



NUWELLIS, INC.

8,419,996 Shares of Common Stock

2,830,004 Pre-Funded Warrants to purchase up to 2,830,004 Shares of Common Stock

16,875,000 Common Warrants to purchase up to 16,875,000 Shares of Common Stock

19,705,004 Shares of Common Stock Underlying the Pre-Funded Warrants and Common Warrants

We are offering on a reasonable best efforts basis 8,419,996 shares of common stock, par value \$0.0001 per share ("common stock"), together with common stock purchase warrants to purchase up to 16,875,000 shares of common stock (the "common warrants"), at a combined public offering price of \$0.24 per share and accompanying common warrant. Each share of our common stock is being sold together with one common warrant to purchase one and a half shares of common stock. The common warrants will have an exercise price of \$0.40, will be exercisable upon issuance and will expire five years from the date of issuance. Each whole common warrant entitles the holder thereof to purchase one share of common stock. This prospectus also relates to the offering of the shares of common stock issuable from time to time upon exercise of the common warrants.

We are also offering to certain purchasers, whose purchase of common stock in this offering would otherwise result in such purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, pre-funded warrants to purchase up to 2,830,004 shares of common stock at an exercise price of \$0.0001 (the "pre-funded warrants"). Each pre-funded warrant will be exercisable upon issuance and will expire when exercised in full. Each pre-funded warrant is being sold together with one common warrant to purchase one and a half shares of common stock. The public offering price for each pre-funded warrant and accompanying common warrant is equal to the price per share of common stock and accompanying common warrant being sold to the public in this offering, minus \$0.0001. This offering also relates to the shares of common stock issuable upon the exercise of the pre-funded warrants.

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

The adjustment provisions described in the above paragraph included in the common warrants will be available only upon receipt of such stockholder approval as may be required by the applicable rules and regulations of the Nasdaq Capital Market to permit the effectiveness of such adjustment provisions (the "Warrant Stockholder Approval"). In the event that we are unable to obtain the Warrant Stockholder Approval, the provisions described in the above paragraph included in the common warrants will not be effective, and therefore the common warrants may have substantially less value. See "Description of Securities We Are Offering" on page 27 of this prospectus for more information regarding the terms of the common warrants.

This offering will terminate on May 15, 2024 unless we decide to terminate the offering (which we may do at any time in our discretion) prior to that date. We will have one closing for all the securities purchased in this offering. The combined public offering price per share (or pre-funded warrant) and accompanying common warrant will be fixed for the duration of this offering.

We have engaged Roth Capital Partners, LLC, or the placement agent, to act as our exclusive placement agent in connection with this offering. The placement agent has agreed to use its reasonable best efforts to arrange for the sale of the securities offered by this prospectus. The placement agent is not purchasing or selling any of the securities we are offering and the placement agent is not required to arrange the purchase or sale of any specific number of securities or dollar amount. We have agreed to pay to the placement agent the placement agent fees set forth in the table below. There is no arrangement for funds to be received in escrow, trust or similar arrangement. There is no minimum offering requirement as a condition of closing of this offering. We may sell fewer than all of the shares of common stock and common warrants and pre-funded warrants and common warrants offered hereby, which may significantly reduce the amount of proceeds received by us. Because there is no escrow account and no minimum number of securities or amount of proceeds, investors could be in a position where they have invested in us, but we have not raised sufficient proceeds in this offering to adequately fund the intended uses of the proceeds as described in this prospectus. See "Risk Factors" for more information regarding risks related to this offering. We will bear all costs associated with the offering. See "Plan of Distribution" for more information regarding these arrangements.

Our common stock is listed on the Nasdaq Capital Market under the symbol "NUWE." On April 25, 2024, the closing price of our common stock on the Nasdaq Capital Market was \$0.289 per share. There is no established trading market for the pre-funded warrants or common warrants, and we do not expect a market to develop. We do not intend to apply for a listing of the pre-funded warrants or the common warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the pre-funded warrants and the common warrants will be limited.

	Per Share and Accompanying Common Warrant	Per Pre-Funded Warrant and Accompanying Common Warrant	Total
Public offering price	\$0.24	\$0.2399	\$2,699,717
Placement agent fees ⁽¹⁾	\$0.0168	\$0.0168	\$189,000
Proceeds to us (before expenses)	\$0.2232	\$0.2231	\$2,510,717

(1) We have agreed to pay the placement agent a cash fee equal to 7.0% of the aggregate gross proceeds raised in this offering, and to reimburse the placement agent for certain of its offering-related expenses. See "Plan of Distribution" for a description of the compensation to be received by the placement agent.

INVESTING IN OUR SECURITIES INVOLVES RISKS. YOU SHOULD REVIEW CAREFULLY THE RISKS AND UNCERTAINTIES DESCRIBED HEREIN UNDER THE HEADING "RISK FACTORS" BEGINNING ON PAGE 9 OF THIS PROSPECTUS AND UNDER SIMILAR HEADINGS IN THE OTHER DOCUMENTS THAT ARE INCORPORATED BY REFERENCE IN THIS PROSPECTUS.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

Delivery of the securities offered hereby is expected to be made on or about April 30, 2024, subject to satisfaction of customary closing conditions.

Roth Capital Partners

The date of this prospectus is April 26, 2024



Restoring Fluid Balance. Transforming Care.®

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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 (“SEC”). It omits some of the information contained in the registration statement and reference is made to the registration statement for further information with regard to us and the securities being offered hereby. You should review the information and exhibits in the registration statement for further information about us and the securities being offered hereby. Statements in this prospectus concerning any document we filed as an exhibit to the registration statement or that we otherwise filed with the SEC are not intended to be comprehensive and are qualified by reference to the filings. You should review the complete document to evaluate these statements.

We have not, and the placement agent and its affiliates have not, authorized anyone to provide you with any information or to make any representation not contained or incorporated by reference in this prospectus or any related free writing prospectus. We do not, and the placement agent and its affiliates do not, take any responsibility for, and can provide no assurance as to the reliability of, any information that others may provide to you. This prospectus is not an offer to sell or an offer to buy securities in any jurisdiction where offers and sales are not permitted. The information in this prospectus is accurate only as of its date, regardless of the time of delivery of this prospectus or any sale of securities. You should also read and consider the information in the documents to which we have referred you under the caption “Where You Can Find More Information” in the prospectus.

You should read this prospectus, any documents that we incorporate by reference in this prospectus and the additional information described below under “Where You Can Find Additional Information” and “Information Incorporated By Reference” before making an investment decision. You should rely only on the information contained in this prospectus and any free-writing prospectus that we authorize to be distributed to you. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

We have not, and the placement agent has not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to the offering of the securities and distribution of this prospectus outside the United States.

We obtained industry and market data used throughout this prospectus through our research, surveys and studies conducted by third parties and industry and general publications. We have not independently verified market and industry data from third-party sources.

Pursuant to Item 10(f) of Regulation S-K promulgated under the Securities Act of 1933, as amended, as indicated herein, we have elected to comply with the scaled disclosure requirements applicable to “smaller reporting companies,” including providing two years of audited financial statements.

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 securities, you should read this entire prospectus carefully, including our financial statements and related notes incorporated herein by reference, the information in the section “Risk Factors” and our filings incorporated by reference herein to which we have referred you in the sections “Where You Can Find Additional Information” and “Information Incorporated by Reference.” Unless the context otherwise requires, references in this prospectus to the “Company,” “NUWE,” the “registrant,” “we,” “us” and “our” refer to Nuwellis, Inc.

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.

Product Development Activities

As we expand our commercialization efforts in the pediatric market, we are developing a Continuous Renal Replacement Therapy (CRRT) device, branded Vivian, to address the unmet and specific needs of pediatric patients weighing 2.5kg and above who do not have functioning kidneys and who need kidney replacement therapy for survival. It is estimated that approximately 11,000 newborn babies require neonatal kidney replacement therapy each year in the United States. Funded in part by a \$1.7 million grant from the National Institute of Health, the Company completed preliminary engineering and testing for its dedicated pediatric system in the fourth quarter of 2023, and finalized its IDE protocol with the FDA. The Company intends to submit an IDE with the FDA in the third quarter of 2024, with U.S. commercialization of this product expected in the fourth quarter of 2025.

Recent Developments

On December 7, 2023, we received a letter (the “Notice”) from the Listing Qualifications Department (the “Staff”) of the Nasdaq Stock Market (“Nasdaq”) informing us that because the closing bid price for our common stock listed on Nasdaq was below \$1.00 for 30 consecutive trading days, we were not in compliance with the Minimum Bid Price Requirement for continued listing on the Nasdaq Capital Market, as set forth in Nasdaq Marketplace Rule 5550(a)(2).

