

PROSPECTUS



NUWELLIS, INC.

15,235,196 Class A Units consisting of shares of common stock and warrants and 23,157,124 Class B Units consisting of Series I convertible preferred stock and warrants (and shares of common stock underlying shares of Series I convertible preferred stock and such warrants)

We are offering 15,235,196 Class A Units, with each Class A Unit consisting of one share of common stock, par value \$0.0001 per share (“common stock”), and 1.5 warrants to purchase one share of our common stock (together with the shares of common stock underlying such warrants, the “Class A Units”) at a public offering price of \$0.25 per Class A Unit.

We are also offering 23,157,124 Class B Units to purchasers who prefer not to beneficially own more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering. Each Class B Unit will consist of one share of Series I Convertible Preferred Stock, par value \$0.0001 per share (the “Series I Preferred Stock”), convertible at any time at the holder’s option into one share of common stock, and 1.5 warrants to purchase one share of common stock at an exercise price of \$0.25 per share (together with the shares of common stock underlying such shares of Series I Preferred Stock and such warrants, the “Class B Units” and, together with the Class A Units, the “Units”) at a public offering price of \$0.25 per Class B Unit.

The Class A Units and Class B Units will not be certificated and the shares of common stock, Series I Preferred Stock and warrants comprising such Units are immediately separable and will be issued separately in this offering. Warrants included in the Units have an exercise price of \$0.25 per whole share, are exercisable beginning on the effective date of a reverse stock split in an amount sufficient to permit the exercise in full of the warrants, contingent upon stockholder approval of such reverse stock split and of the exercisability of the warrants and will expire six years from the initial exercise date.

Our common stock trades on The Nasdaq Capital Market under the ticker symbol “NUWE”. See “Prospectus Summary – Recent Developments” in this prospectus for important information about the listing of our common stock on The Nasdaq Capital Market. We do not intend to list the warrants or preferred stock to be sold in this offering on any stock exchange or other trading market.

Investing in our common stock involves a high degree of risk. Before making any investment in our securities, you should read and carefully consider the risks described in this prospectus under the section of this prospectus entitled “Risk Factors” on page 11 of this prospectus.

	Per Class A Unit	Per Class B Unit(1)	Total
Public offering price	\$0.25	\$0.25	\$9,598,080.00
Underwriting discounts ⁽²⁾	\$0.02	\$0.02	\$ 767,846.40
Proceeds, before expenses, to Nuwellis, Inc.	\$0.23	\$0.23	\$8,830,233.60

(1) The public offering price and underwriting discount corresponds to (x) in respect of the Class A Units (i) a public offering price per share of common stock of \$0.2499 and (ii) a public offering price per 1.5 warrants of \$0.0001 and (y) in respect of the Class B Units (i) a public offering price per share of Series I Preferred Stock of \$0.2499 and (ii) a public offering price per 1.5 warrants to purchase one share of common stock of \$0.0001.

(2) We have agreed to pay certain expenses of the underwriters in this offering. We refer you to “Underwriting” on page 34 for additional information regarding underwriting compensation.

The underwriters have the option to purchase up to (i) 5,758,848 additional shares of common stock, and/or (ii) additional warrants to purchase up to 8,638,272 additional shares of common stock solely to cover over-allotments, if any, at the public offering price per share of common stock and the public offering price per 1.5 warrants set forth above less the underwriting discounts and commissions. The over-allotment option may be used to purchase shares of common stock and/or warrants, or any combination thereof, as determined by the underwriters, but such purchases cannot exceed an aggregate of 15% of the number of shares of common stock (including the number of shares of common stock issuable upon conversion of shares of Series I Preferred Stock) and 15% of the warrants sold in the primary offering. The over-allotment option is exercisable for 45 days from the date of this prospectus.

Neither the SEC 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.

We anticipate that delivery of the securities will be made through the facilities of the Depository Trust Company on or about October 18, 2022.

Sole Book-Running Manager

Ladenburg Thalmann

The date of this prospectus is October 14, 2022

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You should rely only on the information contained in this prospectus and any free-writing prospectus that we authorize to be distributed to you. We have not, and the underwriters have not, authorized anyone to provide you with information different from or in addition to that contained in this prospectus or any related free-writing prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. We are offering to sell, and are seeking offers to buy, the securities offered by this prospectus only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the securities. Our business, financial conditions, results of operations and prospects may have changed since that date. You should also read and consider the information in the documents to which we have referred you under the caption “Where You Can Find Additional Information” in this prospectus.

We have not, and the underwriters have 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 and incorporated by reference into 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.

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.

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 or incorporated by reference in this prospectus. We have not authorized any other person to provide you with different information. If anyone provides you with additional, different or inconsistent information, you should not rely on it. 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.

You should not assume that the information in this prospectus or any documents we incorporate by reference herein is accurate as of any date other than the date on the front of such document. Our business, financial condition, results of operations and prospects may have changed since those dates.

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 device company dedicated to transforming the lives of patients suffering from fluid overload through science, collaboration, and innovative technology. We are 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 20kg or more whose fluid overload is unresponsive to medical management, including diuretics.

Fluid Overload

Fluid overload, also known as hypervolemia, is a condition in which there is too much fluid in the blood and generally refers to the expansion of the extracellular fluid volume. Although the body does need some amount of fluid to remain healthy, too much can cause an imbalance and damage to an individual’s health.¹

The signs and symptoms of fluid overload are not always the same in each patient and may vary. However, signs and symptoms of fluid overload often include pulmonary edema/pleural effusion, peripheral edema, anasarca (generalized swelling) abdominal ascites, jugular vein distention and dyspnea.² Medical conditions or diseases where excess fluid accumulates in the body are heart failure, kidney disease, nephrotic syndrome, liver cirrhosis, or burn injuries/trauma.^{3, 4} Individuals may also suffer from temporary fluid overload following certain surgical procedures, such as cardiac surgery. Fluid overload has a significant association with the combined events of death, infection, bleeding, arrhythmia, and pulmonary edema and is a leading cause of readmissions with patients suffering from heart failure and patients following cardiac surgery.^{5, 6}

The majority of heart failure signs and symptoms are related to fluid overload and congestion.⁷ The congestion mechanism is related to sodium retention and extracellular fluid expansion.⁸ For this reason, diuretics have been the cornerstone of heart failure treatment.⁹ Currently, there is increasing focus on an evidence based approach to diuretic use acute decompensated heart failures (ADHF) and alternative strategies to manage fluid overload when diuretics fail.¹⁰ Peripheral venovenous simplified ultrafiltration has emerged as a technology to manage fluid overload.¹¹

Treatments for Fluid Overload

Diuretics

Treatment for fluid overload has traditionally been achieved through use of loop diuretics which may be accompanied by use of other categories of medications, such as ACE inhibitors, ARNI, beta-blockers, SGLT2

¹ <https://my.clevelandclinic.org/health/diseases/22962-hypervolemia>

² Schwinger RHG. *Cardiovasc Diagn Ther.* 2021;11(1); 263-76.

