensation in connection with the Company's warrant inducement offering that closed on November 6, 2024 (the "**November PA Warrants**"), and (iii) 14,501 shares of Common Stock ("**August PA Warrant Shares**" and together with the November Warrant Shares and the November PA Warrant Shares, the "**Warrant Shares**") issuable upon the exercise of certain outstanding warrants to purchase shares of Common Stock issued to the Company's placement agent as compensation in connection with the Company's registered direct offering and concurrent private placement that closed on August 26, 2024 (the "**August PA Warrants**" and together with the November Warrants and the November PA Warrants, the "**Warrants**"). The holders of the Warrant Shares upon exercise of the Warrants are referred to herein as the "**Selling Securityholders**".

For the purpose of rendering the opinions set forth below, we examined originals or copies of such records, instruments, certificates, opinions, memoranda and other documents as in our judgment are necessary or appropriate to enable us to render the opinions expressed below. In conducting our examination, we assumed, without investigation, the genuineness of all signatures, the correctness of all certificates, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted as certified or photostatic copies, and the authenticity of the originals of such copies, and the accuracy and completeness of all records made available to us by the Company, and the due authorization, execution and delivery by the Selling Securityholders of all documents where authorization, execution and delivery are prerequisites to the legal effectiveness of such documents. As to various questions of fact material to such opinions, we have relied, without independent verification, upon statements or certificates of officials and representatives of the Company and others.

In addition, in connection with this opinion letter, we have assumed that (i) immediately prior to exercise of the Warrants the Warrants will be in full force and effect with no unwaived events of default or breaches thereunder, and will constitute the legal, valid and binding obligation of each party thereto, enforceable against each such party in accordance with its terms, (ii) the Warrants will not have been amended or otherwise modified, (iii) the Warrants will be exercised in accordance with their terms and applicable securities laws, in the manner and on the terms identified or referred to in the Registration Statement and the related prospectus, including all supplements and amendments thereto, and before the resale of the Warrant Shares, and (iv) the Warrant Shares will be duly registered on the books of the transfer agent and registrar therefor in the name and on behalf of the persons exercising the Warrants upon exercise of the Warrants. With respect to the Warrant Shares, we express no opinion to the extent that future issuances of securities of the Company, including the Warrant Shares, and/or antidilution adjustments to outstanding securities of the Company, including the Warrants, may cause the Warrants to be exercisable for more shares of Common Stock than the number that then remain authorized, unissued, unreserved, and available for issuance.

November 15, 2024

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Our opinions are limited solely to matters set forth herein. The law covered by the opinions expressed herein is limited to the Delaware General Corporation Law. We are not admitted to practice in the State of Delaware and, with respect to the opinions set forth below, with your permission, we (i) have limited our review to standard compilations available to us of the Delaware General Corporation Law, which we have assumed to be accurate and complete, and (ii) have not reviewed case law. We express no opinion as to whether the laws of any particular jurisdiction are applicable to the subject matter hereof. We are not rendering any opinion with respect to federal law, including federal securities laws, or state blue sky securities laws. It is understood that this opinion letter is to be used only in connection with the offer and resale of the Warrant Shares while the Registration Statement is effective under the Securities Act.

Based on the foregoing, and upon our examination of such documents and other matters as we deem relevant, we are of the opinion that upon the valid exercise of the Warrants in accordance with their terms, including proper issuance and delivery to the persons exercising such Warrants of the Warrant Shares duly registered on the books of the transfer agent and registrar therefor in the name of and on behalf of the holder of such Warrants, including, without limitation, the payment in full of the exercise price thereof, the Warrant Shares will be validly issued, fully paid and non-assessable.

In giving the opinions set forth above, with respect to the Warrant Shares opined on in this opinion letter, we have assumed that at or prior to the time of the delivery of such Warrant Shares, the authorization of such Warrant Shares will not have been modified or rescinded, and there will not have occurred any change in law affecting such Warrant Shares, including their validity or enforceability.

We hereby consent to the filing of this opinion letter as Exhibit 5.1 to the Registration Statement and to the reference to our firm under the caption "Legal Matters" in the Registration Statement and the related prospectus. In giving such consent, we do not admit that we are within the category of persons whose consent is required by Section 7 of the Securities Act or the rules and regulations promulgated thereunder by the Commission. These opinions are expressed as of the date hereof, and we disclaim any undertaking to advise you of any subsequent changes in the facts stated or assumed herein or of any subsequent changes in applicable law.