In accordance with Nasdaq Marketplace Rule 5810(c)(3)(A), the Company has a period of 180 calendar days from December 7, 2023, or until June 4, 2024, to regain compliance with the Minimum Bid Price Requirement. If at any time before June 4, 2024, the closing bid price of our common stock closes at or above \$1.00 per share for a minimum of 10 consecutive trading days (which number days may be extended by Nasdaq), Nasdaq will provide written notification that we have achieved compliance with the Minimum Bid Price Requirement, and the matter would be resolved.

The Notice also disclosed that in the event we do not regain compliance with the Rule by June 4, 2024, we may be eligible for additional time. To qualify for additional time, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for Nasdaq, with the exception of the bid price requirement, and would need to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. We may not qualify for the additional 180 calendar days, because we do not currently meet all of the continued listing requirements of the Nasdaq Capital Market. If we meet these requirements, Nasdaq will inform us that we have been granted an additional 180 calendar days. However, if it appears to the Staff that we will not be able to cure the deficiency, or if we are otherwise not eligible, Nasdaq will provide notice that our securities will be subject to delisting.

We intend to continue actively monitoring the closing bid price for our common stock between now and June 4, 2024, and we will consider available options to resolve the deficiency and regain compliance with the

Minimum Bid Price Requirement. If we do not regain compliance within the allotted compliance period, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that our common stock will be subject to delisting. We would then be entitled to appeal that determination to a Nasdaq hearings panel. There can be no assurance that we will regain compliance with the Minimum Bid Price Requirement during the 180-day compliance period, secure a second period of 180 calendar days to regain compliance, or maintain compliance with the other Nasdaq listing requirements.

We must satisfy Nasdaq's continued listing requirements or risk delisting, which could have a material adverse effect on our business. If our common stock and warrants are delisted from Nasdaq, it could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock as a result of the loss of market efficiencies associated with Nasdaq and the loss of federal preemption of state securities laws. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. If our common stock are delisted, it could be more difficult to buy or sell our common stock or to obtain accurate quotations, and the price of our common stock could suffer a material decline. Delisting could also impair our ability to raise capital on acceptable terms, if at all.

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 Capital Market 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 Securities and Exchange Commission ("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 or the registration statement of which it forms a part.

We are, and will remain, a "smaller reporting company" as long as our public float remains less than \$250 million as of the last business day of our most recently-completed second fiscal quarter. A smaller reporting company may take advantage of specified reduced reporting and other requirements that are otherwise applicable generally to U.S. public companies. As long as our public float remains below \$75 million as of the last business day of our most recently completed second fiscal quarter, we are exempt from the attestation requirement in the assessment of our internal control over financial reporting by our independent auditors pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, but are required to make our own internal assessment of the effectiveness of our internal control over financial reporting.

The Offering	
Issuer	Nuwellis, Inc.
Common Stock to be Offered	8,419,996 shares of common stock based on a combined public offering price of \$0.24 per share of common stock and accompanying common warrant. Each share of common stock is being sold together with one common warrant to purchase one and a half shares of common stock.
Pre-funded Warrants to be Offered	<p>We are also offering to certain purchasers, whose purchase of shares of common stock in this offering would otherwise result in the purchaser, together with its affiliates, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, in lieu of shares of common stock pre-funded warrants to purchase up to 2,830,004 shares of common stock at an exercise price of \$0.0001. Each pre-funded will be exercisable upon issuance and will expire when exercised in full. Each pre-funded warrant is being sold together with one common warrant to purchase one and a half shares of common stock. The public offering price for each pre-funded warrant and accompanying common warrant is equal to the price per share of common stock and accompanying common warrant being sold to the public in this offering, minus \$0.0001. This offering also relates to the shares of common stock issuable upon the exercise of the pre-funded warrants.</p> <p>See “Description of Securities We Are Offering” for additional information.</p>
Common Warrants Offered	The common warrants will have an exercise price of \$0.40, will be exercisable upon issuance and will expire five years from the date of issuance. This offering also relates to the shares of common stock issuable upon the exercise of the common warrants. See “Description of Securities We Are Offering” for additional information.
Common Stock Outstanding before this Offering	6,801,443 shares of common stock.
Common Stock Outstanding after this Offering	18,051,443 shares (assuming all of the pre-funded warrants offered hereby are exercised and no exercise of the common warrants offered hereby).
Use of Proceeds	Assuming all of the pre-funded warrants offered hereby are exercised and no exercise of the common warrants offered hereby, we estimate that the net proceeds from our sale of securities in this offering will be approximately \$2.1 million, after deducting the placement agent fees and estimated offering expenses payable by us. However, this is a reasonable best efforts offering with no minimum number of securities or amount of proceeds as a condition to closing, and we may not sell all or any of these securities offered pursuant to this prospectus; as a result, we may receive significantly less in net proceeds. We intend to use the

net proceeds of this offering for working capital and for general corporate purposes, including for continued investments in our commercialization efforts. For additional information please refer to the section entitled “Use of Proceeds” on page [19](#) of this prospectus.

Risk Factors

Investing in our securities involves a high degree of risk and purchasers of our securities may lose their entire investment. See the information under the captions “Summary of Risk Factors” and “Risk Factors” beginning on page [7](#) and [9](#), respectively, of this prospectus and the other information included elsewhere and incorporated by reference in this prospectus for a discussion of factors you should consider before deciding to invest in our securities.

Listing of Common Stock

Our common stock is listed on the Nasdaq Capital Market under the ticker symbol “NUWE.” There is no established trading market for the common warrants or the pre-funded warrants, and we do not expect a trading market to develop. We do not intend to list the common warrants or the pre-funded warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the common warrants and the pre-funded warrants will be extremely limited.

Reasonable Best Efforts Offering

We have agreed to offer and sell the securities offered hereby to the purchasers through the placement agent. The placement agent is not required to buy or sell any specific number or dollar amount of the securities offered hereby, but they will use their reasonable best efforts to solicit offers to purchase the securities offered by this prospectus. See “Plan of Distribution” beginning on page [31](#) of this prospectus.

Except as otherwise indicated, all information in this prospectus is based on 6,801,443 shares of common stock outstanding as of March 31, 2024 and excludes the following:

- 147,316 shares of our common stock issuable upon the exercise of outstanding stock options, having a weighted average exercise price of \$26.37 per share;
- 2,137,323 shares of our common stock issuable upon the exercise of outstanding warrants (other than the warrants offered hereby) with a weighted-average exercise price of \$22.91 per share;
- 529,209 shares of our common stock issuable upon the conversion of the 127 outstanding shares of our Series F Preferred Stock;
- 2,029 shares of our common stock issuable upon the conversion of the 82 outstanding shares of our Series J Convertible Preferred Stock;
- 831,287 shares of our common stock issuable upon conversion of 33,584 Series J Convertible Preferred Stock issuable upon the exercise of 67,168 warrants issued in the October 2023 Offering; and
- 1,467,266 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

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incentive plans, there will 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 on January 12, 2017, October 12, 2017, January 2, 2019, October 16, 2020 and December 9, 2022.

Unless otherwise indicated, this prospectus assumes no exercise of the common warrants offered hereby.

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 the end of fiscal year 2024. 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 have identified two material weaknesses in connection with our internal control over financial reporting which, if not remediated, could adversely affect our business, reputation and stock price.
- 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.
- The COVID-19 outbreak and other public health threats or outbreaks of communicable diseases could have a material adverse effect on our operations and overall financial performance.
- We have been negatively impacted by the prioritization of COVID-19 patients in hospitals.
- 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 violate any provisions of the Federal Food, Drug, and Cosmetic Act (“FDC 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.
- This is a best-efforts offering, no minimum amount of securities is required to be sold, and we may not raise the amount of capital we believe is required for our business plans.

RISK FACTORS

An investment in our securities has a high degree of risk. Before you invest you should carefully consider the risks and uncertainties described below and the other information in this prospectus, and under the caption “Risk Factors” in our [Annual Report on Form 10-K for the year ended December 31, 2023](#), which is incorporated by reference and the other information in this prospectus. Any of the risks and uncertainties set forth herein could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the trading price or value of our securities. 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. If any of the matters discussed in the following risk factors were to occur, our business, financial condition, results of operations, cash flows or prospects could be materially adversely affected, the market price of our common stock could decline and you could lose all or part of your investment in our securities. Additional risks and uncertainties not presently known or which we consider immaterial as of the date hereof may also have an adverse effect on our business.

RISKS RELATED TO THIS OFFERING AND OUR COMMON STOCK

This is a reasonable best efforts offering, with no minimum amount of securities required to be sold, and we may sell fewer than all of the securities offered hereby.