³ Hoorn EJ & Ellison DH. *Am J Kidney Dis.* 2016; 69(1): 136-42.

⁴ Wise R et al. *World J Surg.* 2017; 41: 1170-83.

⁵ Stein, A et. al. *Critical Care*, 2012; 16: R99; 1-9

⁶ Iribarne A, et al. *Ann Thorac Surg.* 2014 Oct; 98(4): 1274-80

⁷ Kazory A & Ross EA. *Heart.* 2009; 95: 1047-51.

⁸ Kazory A & Ross EA. *Heart.* 2009; 95: 1047-51.

⁹ Felker MG et al. *J Am Coll Cardiol.* 2012 Jun 12;59(24):2145-53.

¹⁰ Felker MG et al. *J Am Coll Cardiol.* 2012 Jun 12;59(24):2145-53.

¹¹ Felker MG et al. *J Am Coll Cardiol.* 2012 Jun 12;59(24):2145-53.

inhibitors, and inotropic drugs.¹² Although diuretics are the mainstay of treatment for congestion or fluid overload, robust clinical evidence to guide the use of diuretics contribute to persistent uncertainties about appropriate dosing and the overall safety profile.^{13, 14} Furthermore, appropriate titration of diuretics, specifically in the heart failure population, is unclear. Increasing concern exists that diuretics, particularly at high doses, may be deleterious in the inpatient setting.¹⁵ Additionally, diuretics are associated with insufficient symptom relief, increased mortality after discharge, and increased re-hospitalization rates.¹⁶ In addition, patients with heart failure and cardiorenal syndrome have diminished response to loop diuretics, making these agents less effective at relieving congestion.¹⁷

Also, long-term use of diuretics has been associated with kidney damage.¹⁸ Approximately 40% of heart failure patients have poor diuretic response.¹⁹ This poor response is possibly due to noncompliance or high intake of salt, poor drug absorption, insufficient kidney response to drug, and reduced diuretic secretion.^{20, 21} Despite treatment with loop diuretics, patients are frequently hospitalized and treated for recurrent symptoms and signs of fluid overload.²² Among more than 50,000 patients enrolled in the Acute Decompensated Heart Failure National Registry (“ADHERE”) study, only 33% lost ≥ 2.27 kg (5 lbs.), and 16% gained weight during hospitalization.²³

Nearly one-half of hospitalized patients with heart failure are discharged with residual fluid excess after receiving conventional diuretic therapies.^{24, 25} Regardless of diuretic strategy, 42% of acutely decompensated heart failure subjects in the DOSE (Diuretic Optimization Strategies Evaluation) trial reached the composite endpoint of death, rehospitalization, or emergency department visit at 60 days.²⁶ There is an association of chronic loop diuretic therapy and greater resource utilization at hospitals.²⁷ Therefore, an alternative therapy to help stabilize or improve patient care is needed.

Ultrafiltration.

Ultrafiltration, or Aquapheresis, is an alternative therapy to diuretics for fluid removal in patients with volume overload. Ultrafiltration has been a well-documented technique in the treatment of fluid overload in heart failure patients for over 50 years.²⁸ Ultrafiltration is a safe and effective alternative therapy to remove extra fluid and salt by gently filtering blood through an ultrafiltration system.^{29, 30} With ultrafiltration, medical practitioners can specify and control the amount of fluid to be extracted at a safe, predictable, and effective rate.³¹ The use of ultrafiltration therapy in subgroups of patients, such as heart failure and post-cardiac surgery, has demonstrated clinical benefits in treating

¹² Heidenreich P et al. ACC, AHA, HFSA 2022 Heart Failure guidelines. *J Am Coll Cardiol.* 2021. 1-159.

¹³ Felker MG et al. *J Am Coll Cardiol.* 2012 Jun 12;59(24):2145-53.

¹⁴ Felker MG et al. *J Am Coll Cardiol.* 2020; 75(10); 1179-97.

¹⁵ Kamath SA.. *Int J of Nephrol.* 2011. Article ID 190230; 1-6.

¹⁶ Costanzo MR, et al. *J Am Coll Cardiol.* 2017;69(19):2428-45.

¹⁷ Kamath SA.. *Int J of Nephrol.* 2011. Article ID 190230; 1-6.

¹⁸ Felker MG et al. *J Am Coll Cardiol.* 2012 Jun 12;59(24):2145-53.

¹⁹ Heidenreich P et al. ACC, AHA, HFSA 2022 Heart Failure guidelines. *J Am Coll Cardiol.* 2021. 1-159.

²⁰ Wise R et al. *World J Surg.* 2017; 41: 1170-83.

²¹ Felker MG et al. *J Am Coll Cardiol.* 2020; 75(10); 1179-97.

²² Felker GM et al. *New Engl J Med.* 2011; 364(9): 797-805.

²³ Gheorghiadu M, Filippatos G. *Eur Heart J Suppl.* 2005; 7: B13–19.

²⁴ Costanzo MR, et al. *J Am Coll Cardiol.* 2017;69(19):2428-45.

²⁵ Gheorghiadu M, Filippatos G. *Eur Heart J Suppl.* 2005; 7: B13–19.

²⁶ Felker GM et al. *New Engl J Med.* 2011; 364(9): 797-805.

²⁷ Costanzo MR, et al. *J Am Coll Cardiol.* 2007; 49(6): 675-83.

²⁸ Peterangelo M. *Prog Cardiol Nurs.* 2008; 23: 168-72.

²⁹ Costanzo MR, et al. *J Am Coll Cardiol.* 2017; 69(19): 2428-45.

³⁰ Jaski BA et al. *J Card Fail.* 2003; 9(3): 227-31.