Very truly yours,

/s/ Honigman LLP

HONIGMAN LLP

PDT/JMH/EAAL/CPS/JHC

Honigman LLP • 650 Trade Centre Way • Suite 200 • Kalamazoo, Michigan 49002-0402

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements on Form S-1 of Nuwellis, Inc. and Subsidiary of our report dated March 11, 2024, relating to the consolidated financial statements of Nuwellis, Inc. and Subsidiary in the Annual Report on Form 10-K for the years ended December 31, 2023 and 2022, which includes an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 1 to the consolidated financial statements. We also consent to the reference to us under the heading "Experts" in such Registration Statement.

/s/ Baker Tilly US, LLP

Minneapolis, Minnesota
November 15, 2024

Calculation of Filing Fee Tables

FORM S-1
(Form Type)NUWELLIS, INC.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered Securities

| Security Type | Security Class Title | Fee Calculation Rule | Amount Registered ⁽¹⁾ | Proposed Maximum Offering Price Per Unit ⁽⁶⁾ | Maximum Aggregate Offering Price | Fee Rate | Amount of Registration Fee | |
|-----------------------------------|--|----------------------|----------------------------------|---|----------------------------------|-----------------|----------------------------|-------------|
| Equity | Shares of Common Stock, par value \$0.0001 per share, underlying Series I Common Stock Purchase Warrants | Other | 1,832,517 ⁽²⁾ | \$ 1.80 | \$ 3,298,530.60 | \$ 0.00015310 | \$ 505.00 | |
| Equity | Shares of Common Stock, par value \$0.0001 per share, underlying Series II Common Stock Purchase Warrants | Other | 1,832,517 ⁽³⁾ | \$ 1.80 | \$ 3,298,530.60 | \$ 0.00015310 | \$ 505.00 | |
| Equity | Shares of Common Stock, par value \$0.0001 per share, underlying August Placement Agent Common Stock Purchase Warrants | Other | 14,501 ⁽⁴⁾ | \$ 1.80 | \$ 26,101.80 | \$ 0.00015310 | \$ 4.00 | |
| Equity | Shares of Common Stock, par value \$0.0001 per share, underlying November Placement Agent Common Stock Purchase Warrants | Other | 54,976 ⁽⁵⁾ | \$ 1.80 | \$ 98,956.80 | \$ 0.00015310 | \$ 15.15 | |
| Total Offering Amounts | | | | | | \$ 6,722,119.80 | \$ 0.00015310 | \$ 1,029.15 |
| Total Fees Previously Paid | | | | | | — | | — |
| Total Fee Offset | | | | | | — | | — |
| Net Fee Due | | | | | | | | \$ 1,029.15 |

- (1) Represents shares of common stock, par value \$0.0001 per share (the “common stock”) of Nuwellis, Inc. (the “Registrant”) that will be offered for resale by the selling securityholders pursuant to the prospectus to which this exhibit is attached. Pursuant to Rule 416 under the Securities Act of 1933, as amended (the “Securities Act”), the shares being registered hereunder include such indeterminate number of additional shares of common stock as may be issuable as a result of stock splits, stock dividends, or other distributions, recapitalizations or similar events with respect to the shares of common stock being registered pursuant to this registration statement.
- (2) This registration statement registers the resale of 1,832,517 shares of common stock of the Registrant issuable upon the exercise of Series I Stock Purchase Warrants issued by the Registrant at an exercise price of \$1.94 per share.
- (3) This registration statement registers the resale of 1,832,517 shares of common stock of the Registrant issuable upon the exercise of Series II Common Stock Purchase Warrants issued by the Registrant at an exercise price of \$1.94 per share.
- (4) This registration statement registers the resale of 14,501 shares of common stock of the Registrant issuable upon the exercise of August Placement Agent Common Stock Purchase Warrants issued by the Registrant at an exercise price of \$3.04425 per share.
- (5) This registration statement registers the resale of 54,976 shares of common stock of the Registrant issuable upon the exercise of November Placement Agent Common Stock Purchase Warrants issued by the Registrant at an exercise price of \$3.465 per share.
- (6) Estimated solely for purposes of calculating the registration fee pursuant to Rule 457(c) under the Securities Act, based on average of high and low price per share of the common stock as reported on The Nasdaq Capital Market on November 14, 2024.