The placement agent has agreed to use their reasonable best efforts to solicit offers to purchase the shares of common stock together with the common warrants and pre-funded warrants together with common warrants in this offering. The placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. There is no required minimum number of securities that must be sold as a condition to completion of this offering. As there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, placement agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth above. We may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell all of the shares of common stock together with common warrants or pre-funded warrants together with common warrants offered in this offering. The success of this offering will impact our ability to use the proceeds to execute our business plans. We may have insufficient capital to implement our business plans and satisfy current obligations, potentially resulting in greater operating losses or dilution unless we are able to raise the required capital from alternative sources. There is no assurance that alternative capital, if needed, would be available on terms acceptable to us, or at all.

We have broad discretion in the use of the net proceeds we receive from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds we receive in this offering, including for any of the purposes described in the section entitled “Use of Proceeds,” and you will not have the opportunity as part of your investment decision to assess whether our management is using the net proceeds appropriately. Because of the number and variability of factors that will determine our use of our net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business and cause the price of our common stock to decline. Pending their use, we may invest our net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders.

An active trading market for our shares may not be sustained.

Although our shares are listed on the Nasdaq Capital Market, the market for our shares has demonstrated varying levels of trading activity. The current level of trading may not be sustained in the future. The lack of an active market for our shares may impair investors’ ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable, may reduce the fair market value of their shares and may impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire additional intellectual property assets by using our shares as consideration.

This offering may cause the trading price of our common stock to decrease.

The number of shares of common stock underlying the securities we propose to issue and ultimately will issue if this offering is completed, may result in an immediate decrease in the market price of our common stock. This decrease may continue after the completion of this offering. We cannot predict the effect, if any, that the availability of shares for future sale represented by the pre-funded warrants, or common warrants issued in connection with the offering will have on the market price of our common stock from time to time.

Certain provisions in the common warrants will not be effective until we are able to receive stockholder approval of such provisions, and if we are unable to obtain such approval the common warrants may have significantly less value.

Under Nasdaq listing rules, certain anti-dilution provisions in the common warrants will not be effective until, and unless, we obtain the approval of our stockholders. While we intend to promptly seek stockholder approval, there is no guarantee that the Warrant Stockholder Approval will ever be obtained. If we are unable to obtain the Warrant Stockholder Approval, the foregoing provisions will not become effective and the common warrants may have substantially less value. In addition, we will be required to hold a stockholder meeting every sixty days until we obtain the Warrant Stockholder Approval. We will incur substantial costs, and management will devote substantial time and attention, in attempting to obtain the Warrant Stockholder Approval.

Future sales of substantial amounts of our common stock could adversely affect the market price of our common stock.

We may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If additional capital is raised through the sale of equity or convertible debt securities, or perceptions that those sales could occur, the issuance of these securities could result in dilution to investors purchasing our common stock in this offering or result in downward pressure on the price of our common stock, and our ability to raise capital in the future.

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.

On December 7, 2023, we received a Notice informing us that because the closing bid price for our common stock listed on Nasdaq was below \$1.00 for 30 consecutive trading days, we were not in compliance with the Minimum Bid Price Requirement for continued listing on the Nasdaq Capital Market, as set forth in Nasdaq Marketplace Rule 5550(a)(2).

In accordance with Nasdaq Marketplace Rule 5810(c)(3)(A), we have a period of 180 calendar days from December 7, 2023, or until June 4, 2024, to regain compliance with the Minimum Bid Price Requirement. If at any time before June 4, 2024, the closing bid price of our common stock closes at or above \$1.00 per share for a minimum of 10 consecutive trading days (which number days may be extended by Nasdaq), Nasdaq will provide written notification that we have achieved compliance with the Minimum Bid Price Requirement, and the matter would be resolved.

The Notice also disclosed that in the event we do not regain compliance with the Rule by June 4, 2024, we may be eligible for additional time. To qualify for additional time, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for Nasdaq, with the exception of the bid price requirement, and would need to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. We may not qualify for the additional 180 calendar days, because we do not currently meet all of the continued listing requirements of the Nasdaq Capital Market. If we meet these requirements, Nasdaq will inform us that we have been granted an additional 180 calendar days. However, if it appears to the Staff that we will not be able to cure the deficiency, or if we are otherwise not eligible, Nasdaq will provide notice that our securities will be subject to delisting.

We intend to continue actively monitoring the closing bid price for our common stock between now and June 4, 2024, and it will consider available options to resolve the deficiency and regain compliance with the Minimum Bid Price Requirement. If we do not regain compliance within the allotted compliance period, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that our common stock will be subject to delisting. We

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would then be entitled to appeal that determination to a Nasdaq hearings panel. There can be no assurance that we will regain compliance with the Minimum Bid Price Requirement during the 180-day compliance period, secure a second period of 180 calendar days to regain compliance, or maintain compliance with the other Nasdaq listing requirements.

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.

On December 9, 2022, we effected a 1-for-100 reverse stock split of our outstanding common stock. All share amounts and warrant or option exercise prices contained in this report reflect that adjustment. 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 the Nasdaq Capital Market may be negatively impacted by this new Nasdaq rule.

We may not receive any additional funds upon the exercise of the common warrants.

Each common warrant has an exercise price of \$0.40, and may also be exercised in certain circumstances by way of a cashless exercise, meaning that the holder may not pay a cash purchase price upon exercise, but instead would receive upon such exercise the net number of shares of our common stock determined according to the formula set forth in the common warrant. Accordingly, we may not receive any additional funds, or any significant additional funds, upon the exercise of the common warrants.

There is no public market for the common warrants or pre-funded warrants being offered by us in this offering.

There is no established public trading market for the common warrants or the pre-funded warrants, and we do not expect a market to develop. In addition, we do not intend to apply to list the common warrants or the pre-funded warrants on any national securities exchange or other nationally recognized trading system. Without an active market, the liquidity of the common warrants and the pre-funded warrants will be limited.

The common warrants are speculative in nature.

The common warrants represent the right to acquire shares of common stock at a fixed price. Specifically, commencing on the date of issuance, holders of the common warrants may acquire the shares of common stock issuable upon exercise of such warrants at an exercise price of \$0.40. Moreover, following this offering, the market value of the common warrants is uncertain and there can be no assurance that the market value of the common warrants will equal or exceed the public offering price. There can be no assurance that the market price of the shares of common stock will ever equal or exceed the exercise price of the common warrants, and consequently, whether it will ever be profitable for holders of common warrants to exercise the warrants.

Except as otherwise set forth in the common warrants and pre-funded warrants, holders of the common warrants and the pre-funded warrants offered hereby will have no rights as stockholders with respect to the shares of common stock underlying the common warrants and the pre-funded warrants until such holders exercise their common warrants and pre-funded warrants and acquire our common stock.

Except as otherwise set forth in the common warrants and pre-funded warrants, until holders of the common warrants and the pre-funded warrants acquire shares of our common stock upon exercise thereof, such holders of the common warrants and the pre-funded warrants will have no rights with respect to the shares of our common stock underlying such common warrants, such as voting rights. Upon exercise of the common warrants or the pre-funded warrants, as the case may be, the holder will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

Purchasers who purchase our securities in this offering pursuant to a securities purchase agreement may have rights not available to purchasers that purchase without the benefit of a securities purchase agreement.

In addition to rights and remedies available to all purchasers in this offering under federal securities and state law, the purchasers that enter into a securities purchase agreement will also be able to bring claims for breach of contract against us. The ability to pursue a claim for breach of contract provides those investors with the means to enforce the covenants uniquely available to them under the securities purchase agreement including: (i) timely delivery of shares; (ii) agreement to not enter into variable rate financings until the later of (a) 180 days from closing and (b) the date the Warrant Stockholder Approval is obtained, subject to certain exceptions; (iii) agreement to not enter into any financings until the later of (a) 45 days from closing and (b) the date the Warrant Stockholder Approval is obtained; and (iv) indemnification for breach of contract.

Sales of a substantial number of shares of our common stock by our stockholders in the public market could cause our stock price to fall.

The number of shares of common stock issuable upon conversion of our outstanding preferred stock and exercise of outstanding warrants is significant in relation to the number of shares of our common stock currently outstanding.

As of March 31, 2024, we have warrants to purchase 2,137,323 shares of common stock outstanding, with exercise prices ranging from \$3.30 to \$189,000 with a weighted-average exercise price of \$22.91.