³¹ Costanzo MR, et al. *J Am Coll Cardiol.* 2017; 69(19): 2428-45.

fluid overload signs and symptoms.^{32, 33, 34, 35, 36} In addition to the clinical benefits of ultrafiltration, the therapy provides economic advantages. One hospital cost analysis demonstrated a total cost savings of \$3,975, or 14.4%, per patient when using ultrafiltration as compared to diuretic therapy over 90 days.³⁷

The Aquadex System

The Aquadex System is designed and clinically proven to simply, safely, and precisely remove excess fluid (primarily excess salt and water) from patients suffering from fluid overload who have failed diuretic therapy.³⁸ The Aquadex System provides medical practitioners the ability to specify and control the amount of fluid to be extracted at a safe, predictable, and effective rate.³⁹ The Aquadex System has been shown to have no clinically significant impact on electrolyte balance, blood pressure or heart rate.^{40, 41} Unlike other forms of ultrafiltration, which typically require administration specifically by a nephrologist, the Aquadex System may be prescribed by any physician and administered by a healthcare provider, both of whom have received training in extracorporeal therapies.

Benefits of the Aquadex System

The Aquadex System offers a safe approach to treating fluid overload and:

- Provides control over rate and total volume of fluid removed by allowing a medical practitioner to specify the amount of fluid to be removed from each individual patient;⁴²
- Can be performed via peripheral or central venous access⁴³;
- Removes isotonic fluid (extracts sodium while sparing potassium and magnesium);^{44, 45}
- Following ultrafiltration, neurohormonal activation is reset toward a more physiological condition and diuretic efficacy is restored^{46, 47};
- Provides highly automated operation with only one setting required to begin therapy⁴⁸;
- Uses a single-use, disposable auto-loading blood filter circuit that facilitates easy set-up⁴⁹;
- Has a built-in console that guides the medical practitioner through the setup and operational process; and
- Has demonstrated decreased hospital readmissions and reduced length of stay duration resulting in cost savings at 90 days.^{50, 51, 52, 53}

³² Costanzo MR, et al. *J Am Coll Cardiol*. 2017; 69(19): 2428-45.

³³ Kazory A. *Clin J Am Soc Nephro*. 2013; 8; 1816-28.

³⁴ Luciani GB, et al. *Circ*. 2001 Sep 18; 104(12 Suppl 1): I253-I259.

³⁵ Kiziltepe, U, et al. *Ann Thorac Surg*. 2001 Feb;71(2): 684-93.

³⁶ Sahoo, TK, et al. *Indian J Thorac Cardiovas Surg*. 2007 Jun;23(2): 116-124.

³⁷ Costanzo MR, et al. *Value Health*. 2018; 21 (Suppl 1): S167.

³⁸ Felker GM et al. *New Engl J Med*. 2011; 364(9): 797-805.

³⁹ Costanzo MR, et al. *J Am Coll Cardiol*. 2017; 69(19): 2428-45.

⁴⁰ Bart BE et al. *J Am Coll Cardiol*. 2005 Dec 6; 46(11): 2043-46.

⁴¹ Costanzo MR et al. *J Am Coll Cardiol*. 2005; 46(11): 2047-51.

⁴² Peterangelo M. *Prog Cardiol Nurs*. 2008; 23:168-72.

⁴³ Peterangelo M. *Prog Cardiol Nurs*. 2008; 23:168-72.

⁴⁴ Felker GM et al. *New Engl J Med*. 2011; 364(9): 797-805.

⁴⁵ Kazory A. *Clin J Am Soc Nephro*. 2013; 8; 1816-28.

⁴⁶ Costanzo MR, et al. *J Am Coll Cardiol*. 2017; 69(19): 2428-45.

⁴⁷ Kazory A. *Clin J Am Soc Nephro*. 2013; 8; 1816-28.

⁴⁸ Costanzo MR, et al. *J Am Coll Cardiol*. 2007; 49(6): 675-83.

⁴⁹ Felker GM et al. *New Engl J Med*. 2011; 364(9): 797-805.

⁵⁰ Costanzo MR, et al. *J Am Coll Cardiol*. 2017; 69(19): 2428-45.

⁵¹ Kazory A. *Clin J Am Soc Nephro*. 2013; 8; 1816-28.

⁵² Costanzo MR, et al. *Value Health*. 2018; 21 (Suppl 1): S167.

⁵³ Costanzo MR et al. *J Am Coll Cardiol*. 2005; 46(11): 2047-51.

Components of the Aquadex System

The Aquadex System consists of:

- A console, a piece of capital equipment containing electromechanical pumps and an LCD screen;
- A one-time disposable blood circuit set, consisting of an integrated collection of tubing, filter, sensors, and connectors that contain and deliver the blood from and back to the patient; and
- A disposable catheter, consisting of a small, dual-lumen extended length catheter designed to access the peripheral venous system of the patient and to simultaneously withdraw blood and return filtered blood to the patient.

The Aquadex blood circuit set is proprietary and the Aquadex System can only be used with the Aquadex blood circuit set. The dual lumen extended length catheter (dELC) is designed for use with the Aquadex System, although it is one of many potential catheter options available to the healthcare provider.

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 was a wholly owned Australian subsidiary of Nuwellis, Inc. 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 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 ("SOX"), but are required to make our own internal assessment of the effectiveness of our internal controls over financial reporting.

Recent Developments

Nasdaq Notice

On May 31, 2022, 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) (the "Minimum Bid Price Requirement").

In accordance with Nasdaq Marketplace Rule 5810(c)(3)(A), the Company has a period of 180 calendar days from May 31, 2022, or until November 28, 2022, to regain compliance with the Minimum Bid Price Requirement. If at any time before November 28, 2022, the closing bid price of the Company's 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 in the exercise of its discretion), Nasdaq will provide written notification that the Company has achieved compliance with the Minimum Bid Price Requirement, and the matter would be resolved.

The Notice also disclosed that in the event the Company does not regain compliance with the Minimum Bid Price Requirement by November 28, 2022, the Company may be eligible for additional time. To qualify for additional time, the Company 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. If the Company meets these requirements, Nasdaq will inform the Company that it has been granted an additional 180 calendar days. However, if it appears to the Staff that the Company will not be able to cure the deficiency, or if the Company is otherwise not eligible, Nasdaq will provide notice that the Company's securities will be subject to delisting.

The Company intends to continue actively monitoring the closing bid price for the Company's common stock between now and November 28, 2022, and it will consider available options to resolve the deficiency and regain compliance with the Minimum Bid Price Requirement. If the Company does not regain compliance within the allotted compliance period, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that the Company's common stock will be subject to delisting. The Company would then be entitled to appeal that determination to a Nasdaq hearings panel. There can be no assurance that the Company 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.

Departure of George Montague and Appointment of Rob Scott

On September 19, 2022, George Montague notified the Company of his decision to resign as the Company's Chief Financial Officer, on or about October 20, 2022. On September 22, 2022, the board of directors of the Company appointed Nestor Jaramillo, Jr., the Company's current President and Chief Executive Officer, as the Company's interim Chief Financial Officer, effective on or about October 20, 2022, and Rob Scott, the Company's Senior Director, Financial Planning & Analysis, as the Company's interim Principal Accounting Officer, effective on or about October 20, 2022. Mr. Jaramillo has served as the Company's President and Chief Executive Officer since January 2021. Mr. Scott joined the Company in January 2014 and has served in his current position since June 2022.

Appointment of Lynn Blake

Effective October 24, 2022, Lynn Blake will be appointed as Chief Financial Officer of the Company. Ms. Blake, age 55, previously served as a Managing Director at Growth Operators Advisory Services LLC since January 2020. Prior to that, she served as the SVP, Chief Financial Officer of Tactile Systems Technology, Inc. (NASDAQ: TCMD) from 2016 to 2018. Earlier in her career, she served as SVP, Chief Financial Officer of Taylor-Wharton International LLC and as SVP, Chief Financial Officer of Analysts International Corporation. Ms. Blake earned her Bachelor of Business Administration degree from the University of Wisconsin-Madison, with majors in Accounting and Finance and she earned her MBA from the University of Minnesota, Carlson School of Management with a dual concentration in Finance and Strategic Management.

Quarter-ended September 30, 2022 Preliminary Financial Information

The Company's estimated total product revenue for the three months ended September 30, 2022 is projected to be approximately \$2.066 million, an 11% increase over the prior-year quarter ended September 30, 2021. Net cash used in operating activities for the three months ended September 30, 2022 is projected to be approximately \$3.072 million, 31% lower than the net cash used in operating activities for the prior-year quarter ended September 30, 2021. The Company had a cash balance of approximately \$12.1 million as of September 30, 2022. The Company and its auditor have not yet completed their normal quarterly review procedures for the three months ended September 30, 2022, and as such, the final results for this period may differ from these estimates. Any such changes could be material. These estimates should not be viewed as a substitute for full interim financial statements prepared in accordance with U.S. generally accepted accounting principles. The preliminary results provided above are not necessarily indicative of the results to be achieved for the remainder of fiscal 2022 or any future period.

	The Offering
Issuer	Nuwellis, Inc.
Class A Units Offered	We are offering 15,235,196 Class A Units. Each Class A Unit consists of one share of common stock and 1.5 warrants to purchase one share of our common stock (together with the shares of common stock underlying such warrants).
Offering Price per Class A Unit	\$0.25 combined public offering price for each Class A Unit.
Class B Units Offered	We are also offering 23,157,124 Class B Units to purchasers who prefer not to beneficially own more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering. Each Class B Unit will consist of one share of Series I Preferred Stock, par value \$0.0001 per share, convertible into one share of common stock and 1.5 warrants to purchase one share of common stock (together with the shares of common stock underlying such shares of Series I Preferred Stock and such warrants).
Offering Price per Class B Unit	\$0.25 combined public offering price for each Class B Unit.
Description of warrants	Under Nasdaq listing rules, the warrants are not exercisable without stockholder approval. The warrants will be exercisable beginning on the effective date of a reverse stock split in an amount sufficient to permit the exercise in full of the warrants (“Reverse Stock Split Approval”), contingent upon stockholder approval of such stock split and of the exercisability of the warrants (“Warrant Stockholder Approval,” together with the Reverse Stock Split Approval, the “Stockholder Approvals”). We intend to promptly seek, after this offering, such Stockholder Approvals. We cannot assure you that we will be able to obtain these requisite approvals. The warrants will be exercisable beginning on the date the Stockholder Approvals are obtained, if at all, and expire on the sixth anniversary of the initial exercise date and the warrants underlying the Units will have an initial exercise price per share equal to \$0.25 per share, subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock, as well as certain price protections, subject to certain conditions. See “Description of Securities-Description of Warrants Included in the Units” on page 23 of this prospectus. In the event that we are unable to obtain the requisite Stockholder Approvals, the warrants will not be exercisable and therefore have no value.
Description of Series I Preferred Stock	Each share of Series I Preferred Stock is convertible at any time at the holder’s option into one share of common stock. Notwithstanding the foregoing, we shall not affect any conversion of Series I Preferred Stock, with certain exceptions, to the extent that, after giving effect to an attempted conversion, the holder of shares of Series I Preferred Stock (together with such holder’s affiliates, and any persons acting as a group together with such holder or any of such holder’s affiliates) would beneficially own a number of shares of our common stock in excess of 4.99% (or, upon election by a

	holder prior to the issuance of any Series I Preferred Stock, 9.99%) of the shares of our common stock then outstanding after giving effect to such conversion. For additional information, see “Description of Securities-Description of Capital Stock-Preferred Stock-Series I Convertible Preferred Stock Being Offered Pursuant to this Prospectus” on page 28 of this prospectus.
Shares of common stock underlying the warrants	57,588,480 shares.
Shares of common stock outstanding immediately before this offering	10,537,606 shares as of September 15, 2022.
Shares of common stock outstanding immediately after this offering	25,772,802 shares (48,929,926 shares on an as-converted basis, assuming the conversion of the Series I Preferred Stock in full).
Shares of Preferred Stock outstanding immediately before this offering	We have no shares of Series I Preferred Stock outstanding prior to this offering and we have 127 shares of Series F Convertible Preferred Stock (the “Series F Preferred Stock”) outstanding prior to this offering as of September 15, 2022.
Shares of Preferred Stock outstanding immediately after this offering	23,157,124 shares of Series I Preferred Stock and 127 shares of Series F Preferred Stock.
Over-allotment option	We have granted the underwriters an option to purchase up to (i) 5,758,848 additional shares of common stock, and/or (ii) additional warrants to purchase up to 8,638,272 additional shares of common stock solely to cover over-allotments, if any, at the public offering price per share of common stock and the public offering price per 1.5 warrants set forth above less the underwriting discounts and commissions. The over-allotment option may be used to purchase shares of common stock and/or warrants, or any combination thereof, as determined by the underwriters, but such purchases cannot exceed an aggregate of 15% of the number of shares of common stock (including the number of shares of common stock issuable upon conversion of shares of Series I Preferred Stock) and 15% of the warrants sold in the primary offering.
Exchange listing	Our common stock is listed on The Nasdaq Capital Market under the symbol “NUWE”. See “Prospectus Summary – Recent Developments” above for important information about the listing of our common stock on The Nasdaq Capital Market.
No listing of warrants	We do not intend to apply for listing of the warrants on any securities exchange or trading system. Without an active trading market, the liquidity of the warrants will be limited.
No listing of Series I Preferred Stock	We do not intend to apply for listing of the Series I Preferred Stock on any securities exchange or trading system. Without an active trading market, the liquidity of the Series I Preferred Stock will be limited.
Leak-out Agreements	Certain investors in the offering may enter into leak-out agreements pursuant to which each such investor will agree to certain limits on sales of the shares of common stock, including

shares of common stock purchased in this offering and the shares of common stock issuable upon the exercise of the warrants and conversion of the Series I Preferred Stock. See “Underwriting” for additional information.