As of March 31, 2024, there were 127 shares of Series F Preferred Stock outstanding, convertible into 125,857 shares of common stock. The certificate of designation for our Series F Preferred Stock contains an anti-dilution provision, which provision requires the lowering of the applicable conversion price, as then in effect, to the purchase price per share of common stock or common stock equivalents issued in the future. If the effective price per share on a common-stock equivalent basis in a future equity offering is lower than the then-current conversion price of the Series F Convertible Preferred Stock, then such conversion price shall be reduced to such lower price and additional shares of common stock will be issuable upon the conversion of the of the Series F Convertible Preferred Stock. To the extent the outstanding shares of Series F Convertible Preferred Stock become exercisable for additional shares of common stock, holders of our common stock will

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experience further dilution. As a result of this offering, the number of shares of common stock issuable upon conversion of the Series F Preferred Stock will be increased to 529,209 because the public offering price in this offering is less than the current conversion price of the Series F Preferred Stock, which will be adjusted to the offering price in this offering.

As of March 31, 2024, there were 82 shares of Series J Convertible Preferred Stock outstanding, convertible into 2,029 shares of common stock and 33,584 Series J Convertible Preferred Stock issuable upon the exercise of 67,168 warrants issued in the October 2023 Offering.

If any security holder determines to sell a substantial number of shares into the market at any given time, there may not be sufficient demand in the market to purchase the shares without a decline in the market price for our common stock. Moreover, continuous sales into the market of a number of shares in excess of the typical trading volume for our common stock could depress the trading market for our common stock over an extended period of time. Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. As of March 31, 2024, we have outstanding warrants to purchase an aggregate of approximately 2,137,323 shares of our common stock, and options to purchase an aggregate of approximately 147,316 shares of our common stock, which, if exercised, may further increase the number of shares of our common stock outstanding and the number of shares eligible for resale in the public market.

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.

Our board of directors has authority, without further stockholder approval, to issue additional shares of preferred stock with such rights, preferences and privileges as our board may determine. These rights, preferences and privileges may include dividend rights, conversion rights, voting rights and liquidation rights that may be greater than the rights of our common stock.

Our board of directors has previously approved, pursuant to this authority, the issuance of preferred stock, and we have 127 shares of Series F Preferred Stock outstanding and 82 shares of Series J Convertible Preferred Stock outstanding as of March 31, 2024. Upon liquidation, dissolution or winding-up of the Company, holders of our Series F Preferred Stock and Series J Convertible Preferred Stock have the right to receive, out of the assets, whether capital or surplus, of the Company an amount equal to the par value, plus any accrued and unpaid dividends thereon, for each share of such preferred stock held by such holder before any distribution or payment shall be made to the holders of our common stock, and, following such payment, such holders are entitled to receive the same amount that a holder of common stock would receive if such preferred stock was fully converted, pari passu with all the holders of common stock.

Our board of directors may issue additional series of preferred stock. As a result, the rights of holders of our capital stock will be subject to, and could be adversely affected by, the rights of holders of any stock that may be issued in the 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.

We are generally not restricted from issuing additional common stock, including any securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. The market price of our common stock could decline as a result of sales of common stock or securities that are convertible into or exchangeable for, or that represent the right to receive, common stock after this offering or the perception that such sales could occur.

We have a large number of authorized but unissued shares of stock, which could negatively impact a potential investor if they purchased our common stock.

On December 9, 2022, we effected a 1-for-100 reverse split of our outstanding common stock. This reverse stock split did not change the par value of our common stock or the number of common or preferred shares authorized by our Certificate of Incorporation. Because the number of authorized shares of our common stock was not reduced

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proportionately, the reverse stock split increased our board of directors' ability to issue authorized and unissued shares without further stockholder action. As of March 31, 2024 our certificate of incorporation provides for 100,000,000 shares of authorized common stock and 40,000,000 shares of authorized preferred stock, 30,000 of which are designated Series A Junior Participating Preferred Stock, 18,000 of which are designated Series F Preferred Stock, 600,000 of which are designated Series J Convertible Redeemable Preferred Stock and we have 6,801,443 shares of common stock outstanding, 2,412,526 shares reserved for issuance upon the conversion, exercise or vesting of outstanding preferred stock, warrants and options, 33,584 Series J Convertible Preferred Stock issuable upon the exercise of 67,168 warrants issued in the October 2023 Offering, and 1,467,266 shares of common stock reserved for future grant under the Company's equity incentive plans.

With respect to authorized but unissued and unreserved shares, we could also use such shares to oppose a hostile takeover attempt or delay or prevent changes in control or changes in or removal of management. The issuance of additional shares of common stock or securities convertible into common stock may have a dilutive effect on earnings per share and relative voting power and may cause a decline in the trading price of our common stock. We could use the shares that are available for future issuance in dilutive equity financing transactions, or to oppose a hostile takeover attempt or delay or prevent changes in control or changes in or removal of management, including transactions that are favored by a majority of the stockholders or in which the stockholders might otherwise receive a premium for their shares over then-current market prices or benefit in some other manner.

A more active, liquid trading market for our common stock may not develop, and the price of our common stock may fluctuate significantly.

Historically, the market price of our common stock has fluctuated over a wide range. There has been relatively limited trading volume in the market for our common stock, and a more active, liquid public trading market may not develop or may not be sustained. Limited liquidity in the trading market for our common stock may adversely affect a stockholder's ability to sell its shares of common stock at the time it wishes to sell them or at a price that it considers acceptable. If a more active, liquid public trading market does not develop we may be limited in our ability to raise capital by selling shares of common stock and our ability to acquire other companies or assets by using shares of our common stock as consideration. In addition, if there is a thin trading market or "float" for our stock, the market price for our common stock may fluctuate significantly more than the stock market as a whole. Without a large float, our common stock would be less liquid than the stock of companies with broader public ownership and, as a result, the trading prices of our common stock may be more volatile and it would be harder for a stockholder to liquidate any investment in our common stock. Furthermore, the stock market is subject to significant price and volume fluctuations, and the price of our common stock could fluctuate widely in response to several factors, including:

- our quarterly or annual operating results;
- changes in our earnings estimates;
- investment recommendations by securities analysts following our business or our industry;
- additions or departures of key personnel;
- changes in the business, earnings estimates or market perceptions of our competitors;
- our failure to achieve operating results consistent with securities analysts' projections;
- future announcements concerning us, including our clinical and product development strategy,
- or our competitors;
- regulatory developments, disclosure regarding completed, ongoing or future clinical studies and
- enforcement actions bearing on advertising, marketing or sales;
- acquisition or loss of significant manufacturers, distributors or suppliers or an inability
- to obtain sufficient quantities of materials needed to manufacture our system;
- fluctuations of investor interest in the medical device sector;
- changes in industry, general market or economic conditions; and
- announcements of legislative or regulatory changes.

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The stock market has experienced extreme price and volume fluctuations in recent years that have significantly affected the quoted prices of the securities of many companies, including companies in the health care industry. The changes often appear to occur without regard to specific operating performance. The price of our common stock could fluctuate based upon factors that have little or nothing to do with us and these fluctuations could materially reduce our stock price.

Our ability to use U.S. net operating loss carryforwards might be limited.

As of December 31, 2023, we had U.S. net operating loss (“NOL”) carryforwards of approximately \$212.2 million for U.S. federal income tax purposes. Approximately \$119.7 million of NOL carryforwards will expire from 2024 through 2037. Pursuant to the Tax Cuts and Jobs Act of 2017, the NOL carryforwards generated in 2018 through 2020 totaling approximately \$92.5 million do not expire. The expiration of state NOL carryforwards will vary by jurisdiction. In addition, future utilization of NOL carryforwards in the U.S. may be subject to certain limitations under Section 382 of the Internal Revenue Code. The Company does not have any foreign tax loss carryovers.

We believe the Company may have experienced additional ownership changes under Section 382 of the Internal Revenue Code in the current and earlier years further limiting the NOL carryforwards that may be utilized. We have not yet completed a formal Section 382 analysis. As a result, prior or future changes in ownership could put limitations on the availability of our NOL carryforwards. In addition, our ability to utilize the current NOL carryforwards might be further limited by future issuances of our common stock.

We do not intend to pay cash dividends on our common stock in the foreseeable future.

We have never declared or paid any cash dividends on our common stock, and we currently do not anticipate paying any cash dividends in the foreseeable future. We intend to retain any earnings to finance the development and expansion of our products and business. Accordingly, our stockholders will not realize a return on their investments unless the trading price of our common stock appreciates.

Provisions in our charter documents and Delaware law may delay or deter a change-in-control transaction or limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Delaware law and certain provisions of our Certificate of Incorporation and bylaws make it harder for a third party to acquire us, even if doing so might be beneficial to our stockholders. These provisions include, among other things: authorizing our board of directors to issue, from time to time, any series of preferred stock and fix the designation, powers, preferences and rights of the shares of such series of preferred stock; prohibiting stockholders from acting by written consent; 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; and requiring at least two-thirds of the voting power of our outstanding stock entitled to vote to amend or repeal certain provisions of our Certificate of Incorporation or bylaws. Section 203 of the Delaware General Corporation Law from which we did not elect to opt out, provides that if a holder acquires 15% or more of our stock without prior approval of our board of directors, that holder will be subject to certain restrictions on its ability to acquire us within three years. These provisions may delay or deter a change in control of us, and they could limit the price that investors might be willing to pay in the future for shares of our common stock.

Further, our Certificate of Incorporation establishes 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 Delaware General Corporation Law; or any action asserting a claim against us that is governed by the internal affairs doctrine. This choice of forum provision may limit a stockholder’s ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees.

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

Healthcare professionals may choose to use and prescribe medical devices for uses that are not described in the product’s labeling and for uses that differ from those tested in clinical trials and approved or authorized by

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

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

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

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

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

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

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

If we or any of our independent contractors, consultants, collaborators, manufacturers, vendors or service providers fail to comply with healthcare laws and regulations, we or they could be subject to enforcement actions, which could result in penalties and affect our ability to develop, market and sell our product candidates and may harm our reputation.

We are subject to federal, state, and foreign healthcare laws and regulations pertaining to fraud and abuse and patients' rights. These laws and regulations include:

- the U.S. federal healthcare program anti-kickback law, which prohibits, among other things, persons and entities from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for a healthcare item or service, or the purchasing or ordering of an item or service, for which payment may be made under a federal healthcare program such as Medicare or Medicaid;
- the U.S. federal false claims and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting or causing to be presented, claims for payment by government funded programs such as Medicare or Medicaid that are false or fraudulent, and which may apply to us by virtue of statements and representations made to customers or third parties;
- the U.S. federal Health Insurance Portability and Accountability Act ("*HIPAA*"), which prohibits, among other things, executing a scheme to defraud healthcare programs;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, imposes requirements relating to the privacy, security, and transmission of individually identifiable health information, and requires notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;
- the federal Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians, other healthcare providers and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members, which is published in a searchable form on an annual basis; and
- state laws comparable to each of the above federal laws, such as, for example, anti-kickback and false claims laws that may be broader in scope and also apply to commercial insurers and other non-federal payors, requirements for mandatory corporate regulatory compliance programs, and laws relating to patient data privacy and security.

If our operations are found to be in violation of any such health care laws and regulations, we may be subject to penalties, including administrative, civil and criminal penalties, monetary damages, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, or exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, any of which could adversely affect our financial results. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the information incorporated by reference herein contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of 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. These statements are often, but are not always, made through the use of words or phrases such as “anticipates,” “estimates,” “plans,” “projects,” “continuing,” “ongoing,” “expects,” “management believes,” “we believe,” “we intend” and similar words or phrases. Accordingly, these statements involve estimates, assumptions and uncertainties which could cause actual results to differ materially from those expressed in them. 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 section entitled “Risk Factors.”

Because the factors referred to in the preceding paragraph could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements we make, you should not place undue reliance on any such forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

You should carefully read this prospectus and any related free writing prospectus and with the understanding that our actual future results may materially differ from what we expect.

Except as required by law, forward-looking statements speak only as of the date they are made, and we assume no obligation to update any forward-looking statements publicly, or to update the reasons why actual results could differ materially from those anticipated in any forward-looking statements, even if new information becomes available.

This prospectus also refers to estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately \$2.1 million, after deducting placement agent fees and estimated offering expenses payable by us, and assuming all of the pre-funded warrants offered hereby are exercised and no exercise of the common warrants offered hereby. However, because this is a reasonable best efforts offering with no minimum number of securities or amount of proceeds as a condition to closing, the actual offering amount, placement agent fees and net proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth on the cover page of this prospectus, and we may not sell all or any of the securities we are offering.

If all of the common warrants sold in the offering were sold and exercised for cash, we would receive additional net proceeds of approximately \$6.8 million.

We currently intend to use the net proceeds of this offering for working capital and general corporate purposes, including for continued investments in our commercialization efforts. We cannot currently allocate specific percentages of the net proceeds to us from this offering that we may use for these purposes and our management will have broad discretion in the allocation of such net proceeds.

Circumstances that may give rise to a change in the use of proceeds and the alternate purposes for which the proceeds may be used include:

- The existence of other opportunities or the need to take advantage of changes in timing of our existing activities;
- The need or desire on our part to accelerate, increase or eliminate existing initiatives due to, among other things, changing market conditions and competitive developments; and/or
- If strategic opportunities present themselves (including acquisitions, joint ventures, licensing and other similar transactions).

From time to time, we evaluate these and other factors and we anticipate continuing to make such evaluations to determine if the existing allocation of resources, including the proceeds of this offering, is being optimized.

Pending the application of the net proceeds as described above, we will hold the net proceeds from this offering in short-term, interest-bearing securities.

CAPITALIZATION

The following table summarizes our capitalization as of December 31, 2023. Such information is set forth on the following basis (i) on an actual basis; (ii) pro forma basis, giving effect to the exercise of warrants for shares of Series J Convertible Preferred Stock and conversion of 45,207 shares of Series J Convertible Preferred Stock into 1,118,982 shares of our common stock after December 31, 2023 and net cash proceeds related to the exercise of warrants for approximately \$500,000 (the “Conversion”), and (iii) on an as adjusted basis, giving effect to the sale of 8,419,996 shares of common stock and accompanying warrants at an offering price of \$0.24 per share and accompanying warrant and pre-funded warrants to purchase up to 2,830,004 shares of common stock and accompanying warrant at an offering price of \$0.2399 per pre-funded warrant and accompanying warrant in this offering, and assuming all of the pre-funded warrants offered in this offering are exercised and that no value is attributed to the common warrants and that such common warrants are classified as and accounted for as equity, after deducting placement agent fees and estimated offering expenses, and excluding the proceeds, if any, from the subsequent exercise of the common warrants issued pursuant to this offering.

You should read this table together with “Management’s Discussion and Analysis of Financial Condition and Results of Operation,” as well as our financial statements and related notes and the other financial information appearing in our [Annual Report on Form 10-K for the year ended December 31, 2023](#), which are each incorporated by reference in this prospectus. The information presented in the capitalization table has been adjusted to reflect the effect of this current offering.

The pro forma information set forth in the table below is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

	As of December 31, 2023 (in thousands, except share and per share data)		
	Actual	Pro Forma	Pro Forma As Adjusted
Cash and cash equivalents	\$ 3,800	\$ 4,300	\$ 6,445
Mezzanine Equity:			
Series J convertible preferred stock, par value \$0.0001 per share; authorized 600,000 shares, issued and outstanding 11,950, 82 and 82 shares, actual, pro forma, and pro forma as adjusted, respectively	—	—	—
Stockholders’ equity:			
Series A junior participating preferred stock, par value \$0.0001 per share; authorized 30,000 shares, none outstanding actual and pro forma, and pro forma as adjusted	—	—	—
Series F convertible preferred stock, par value \$0.0001 per share; authorized 18,000 shares, issued and outstanding 127 shares actual, pro forma and pro forma as adjusted	—	—	—
Common stock, par value \$0.0001 per share; authorized 100,000,000 shares, issued and outstanding 5,682,461, 6,801,443 and 18,051,443 shares actual, pro forma, and pro forma as adjusted, respectively	1	1	2
Additional paid-in capital	290,646	291,146	293,291
Accumulated other comprehensive income:			
Foreign currency translation adjustment	(31)	(31)	(31)
Unrealized gain on marketable securities	—	—	—
Accumulated deficit	(287,626)	(287,626)	(287,626)
Total stockholders’ equity	\$ 2,990	\$ 3,490	\$ 5,635

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The pro forma column reflects the effect of the Conversions and the as adjusted column reflects our sale of securities in this offering assuming all of the pre-funded warrants offered hereby are exercised. The number of shares of our common stock to be outstanding after this offering is based on 5,682,461 shares of common stock outstanding as of December 31, 2023 (6,801,443 shares of our common stock outstanding on a pro forma basing after giving effect to the Conversions) and excludes the following:

- 110,916 shares of our common stock issuable upon the exercise of outstanding stock options, having a weighted average exercise price of \$35.90 per share;
- 2,963,192 shares of our common stock issuable upon the exercise of outstanding warrants (other than the warrants offered hereby) with a weighted-average exercise price of \$30.86 per share;
- 125,857 shares of our common stock issuable upon the conversion of the 127 outstanding shares of our Series F Preferred Stock;
- 295,792 shares of our common stock (2,029 shares on a pro forma basis after giving effect to the Conversions) issuable upon the conversion of the 11,950 outstanding shares of our Series J Convertible Preferred Stock;
- 1,656,361 shares of our common stock issuable upon conversion of 66,917 Series J Convertible Preferred Stock issuable upon the exercise of 133,834 warrants issued in the October 2023 Offering; and
- 41,871 shares of our common stock reserved for future issuance under our equity incentive plans.