Use of Proceeds

We currently intend to use the net proceeds from the sale of Units in this offering for general corporate purposes, including for continued investments in our commercialization efforts. See “Use of Proceeds.”

Risk Factors

Investing in our securities involves a high degree of risk. You should carefully review and consider the section of this prospectus entitled “Risk Factors” on page [11](#) of this prospectus for a discussion of factors to consider before deciding to invest in this offering.

Except as otherwise indicated, all information in this prospectus is based on 10,537,606 shares of common stock outstanding as of September 15, 2022, assuming no exercise of the overallotment option granted to the underwriters and excludes the following:

- 1,200,259 shares of common stock issuable upon the exercise of outstanding stock options, having a weighted average exercise price of \$4.78 per share;
- 1,630,627 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 \$25.47 per share;
- 50,800 shares of common stock issuable upon the conversion of the 127 outstanding shares of our Series F Preferred Stock;
- 1,921,713 shares of our common stock reserved for future issuance under our equity incentive plans;
- 23,157,124 shares of common stock underlying the Series I Preferred Stock; and
- 57,588,480 shares of common stock underlying the warrants.

To the extent that additional shares of common stock are issued upon the exercise of outstanding options or warrants, the conversion of our outstanding Series F Convertible Preferred Stock the vesting of restricted stock units or additional grants are made pursuant to our equity 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 and October 16, 2020.

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, the Company has been funded by equity financings, and although the Company believes that it will be able to successfully fund its operations, there can be no assurance that it will be able to do so or that it will ever operate profitably. If this financing is not successful or if we raise less than we intend, we will need to raise additional capital to fund our operations beyond the second quarter of 2023. 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.
- 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.

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, 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, 2021](#) and our [Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2022 and June 30, 2022](#), each of 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.

Risks Related to Our Common Stock

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

On May 31, 2022, we received the Notice from the Staff of 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 May 31, 2022, or until November 28, 2022, to regain compliance with the Minimum Bid Price Requirement. If at any time before November 28, 2022, the closing bid price of the Company’s 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 the Company has achieved compliance with the Minimum Bid Price Requirement, and the matter would be resolved.

The Notice also disclosed that in the event the Company does not regain compliance with the Rule by November 28, 2022, the Company may be eligible for additional time. To qualify for additional time, the Company 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. If the Company meets these requirements, Nasdaq will inform the Company that it has been granted an additional 180 calendar days. However, if it appears to the Staff that the Company will not be able to cure the deficiency, or if the Company is otherwise not eligible, Nasdaq will provide notice that the Company’s securities will be subject to delisting.

The Company intends to continue actively monitoring the closing bid price for the Company’s common stock between now and November 28, 2022, and it will consider available options to resolve the deficiency and regain compliance with the Minimum Bid Price Requirement. If the Company does not regain compliance within the allotted compliance period, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that the Company’s common stock will be subject to delisting. The Company would then be entitled to appeal that determination to a Nasdaq hearings panel. There can be no assurance that the Company 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 our Company; 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.

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 September 15, 2022, we have warrants to purchase 1,630,627 shares of common stock outstanding, with exercise prices ranging from \$2.50 to \$890.40 with a weighted-average exercise price of \$25.47.

As of September 15, 2022, there were 127 shares of Series F Preferred Stock outstanding, convertible into 50,800 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 experience further dilution.

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 September 15, 2022, we have

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outstanding warrants to purchase an aggregate of approximately 1,630,627 shares of our common stock, and options to purchase an aggregate of approximately 1,200,259 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 of directors 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 as of September 15, 2022. Upon liquidation, dissolution or winding-up of the Company, holders of our Series F 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.

Our business could be negatively affected as a result of actions of activist stockholders, and such activism could impact the trading value of our securities.

Stockholders may, from time to time, engage in proxy solicitations or advance stockholder proposals, or otherwise attempt to effect changes and assert influence on our board of directors and management. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs and require significant time and attention by our board of directors and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our board of directors or senior management team arising from a proxy contest could lead to the perception of a change in the direction of our business or instability which may result in the loss of potential business opportunities, make it more difficult to pursue our strategic initiatives, or limit our ability to attract and retain qualified personnel and business partners, any of which could adversely affect our business and operating results. If individuals are ultimately elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively implement our business strategy and create additional value for our stockholders. We may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would serve as a further distraction to our board of directors and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant fluctuations in our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

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.

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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 October 12, 2020, we effected a 1-for-30 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 proportionately, the reverse stock split increased our board of directors' ability to issue authorized and unissued shares without further stockholder action. As of September 15, 2022, 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, 127 of which are designated Series F Preferred Stock, and we have 10,537,606 shares of common stock outstanding, 2,881,686 shares reserved for issuance upon the conversion, exercise or vesting of outstanding preferred stock, warrants and options, and 1,921,713 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;

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- fluctuations of investor interest in the medical device sector;
- changes in industry, general market or economic conditions; and
- announcements of legislative or regulatory changes.

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, 2021, we had U.S. net operating loss (“NOL”) carryforwards of approximately \$186.4 million for U.S. federal income tax purposes. Approximately \$120.1 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 \$66.3 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. As of December 31, 2021, the Company no longer had tax loss carryforwards in the Commonwealth of Australia due to the dissolution of the subsidiary in November 2020.

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.

We will continue to incur increased costs as a result of being a U.S. reporting company.

In connection with the effectiveness of our registration statement on Form 10, as of February 14, 2012, we became subject to the periodic reporting requirements of the Exchange Act. Although we were previously listed on the Australian Securities Exchange and had been required to file financial information and make certain other filings with the Australian Securities Exchange, our status as a U.S. reporting company under the Exchange Act has caused us, and will continue to cause us, to incur additional legal, accounting and other expenses that we did not previously incur, including costs related to compliance with the requirements of SOX and the listing requirements of the Nasdaq Capital Market. We expect these rules and regulations will continue to increase our legal and financial compliance costs and make some activities more time-consuming and costly, and these activities may increase general and administrative expenses and divert management’s time and attention away from revenue-generating activities. Furthermore, now that we are a revenue-generating company following the acquisition of the Aquadex Business in August 2016, our costs to comply with regulations applicable to U.S. reporting companies may further increase. We also expect these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers.

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Investors could lose confidence in our financial reports, and the value of our common stock may be adversely affected, if our internal controls over financial reporting are found not to be effective by management or by an independent registered public accounting firm or if we make disclosure of existing or potential material weaknesses in those controls.

As long as we remain a non-accelerated filer, 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 SOX, but are required to make our own internal assessment of the effectiveness of our internal controls over financial reporting.

We continue to evaluate our existing internal controls over financial reporting. During the course of our ongoing evaluation of the internal controls, we may identify areas requiring improvement and may have to design enhanced processes and controls to address issues identified through this review. Remediating any deficiencies, significant deficiencies or material weaknesses that we or our independent registered public accounting firm may identify may require us to incur significant costs and expend significant time and management resources. We cannot assure you that any of the measures we implement to remedy any such deficiencies will effectively mitigate or remedy such deficiencies. The existence of one or more material weaknesses could affect the accuracy and timing of our financial reporting. It may be more difficult for us to manage our internal control over financial reporting following our acquisition of the Aquadex Business now that we are a revenue generating company. Investors could lose confidence in our financial reports, and the value of our common stock may be harmed, if our internal controls over financial reporting are found not to be effective by management or by our independent registered public accounting firm or if we make disclosure of existing or potential material weaknesses in those controls.

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 sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

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 Delaware General Corporation Law (the "DGCL"); or any action asserting a claim against us that is governed by the internal affairs doctrine. This choice of forum provision does not preclude or contract the scope of exclusive federal or concurrent jurisdiction for any actions brought under the Securities Act of 1933 ("Securities Act") or the Exchange Act. Accordingly, 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.

Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. These exclusive-forum provisions 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 a court were to find the choice of forum provision contained in our Fourth Amended and Restated Certificate of Incorporation, as amended, to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our certificate of incorporation and bylaws, as well as certain provisions of the DGCL, may delay or deter a change in control transaction.

Certain provisions of our certificate of incorporation and bylaws may have the effect of deterring takeovers, such as those provisions 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 in lieu of a meeting; requiring advance notice of

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stockholder intention to put forth director nominees or bring up other business at a stockholders' meeting; prohibiting stockholders from calling a special meeting of stockholders; requiring a 66 2/3% majority stockholder approval in order for stockholders to amend certain provisions of our certificate of incorporation or bylaws or adopt new bylaws; providing that, subject to the rights of preferred shares, the directors will be divided into three classes and the number of directors is to be fixed exclusively by our board of directors; and providing that none of our directors may be removed without cause. Section 203 of the DGCL, 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 could limit the price that investors might be willing to pay in the future for shares of our common stock.

We are a “smaller reporting company” under federal securities laws and we cannot be certain whether the reduced reporting requirements applicable to such companies will make our common stock less attractive to investors.

We are a “smaller reporting company” under federal securities laws. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We will remain a smaller reporting company so long as our public float remains less than \$250 million as of the last business day of our most recently completed second fiscal quarter. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline or be more volatile.

Stockholder litigation could divert the attention of management from the day-to-day operation of our business or result in us incurring substantial costs and liabilities.

We cannot be sure that our stockholders will not initiate securities litigation against us in the future. If securities or stockholder derivative litigation were to be commenced against us, our defense of such litigation could divert the attention of management from the day-to-day operation of our business or result in us incurring substantial costs and liabilities, irrespective of the merits of the litigation.

Risks Relating to this Offering

Because our management will have broad discretion and flexibility in how the net proceeds from this offering are used, our management may use the net proceeds in ways with which you disagree or which may not prove effective.

We currently intend to use the net proceeds from this offering as discussed under “Use of Proceeds” in this prospectus. We have not allocated specific amounts of the net proceeds from this offering for any of the foregoing purposes. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds of this offering. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the net proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for us. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flow.

The Series I Preferred Stock and the warrants are unlisted securities and there is no public market for them.

There is no established public trading market for the Series I Preferred Stock or the warrants, and we do not expect a market to develop. In addition, neither the Series I Preferred Stock nor the warrants are listed, and we do not intend to apply for listing of the Series I Preferred Stock or the warrants on any securities exchange or trading system. Without an active market, the liquidity of the Series I Preferred Stock and the warrants is limited, and investors may be unable to liquidate their investments in the Series I Preferred Stock or the warrants.

The value of our Series I Preferred Stock is directly tied to the value of our common stock, and any change in the value of our common stock will be reflected in the value of our Series I Preferred Stock.

There is no established public trading market for the Series I Preferred Stock, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series I Preferred Stock on any national securities exchange or other nationally recognized trading system. As a result, because each share of

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Series I Preferred Stock is initially convertible into one share of common stock, subject to certain beneficial ownership limitations, we expect the value of the Series I Preferred Stock to have a value directly tied to the value of our common stock. Accordingly, any change in the trading price of our common stock will be reflected in the value of our Series I Preferred Stock, and the price of our common stock may be volatile as described above.

The Company has used almost all of its unreserved, authorized shares.

After giving effect to this offering, we will have used almost all of our unreserved authorized shares and will need stockholder approval to conduct a reverse stock split. There are no assurances that such stockholder approval will be obtained. In the event that stockholder approval for the reverse split is not obtained, we will be unable to raise additional capital through the issuance of shares of common stock to fund our future operations.

The warrants may not have any value.

The warrants will be exercisable for six years from the initial exercise date at an initial exercise price of \$0.25 per share. In the event that the price of a share of our common stock does not exceed the exercise price of the warrants during the period when the warrants are exercisable, the warrants may not have any value. Additionally, such warrants will not be exercisable unless and until we obtain stockholder approval to permit the exercise of the warrants and to effect a reverse stock split in an amount sufficient to permit the exercise in full of the warrants. In the event that we are unable to obtain the Stockholder Approvals, the warrants will not be exercisable and therefore have no value and will expire.

The warrants purchased in this offering do not entitle the holder to any rights as common stockholders until the holder exercises the warrant for shares of our common stock.

Until you acquire shares of our common stock upon exercise of your warrants purchased in this offering, such warrants will not provide you any rights as a common stockholder, except as set forth in the warrants. Upon exercise of your warrants purchased in this offering, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs on or after the exercise date.