DESCRIPTION OF CAPITAL STOCK

The following summary descriptions of our current capital stock 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 March 31, 2024. Once shares of Series F 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 March 31, 2024, we had (i) 6,801,443 outstanding shares of common stock, (ii) 127 outstanding shares of Series F Preferred Stock, which, at the currently applicable conversion price, would convert into 529,209 shares of common stock, which contain price protection anti-dilution and are subject to future adjustment, including as a result of this offering as described under “Risk Factors Sales of a substantial number of shares of our common stock by our stockholders in the public market could cause our stock price to fall.” (iii) 82 outstanding shares of Series J Convertible Preferred Stock, which, at the currently applicable conversion price, would convert into 2,029 shares of common stock, subject to future adjustment, (iv) outstanding options to acquire 147,316 shares of our common stock, (v) outstanding warrants to purchase 2,137,323 shares of our common stock, (vi) 33,584 Series J Convertible Preferred Stock underlying the warrants issued in the October 2023 Offering, and (vii) 2,029 shares of common stock underlying the outstanding Series J Convertible Preferred Stock.

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, 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).

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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;
- the limitations on removal of any of our directors described below under “Description of 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 Capital Stock – Choice of Forum;”
- the limitations on director liability and indemnification described below under the heading “Description of 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.

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.

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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.

Anti-Takeover Effects of Certain Provisions of Our Certificate of Incorporation and 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;
- 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 66²/₃% super-majority stockholder approval in order for stockholders to alter, amend or repeal certain provisions of our certificate of incorporation;
- requiring a 66²/₃% 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

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- 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 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;
- 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 Second 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.

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.

Registration Rights

DaVita Supply Agreement. Concurrent with the signing of the Supply Agreement and issuance of the DaVita Warrant June 19, 2023, the Company entered into a Registration Rights Agreement ("Registration Rights Agreement") with DaVita, whereby the Company agreed, subject to DaVita's delivery of the Ultrafiltration Services Approval (as defined in the Registration Rights Agreement), to register the resale of the shares of common stock issuable upon exercise of the DaVita Warrant ("Underlying Shares") on a Form S-1 or Form S-3, if eligible, upon DaVita's demand. Furthermore, subject to DaVita's delivery of the Ultrafiltration Services Approval DaVita has "piggyback" registration rights allowing it to include its Underlying Shares in a registration effected by the Company for stockholders other than DaVita. The Company is responsible for all fees and expenses incident to the performance of or compliance with the Registration Rights Agreement borne by the Company whether or not any registrable securities are sold pursuant to a registration statement. The Registration Rights Agreement also contains customary indemnification provisions.

DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering 8,419,996 shares of our common stock and common warrants to purchase up to 16,875,000 shares of common stock. We are also offering pre-funded warrants to purchase up to 2,830,004 shares of common stock to those purchasers whose purchase of shares of common stock in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding shares of common stock following the consummation of this offering in lieu of the shares of common stocks that would result in such excess ownership. The shares of our common stock and/or pre-funded warrants and related common warrants will be issued separately. We are also registering the shares of our common stock issuable from time to time upon exercise of the pre-funded warrants and common warrants offered hereby.

Common Stock

The material terms of our common stock are described under the caption “Description of Capital Stock” in this prospectus.

Common Warrants

The following summary of certain terms and provisions of the common warrants and pre-funded warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the warrants, the forms of which are filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the forms of warrants for a complete description of the terms and conditions of the warrants.

Duration, Exercise Price and Form. The common warrants will have an exercise price of \$0.40 and will be exercisable beginning on the Initial Exercise Date. The common warrants will expire on the five-year anniversary of the Initial Exercise Date. The exercise price and number of shares of common stock issuable upon exercise of the common warrants is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The common warrants will be issued separately from the common stock and pre-funded warrants and may be transferred separately immediately thereafter. The common warrants will be issued in electronic form.

Exercisability. The warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of such holder’s warrants to the extent that the holder would own more than 4.99% of the outstanding common stock (or at the election of a holder prior to the date of issuance, 9.99%) immediately after exercise, except that upon at least 61 days’ prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder’s warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants.

Cashless Exercise. If, at the time a holder exercises its warrants, there is no effective registration statement registering, or the prospectus contained therein is not available for an issuance of the shares underlying the warrants to the holder, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the applicable warrant. On the termination date of the warrants, the warrants will be automatically exercised via cashless exercise.

Warrant Stockholder Approval. Under Nasdaq listing rules, the anti-dilution provisions and the reverse stock split provision in the common warrants (each described below) will not be effective until, and unless, we obtain the approval of our stockholders. While we intend to promptly seek stockholder approval, there is no guarantee that the Warrant Stockholder Approval will ever be obtained. If we are unable to obtain the Warrant Stockholder Approval, the foregoing provisions will not become effective and the common warrants will have substantially less value. In addition, we will be required to hold a stockholder meeting every sixty days until we obtain the Warrant Stockholder Approval. We will incur substantial costs, and management will devote substantial time and attention, in attempting to obtain the Warrant Stockholder Approval.

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Reverse Stock Split. If at any time on or after the Warrant Stockholder Approval, there occurs any stock split, stock dividend, stock combination recapitalization or other similar transaction involving our common stock and the lowest daily volume weighted average price during the five consecutive trading days immediately following such event is less than the exercise price of the common warrants then in effect, then the exercise price of the common warrants will be reduced to the lowest daily volume weighted average price during such period and the number of shares issuable upon exercise will be proportionately adjusted such that the aggregate price will remain unchanged. If prior to the Warrant Stockholder Approval, there occurs any stock split, stock dividend, stock combination recapitalization or other similar transaction involving our common stock, the exercise price of the common warrants will be reduced to the lower of (i) lowest volume weighted average price for the five trading days immediately following the date such event and (ii) the lowest volume weighted average price for the five trading days immediately following the date we obtain the Warrant Stockholder Approval, and the number of shares issuable upon exercise will be proportionately adjusted such that the aggregate price will remain unchanged. An adjustment to the exercise price as a result of any such combination event shall only take place one time. In no event will the exercise price of the common warrants be reduced below a floor price of \$0.06, which is equal to 20% of the Minimum Price (as defined under Nasdaq Listing Rule 5635(d)) as of the pricing date of this offering.

Subsequent Financing. Conditioned upon the receipt of the Warrant Stockholder Approval, and subject to certain exemptions, if we sell, enter into an agreement to sell, or grant any option to purchase, or sell, enter into an agreement to sell, or grant any right to reprice, or otherwise dispose of or issue (or announce any offer, sale, grant or any option to purchase or other disposition) any shares of common stock, at an effective price per share less than the exercise price of the common warrants then in effect, the exercise price of the common warrants will be reduced to such price, and the number of shares issuable upon exercise will be proportionately adjusted such that the aggregate exercise price will remain unchanged. In no event will the exercise price of the common warrants be reduced below a floor price of \$0.06, which is equal to 20% of the Minimum Price (as defined under Nasdaq Listing Rule 5635(d)) as of the pricing date of this offering.

Fundamental Transactions. In the event of a fundamental transaction, as described in the warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation with or into another person, the acquisition of more than 50% of our outstanding common stock, the holders of the warrants will be entitled to receive upon exercise of the warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the warrants immediately prior to such fundamental transaction, and the successor entity will succeed to, and be substituted for us, and may exercise every right and power that we may exercise and will assume all of our obligations under the warrants with the same effect as if such successor entity had been named in the warrant itself. If holders of our common stock are given a choice as to the securities, cash or property to be received in a fundamental transaction, then the holder shall be given the same choice as to the consideration it receives upon any exercise of the warrant following such fundamental transaction. 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 warrants for cash in an amount equal to the value of the remaining unexercised portion of such holder's warrants, determined in accordance with the Black Scholes option pricing model as more particularly set forth in the warrants.

Warrant Agent; Global Certificate. The warrants will be issued in registered form under a warrant agency agreement between our transfer agent or other warrant agent and us. The warrants will initially be represented only by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company, or DTC, and registered in the name of Cede & Co, a nominee of DTC, or as otherwise directed by DTC.

Transferability. Subject to applicable laws, a warrant may be transferred at the option of the holder upon surrender of the warrant to us together with the appropriate instruments of transfer.