Purchasers in this offering may experience dilution of their investment in the future.

Subject to lock-up provisions described under “Underwriting,” we are generally not restricted from issuing additional securities, including shares of common stock, securities that are convertible into or exchangeable for, or that represent the right to receive, common stock or substantially similar securities. The issuance of securities may cause dilution to our stockholders, including investors in this offering. In order to raise additional capital, such securities may be at prices that are not the same as the price per share in this offering. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders, including investors who purchase securities in this offering. The price per share at which we sell additional shares of our common stock or securities convertible into common stock in future transactions may be higher or lower than the price per share in this offering. The exercise of outstanding stock options or warrants and the vesting of outstanding restricted stock units may also result in dilution of your investment.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus 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.

USE OF PROCEEDS

We estimate the net proceeds to us from the sale of Units in this offering will be approximately \$8.5 million (or \$9.8 million if the underwriters fully exercise their over-allotment option), after deducting underwriting discounts and estimated offering expenses payable by us. We will not receive any additional proceeds from any future conversions of the Series I Preferred Stock. We will only receive additional proceeds from the exercise of the warrants issuable in connection with this offering if the warrants are exercised and the holders of such warrants pay the exercise price in cash upon such exercise and do not utilize the cashless exercise provision of the warrants. We currently intend to use the net proceeds from this offering for general corporate purposes, including for continued investments in our commercialization efforts. We may use a portion of the net proceeds for the acquisitions of businesses, products, technologies or licenses that are complementary to our business, although we have no present commitments or agreements to do so.

The net proceeds of the offering set forth above represents our estimates based upon our current plans and assumptions regarding industry and general economic conditions, our future revenues and expenditures.

The amounts and timing of our actual expenditures may vary significantly and will depend on numerous factors, including market conditions, cash generated or used by our operations, business developments and opportunities that may arise and related rate of growth. We may find it necessary or advisable to use portions of the proceeds from this offering for other purposes.

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 sets forth our actual cash and cash equivalents and our capitalization as of June 30, 2022 and on an adjusted basis to give effect to the sale of the securities offered hereby and the use of proceeds, as described in the section entitled “Use of Proceeds.”

You should read this information in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and related notes appearing in our [Annual Report on Form 10-K for the year ended December 31, 2021](#), and our condensed consolidated financial statements and related notes appearing in our Quarterly Reports on Form 10-Q for the periods ended [March 31, 2022](#) and [June 30, 2022](#), which are each incorporated by reference in this prospectus. The information below 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 June 30, 2022 (in thousands, except share and per share data)	
	Actual	As Adjusted
Cash and cash equivalents	\$ 15,345	\$ 23,811
Stockholders’ equity:		
Series A junior participating preferred stock, par value \$0.0001 per share; authorized 30,000 shares, none outstanding	—	
Series F convertible preferred stock, par value \$0.0001 per share; authorized 127 shares, issued and outstanding 127 shares	—	
Series I convertible preferred stock, par value \$0.0001 per share; authorized none and 23,157,124 shares, respectively, issued and outstanding none and 23,157,124 shares, respectively		
Preferred stock, par value \$0.0001 per share; authorized 39,969,873 shares, respectively, none outstanding		
Common stock, par value \$0.0001 per share; authorized 100,000,000 shares, issued and outstanding 10,537,606 shares	1	5
Additional paid-in capital	279,350	287,812
Accumulated other comprehensive income:		
Foreign currency translation adjustment	(12)	(12)
Accumulated deficit	(261,675)	(261,675)
Total stockholders’ equity	17,664	26,130

The pro forma as adjusted column above reflects our sale of Series I Preferred Stock, common stock and warrants in this offering at a public offering price of \$0.25 per Class A Unit and a public offering price of \$0.25 per Class B Unit. The above discussion and table are based 10,537,606 shares of common stock outstanding as of September 15, 2022, assuming no exercise of the overallotment option granted to the underwriters and excludes:

- 1,200,259 shares of common stock issuable upon the exercise of outstanding stock options, having a weighted average exercise price of \$4.78 per share;
- 1,630,627 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 \$25.47 per share;
- 50,800 shares of common stock issuable upon the conversion of the 127 outstanding shares of our Series F Preferred Stock;
- 1,921,713 shares of our common stock reserved for future issuance under our equity incentive plans;
- 23,157,124 shares of common stock underlying the Series I Preferred Stock; and
- 57,588,480 shares of common stock underlying the warrants.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information regarding the beneficial ownership (as defined in Rule 13d-3 of the Exchange Act) of our common stock as of September 15, 2022 by (i) each of the directors and named executive officers, (ii) all of the directors and executive officers as a group, and (iii) to our knowledge, beneficial owners of more than 5% of our common stock. As of September 15, 2022, there were 10,537,606 shares of our common stock outstanding. Unless otherwise indicated and subject to applicable community property laws, each owner has sole voting and investment powers with respect to the securities listed below.

Name of Beneficial Owner	Number of Shares	Right to Acquire ⁽¹⁾	Total	Aggregate Percent of Class ⁽²⁾
John L. Erb	385	56,038 ⁽³⁾	56,423	*%
Steve Brandt	—	17,176	17,176	*
Maria Rosa Costanzo, M.D.	—	—	—	—
Jon W. Salveson	—	17,208	17,208	*
Gregory D. Waller	—	17,223	17,223	*
Warren S. Watson	—	17,208	17,208	*
Nestor Jaramillo, Jr.	—	63,911	63,911	*
George Montague	—	20,845	20,845	*
Neil P. Ayotte	—	13,896	13,896	*
All current directors and executive officers as a group (9 persons)	385	223,505	223,890	2.1%

* Less than one percent.

- (1) Except as otherwise described below, amounts reflect the number of shares that such holder could acquire through (i) the exercise of outstanding stock options, (ii) the vesting/settlement of outstanding RSUs, (iii) the exercise of outstanding warrants to purchase common stock, and (iv) the conversion of outstanding Series F Preferred Stock, in each case within 60 days after September 15, 2022.
- (2) Based on 10,537,606 shares outstanding as of September 15, 2022.
- (3) Consists of (i) 15,338 shares issuable upon the exercise of outstanding stock options, (ii) 700 shares issuable upon the exercise of outstanding warrants to purchase common stock and (iii) 40,000 shares issuable upon conversion of outstanding shares of Series F Convertible Preferred Stock (assuming all 100 shares of Series F Convertible Preferred Stock held by Mr. Erb are converted at once and rounded up to the nearest whole share).