Fractional Shares. No fractional shares of common stock will be issued upon the exercise of the warrants. Rather, the number of shares of common stock to be issued will be rounded up to the nearest whole number or we will pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price.

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Trading Market. There is no established trading market for the warrants, and we do not expect a market to develop. We do not intend to apply for a listing of the warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the warrants will be limited. The common stock issuable upon exercise of the warrants is currently listed on Nasdaq.

Rights as a Stockholder. Except as otherwise provided in the warrants or by virtue of the holders' ownership of shares of common stock, the holders of the warrants do not have the rights or privileges of holders of our shares of common stock, including any voting rights, until such warrant holders exercise their warrants.

Governing Law. The warrants and the warrant agency agreement are governed by New York law.

Pre-Funded Warrants

The following summary of certain terms and provisions of the pre-funded warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the pre-funded warrant, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of pre-funded warrant for a complete description of the terms and conditions of the pre-funded warrants.

Duration, Exercise Price and Form. Each pre-funded warrant will have an initial exercise price per share equal to \$0.0001. The pre-funded warrants will be immediately exercisable and will not expire prior to exercise. The exercise price and number of shares of common stock issuable upon exercise are subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock. The pre-funded warrants will be issued in paper form.

Exercisability. The pre-funded warrants will be 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 shares of common stock underlying the pre-funded warrants under the Securities Act of 1933, as amended (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 shares of common stock purchased upon such exercise. A holder (together with its affiliates) may not exercise any portion of the pre-funded warrant to the extent that the holder would own more than 4.99% (or, at the election of the holder, 9.99%) of the outstanding common stock immediately after exercise, except that upon notice from the holder to us, the holder may increase or decrease the beneficial ownership limitation in the holder's pre-funded warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants provided that any increase in the beneficial ownership limitation shall not be effective until 61 days following notice to us.

Cashless Exercise. A holder of pre-funded warrants may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the pre-funded warrant.

Transferability. Subject to applicable laws, a pre-funded warrant may be transferred at the option of the holder upon surrender of the pre-funded warrant to us together with the appropriate instruments of transfer.

Fractional Shares. No fractional shares of common stock will be issued upon the exercise of the pre-funded warrants. Rather, the number of shares of common stock to be issued will be rounded up to the nearest whole number.

Trading Market. There is no established public trading market for the pre-funded warrants, and we do not expect a market to develop. In addition, we do not intend to apply to list the pre-funded warrants on any national securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the pre-funded warrants will be limited.

Right as a Stockholder. Except as otherwise provided in the pre-funded warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the pre-funded warrants do not have the rights or privileges of holders of our common stock with respect to the shares of common stock underlying the pre-funded warrants, including any voting rights, until they exercise their pre-funded warrants. The pre-funded warrants will provide that holders have the right to participate in distributions or dividends paid on our common stock.

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Fundamental Transaction. In the event of a fundamental transaction, as described in the pre-funded warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the pre-funded warrants will be entitled to receive upon exercise of the pre-funded warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the pre-funded warrants immediately prior to such fundamental transaction, and the successor entity will succeed to, and be substituted for us, and may exercise every right and power that we may exercise and will assume all of our obligations under the pre-funded warrants with the same effect as if such successor entity had been named in the pre-funded warrant itself. If holders of our common stock are given a choice as to the securities, cash or property to be received in a fundamental transaction, then the holder shall be given the same choice as to the consideration it receives upon any exercise of the pre-funded warrant following such fundamental transaction.

Amendment and Waiver. The pre-funded warrants may be modified or amended or the provisions thereof waived with the written consent of our company and the respective holder.

Governing Law. The pre-funded warrants are governed by New York law.

PLAN OF DISTRIBUTION

We have engaged Roth Capital Partners, LLC to act as the exclusive placement agent (the “placement agent”) to solicit offers to purchase the securities offered by this prospectus. The placement agent is not purchasing or selling any securities, nor is it required to arrange for the purchase and sale of any specific number or dollar amount of securities, other than to use its “reasonable best efforts” to arrange for the sale of the securities by us. Therefore, we may not sell the entire amount of securities being offered. There is no minimum amount of proceeds that is a condition to closing of this offering. The placement agent does not guarantee that it will be able to raise new capital in this offering. The terms of this offering are subject to market conditions and negotiations between us and prospective investors in consultation with the placement agents. The placement agent will have no authority to bind us. This offering will terminate no later than May 15, 2024, unless we decide to terminate the offering (which we may do at any time in our discretion) prior to that date. We will have one closing for all the securities purchased in this offering. The public offering price per share and accompanying common warrant will be fixed for the duration of this offering. The placement agents may engage one or more sub-placement agents or selected dealers to assist with the offering.

We have entered into a securities purchase agreement with certain investors purchasing the securities offered hereby. In addition to rights and remedies available to all purchasers in this offering under federal securities and state law, the purchasers which enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. The ability to pursue a claim for breach of contract is material to larger purchasers in this offering as a means to enforce the following covenants uniquely available to them under the securities purchase agreement: (i) a covenant to not enter into variable rate financings until the later of (a) for a period of 180 days following the closing of the offering and (b) the date the Warrant Stockholder Approval is obtained, subject to certain exceptions; and (ii) a covenant to not enter into any equity financings until the later of (a) 45 days from closing of the offering and (b) the date the Warrant Stockholder Approval is obtained, subject to certain exceptions. The nature of the representations, warranties and covenants in the securities purchase agreements shall include:

- standard issuer representations and warranties on matters such as organization, qualification, authorization, no conflict, no governmental filings required, current in SEC filings, no litigation, labor or other compliance issues, environmental, intellectual property and title matters and compliance with various laws such as the Foreign Corrupt Practices Act; and
- covenants regarding matters such as no integration with other offerings, no stockholder rights plans, no material nonpublic information, use of proceeds, indemnification of purchasers, listing of shares of common stock, and no subsequent equity sales until the later of (a) 45 days from closing of the offering and (b) the date the Warrant Stockholder Approval is obtained.

We will deliver the securities being issued to the investors upon receipt of investor funds for the purchase of the securities offered pursuant to this prospectus. We expect to deliver the securities being offered pursuant to this prospectus on or about April 30, 2024.

Placement Agent Fees and Expenses

Upon the closing of this offering, we will pay the placement agent a cash transaction fee equal to 7.0% of the aggregate gross cash proceeds to us from the sale of the securities in the offering. In addition, we will reimburse the placement agent for certain of its out-of-pocket expenses incurred in connection with this offering, including the placement agent’s legal fees, and actual travel and reasonable out-of-pocket expenses, in an amount not to exceed \$108,000.

The following table shows the public offering price, placement agent fees and proceeds, before expenses, to us.

	Per Share and Accompanying Common Warrant	Per Pre-Funded Warrant and Accompanying Common Warrant	Total
Public offering price	\$0.24	\$0.2399	\$2,699,717
Placement agent’s fees (7.0%)	\$0.0168	\$0.0168	\$189,000

	Per Share and Accompanying Common Warrant	Per Pre-Funded Warrant and Accompanying Common Warrant	Total
Proceeds to us (before expenses)	\$0.2232	\$0.2231	\$2,510,717

We estimate that the total expenses of the offering, including registration and filing fees, printing fees and legal and accounting expenses, but excluding the placement agent fees, will be approximately \$365,500, all of which are payable by us. This figure includes, among other things, the placement agent’s expenses (including the legal fees, costs and expenses for the placement agent’s legal counsel) that we have agreed to reimburse.

Lock-Up Agreements

Each of our executive officers and directors have agreed to be subject to a lock-up period of 90 days following the date of this prospectus. This means that, during the applicable lock-up period, they may not offer for sale, contract to sell, or sell any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock subject to certain customary exceptions. In addition, we have agreed to not issue any shares of common stock or securities exercisable or convertible into shares of common stock until the later of (a) 45 days from closing of the offering and (b) the date the Warrant Stockholder Approval is obtained, subject to certain exceptions, and to not issue any securities that are subject to a price reset based on trading prices of our common stock or upon a specified or contingent event in the future, or enter into an agreement to issue securities at a future determined price, until the later of (a) 180 days from closing of the offering and (b) the date the Warrant Stockholder Approval is obtained, subject to certain exceptions.

Tail

We have also agreed to pay the placement agent a tail fee equal to the cash compensation in this offering, if any investor, who was contacted or introduced to us by the placement agent during the term of their engagement who was not a prior investor in us, provides us with capital in any public or private offering or other financing or capital raising transaction during the 12-month period following the termination or expiration of our engagement letter with the placement agent, subject to certain exceptions.

Indemnification

We have agreed to indemnify the placement agent against certain liabilities, including certain liabilities arising under the Securities Act or to contribute to payments that the placement agent may be required to make for these liabilities.

Regulation M

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by it and any profit realized on the resale of the securities sold by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. As an underwriter, the placement agent would be required to comply with the requirements of the Securities Act and the Securities Exchange Act of 1934, as amended (the “Exchange Act”), including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the placement agent acting as principal. Under these rules and regulations, the placement agent (i) may not engage in any stabilization activity in connection with our securities and (ii) may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

Determination of Offering Price and Warrant Exercise Price

The combined public offering price per share and accompanying common warrants and the combined public offering price per pre-funded warrant and accompanying warrants we are offering, and the exercise price of the common warrants included with the common stock or pre-funded warrants that we are offering, were negotiated

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between us, the placement agent and the investors in the offering based on the trading of our shares of common stock prior to the offering, among other things. Other factors considered in determining the public offering price of the securities we are offering, as well as the exercise price of the warrants that we are offering, include our history and prospects, the stage of development of our business, our business plans for the future and the extent to which they have been implemented, an assessment of our management, the general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant.

Electronic Distribution

A prospectus in electronic format may be made available on a website maintained by the placement agent or an affiliate. Other than this prospectus, the information on any of the placement agent's websites and any information contained in any other website maintained by the placement agent is not part of this prospectus or the registration statement of which this prospectus form a part, has not been approved and/or endorsed by us or any of the placement agent, and should not be relied upon by investors. In connection with the offering, the placement agent or selected dealers may distribute prospectuses electronically. No forms of electronic prospectus other than prospectuses that are printable as Adobe® PDF will be used in connection with this offering.

Other than the prospectus in electronic format, the information on any of the placement agent's websites and any information contained in any other website maintained by the placement agent is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the placement agent in its capacity as placement agent and should not be relied upon by investors.

Other Relationships

The placement agent and certain of its affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The placement agent and certain of its affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses. However, except as disclosed in this prospectus, we have no present arrangements with the placement agent for any further services.

In the ordinary course of their various business activities, the placement agent and certain of its affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the placement agent or its affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The placement agent and its affiliates may hedge such exposure by entering into transactions that consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the securities offered hereby. Any such short positions could adversely affect future trading prices of the securities offered hereby. The placement agent and certain of its affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Listing

Our common stock is traded on Nasdaq under the symbol "NUWE." There is no established trading market for the common warrants or the pre-funded warrants, and we do not expect a trading market to develop. We do not intend to list the common warrants or the pre-funded warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the common warrants and the pre-funded warrants will be extremely limited.

Transfer Agent and Registrar

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

Selling Restrictions

Notice to prospective investors in the United Kingdom

In relation to the United Kingdom, no securities have been offered or will be offered to the public in the United Kingdom prior to the publication of a prospectus in relation to the securities which has been approved by the competent authority in the United Kingdom, except that offers of securities may be made to the public in the United Kingdom at any time under the following exemptions under the Prospectus Regulation:

- i. to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- ii. to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Regulation), subject to obtaining the prior consent of the placement agent; or
- iii. in any other circumstances falling within Article 1(4) of the Prospectus Regulation;

provided that no such offer of shares shall require the issuer or any placement agent to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any securities or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the placement agent and us that it is a “qualified investor” within the meaning of Article 2(e) of the Prospectus Regulation. In the case of any securities being offered to a financial intermediary as that term is used in the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the securities acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any securities to the public other than their offer or resale in the United Kingdom to qualified investors as so defined or in circumstances in which the prior consent of the placement agent have been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an “offer to the public” in relation to any securities in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any securities to be offered so as to enable an investor to decide to purchase or subscribe for any securities, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129. References to the Prospectus Regulation includes, in relation to the United Kingdom, the Prospectus Regulation as it forms part of United Kingdom domestic law by virtue of the European Union (Withdrawal) Act 2018.

In addition, in the United Kingdom, this prospectus is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are “qualified investors” (as defined in the Prospectus Regulation) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order, all such persons together being referred to as “relevant persons” or otherwise in circumstances which have not resulted and will not result in an offer to the public of the securities in the United Kingdom within the meaning of the Financial Services and Markets Act 2000.

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this prospectus or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this prospectus relates to may be made or taken exclusively by relevant persons.

Notice to prospective investors in Canada

The securities may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation,

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provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to prospective investors in Australia

This prospectus:

- does not constitute a disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth), or the Corporations Act;
- has not been, and will not be, lodged with the Australian Securities and Investments Commission, or ASIC, as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document for the purposes of the Corporations Act; and
- may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, available under section 708 of the Corporations Act, or the Exempt Investors.

The securities may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the securities may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any securities may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the securities, you represent and warrant to us that you are an Exempt Investor.

As any offer of securities under this prospectus will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in section 708 applies to that resale. By applying for the securities, you undertake to us that you will not, for a period of 12 months from the date of issue of the securities, offer, transfer, assign or otherwise alienate those securities to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

Notice to prospective investors in the British Virgin Islands

The securities are not being, and may not be offered to the public or to any person in the British Virgin Islands for purchase or subscription by or on behalf of us. The securities may be offered to companies incorporated under the BVI Business Companies Act, 2004 (British Virgin Islands), or BVI Companies, but only where the offer will be made to, and received by, the relevant BVI Company entirely outside of the British Virgin Islands. This prospectus has not been, and will not be, registered with the Financial Services Commission of the British Virgin Islands. No registered prospectus has been or will be prepared in respect of the securities for the purposes of the Securities and Investment Business Act, 2010 or the Public Issuers Code of the British Virgin Islands.

Notice to prospective investors in Israel

In the State of Israel, this prospectus shall not be regarded as an offer to the public to purchase the securities under the Israeli Securities Law, 5728-1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728-1968, including, inter alia, if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions, or the Addressed Investors; or (ii) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728-1968, subject to certain conditions, or the Qualified Investors. The Qualified Investors shall not be taken into account

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in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. The company has not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728-1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for the securities to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors. Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728-1968. In particular, we may request, as a condition to be offered common stock, that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728-1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728-1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728-1968 and the regulations promulgated thereunder in connection with the offer of the securities; (iv) that the securities that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728-1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728-1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor's name, address and passport number or Israeli identification number.

LEGAL MATTERS

Honigman LLP, Kalamazoo, Michigan, will issue a legal opinion as to the validity of the securities offered by this prospectus. Lowenstein Sandler LLP, New York, New York, is acting as counsel to the placement agent in connection with certain legal matters related to this offering.

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 our Annual Report on Form 10-K for the year ended December 31, 2023, which are incorporated by reference into this prospectus and elsewhere in the registration statement, 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 ADDITIONAL INFORMATION

We file reports, proxy statements and other information with the SEC in accordance with the Exchange Act. Our reports, proxy statements and other information filed with the SEC are available free of charge to the public over the Internet at the SEC's website at <http://www.sec.gov>. 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.

INFORMATION INCORPORATED BY REFERENCE

SEC rules allow us to "incorporate by reference" into this prospectus much of the information we file with the SEC, which means that we can disclose important information to you by referring you to those publicly available documents. The information that we incorporate by reference into this prospectus, including the consolidated financial statements, is considered to be part of this prospectus. These documents may include Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as proxy statements. You should read the information incorporated by reference because it is an important part of this prospectus.

This prospectus incorporates by reference the documents listed below, other than those documents or the portions of those documents deemed to be furnished and not filed in accordance with SEC rules:

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on [March 11, 2024](#);
- our Current Report on Form 8-K filed with the SEC on [February 6, 2024](#) and [March 26, 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) on or after the date of the initial filing of the registration statement containing this prospectus and prior to the effectiveness of the registration statement and (ii) on or after the date of this prospectus until the earlier of the date on which all of the securities registered hereunder have been sold or this prospectus 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. The information in documents that we file in the future will update and supersede the information currently included and incorporated by reference in this prospectus. 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 <https://www.nuwellis.com/>. Information contained in, or accessible through, our website is not a part of this prospectus.

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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.
12988 Valley View Road
Eden Prairie, Minnesota 55344
(952) 345-4200
ir@nuwellis.com
Attention: Robert B. Scott
Chief Financial Officer

8,419,996 Shares of Common Stock

2,830,004 Pre-Funded Warrants to purchase up to 2,830,004 Shares of Common Stock

16,875,000 Common Warrants to purchase up to 16,875,000 Shares of Common Stock

19,705,004 Shares of Common Stock Underlying the Pre-Funded Warrants and Common Warrants



PROSPECTUS

Roth Capital Partners LLC

APRIL 26, 2024