DESCRIPTION OF SECURITIES

Description of Units

We are offering 15,235,196 Class A Units, with each Class A Unit consisting of one share of common stock and 1.5 warrants to purchase one share of our common stock (together with the shares of common stock underlying such warrants) at a public offering price of \$0.25 per Class A Unit. Each warrant included in the Class A Units entitles its holder to purchase one share of common stock at an exercise price of \$0.25.

We are also offering 23,157,124 Class B Units to purchasers who prefer not to beneficially own more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering with each Class B Unit consisting of one share of Series I Preferred Stock, par value \$0.0001 per share, convertible into one share of common stock, and 1.5 warrants to purchase one share of common stock (together with the shares of common stock underlying the Series I Preferred Stock and such warrants) at a public offering price of \$0.25 per Class B Unit. Each warrant included in the Class B Units entitles its holder to purchase one share of common stock at an exercise price of \$0.25.

The securities of which the Units are composed (the “underlying securities”) are being sold in this offering only as part of the Units. However, the Class A Units and Class B Units will not be certificated and the underlying securities comprising such Units are immediately separable. Each underlying security purchased in this offering will be issued independent of each other underlying security and not as part of a Unit. Upon issuance, each underlying security may be transferred independent of any other underlying security, subject to applicable law and transfer restrictions.

Under Nasdaq listing rules, the warrants are not exercisable without stockholder approval. We intend to promptly seek, after the closing of this offering, stockholder approval for issuances of shares of common stock issuable upon exercise of the warrants.

Description of Warrants Included in the Units

The material terms and provisions of the warrants being offered pursuant to this prospectus are summarized below. This summary of some provisions of the warrants is not complete. For the complete terms of the warrants, you should refer to the form of warrant filed as an exhibit to the registration statement of which this prospectus is a part.

Pursuant to a warrant agency agreement between us and American Stock Transfer & Trust Company LLC, as warrant agent, subject to obtaining stockholder approval, the warrants will be issued in book-entry form and shall 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.

Each Class A Unit and each Class B Unit includes 1.5 warrants to purchase one share of our common stock at an exercise price of \$0.25 per share at any time after the Stockholder Approvals for up to six years after the initial exercise date. The warrants issued in this offering will be governed by the terms of a global warrant held in book-entry form. The holder of a warrant will not be deemed a holder of our underlying common stock until the warrant is exercised, except as set forth in the warrants.

Subject to limited exceptions, a holder of warrants will not have the right to exercise any portion of its warrants if the holder (together with such holder’s affiliates, and any persons acting as a group together with such holder or any of such holder’s affiliates) would beneficially own a number of shares of common stock in excess of 4.99% (or, upon election by a holder prior to the issuance of any warrants, 9.99%) of the shares of our common stock then outstanding after giving effect to such exercise (the “Beneficial Ownership Limitation”); provided, however, that upon notice to the Company, the holder may increase or decrease the Beneficial Ownership Limitation, provided that in no event shall the Beneficial Ownership Limitation exceed 9.99% and any increase in the Beneficial Ownership Limitation will not be effective until 61 days following notice of such increase from the holder to us.

The exercise price and the number of shares issuable upon exercise of the warrants is subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock. The warrant holders must pay the

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exercise price in cash upon exercise of the warrants, unless such warrant holders are utilizing the cashless exercise provision of the warrants, which is only available in certain circumstances such as if the underlying shares are not registered with the SEC pursuant to an effective registration statement. We intend to use commercially reasonable efforts to have the registration statement of which this prospectus forms a part, effective when the warrants are exercised. Additionally, holders of warrants may exercise such warrants on a “cashless” basis after the initial exercise date. In such event, the aggregate number of shares of common stock issuable in such cashless exercise shall equal the product of (x) the aggregate number of shares of common stock that would be issuable upon exercise of the warrants in accordance with its terms if such exercise were by means of a cash exercise rather than a cashless exercise and (y) 1.00.

The warrants contain a one-time reset of the exercise price to a price equal to the lesser of (i) the then exercise price and (ii) 90% of the five-day volume weighted average price for the five trading days immediately preceding the date that is ninety days after issuance of the warrants.

If we, while the warrants are outstanding, sell shares of common stock at a price per share less than the exercise price then in effect, then the exercise price of the warrants will be adjusted to that lower price and the number of shares underlying the warrants will be increased such that the aggregate exercise price payable thereunder, after taking into account the decrease in the exercise price, shall be equal to (x)-(y) where (x) is equal to the aggregate exercise price in effect at the time of issuance of the warrants and (y) is equal to the aggregate cash exercise price paid in connection with any warrant exercises prior to any dilutive issuance plus the cash exercise price that would have been payable in connection with any “cashless exercises”, if any such exercises were by means of a cash exercise rather than a cashless exercise, subject to customary conditions and carve outs.

In addition, in the event we consummate a merger or consolidation with or into another person or other reorganization event in which our common shares are converted or exchanged for securities, cash or other property, or we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets or we or another person acquire 50% or more of our outstanding shares of common stock, then following such event, the holders of the warrants will be entitled to receive upon exercise of the warrants the same kind and amount of securities, cash or property which the holders would have received had they exercised the warrants immediately prior to such fundamental transaction. Any successor to us or surviving entity shall assume the obligations under the warrants.

Assuming the Stockholder Approvals are obtained, upon the holder’s exercise of a warrant, we will issue the shares of common stock issuable upon exercise of the warrant within the earlier of two trading days following our receipt of a notice of exercise or the standard settlement period for the market on which the common stock is then listed, provided that payment of the exercise price has been made (unless exercised via the “cashless” exercise provision).

Prior to the exercise of any warrants to purchase common stock, holders of the warrants will not have any of the rights of holders of the common stock purchasable upon exercise, including the right to vote, except as set forth therein.

Warrant holders may exercise warrants only if Warrant Stockholder Approval is obtained and if the issuance of the shares of common stock upon exercise of the warrants is covered by an effective registration statement, or an exemption from registration is available under the Securities Act and the securities laws of the state in which the holder resides. We intend to use commercially reasonable efforts to have the registration statement of which this prospectus forms a part effective when the warrants are exercised. The warrant holders must pay the exercise price in cash upon exercise of the warrants unless there is not an effective registration statement or, if required, there is not an effective state law registration or exemption covering the issuance of the shares underlying the warrants (in which case, the warrants may only be exercised via a “cashless” exercise provision).

The warrants are exercisable on the date we file an amendment to our restated Certificate of Incorporation to reflect a reverse stock split in an amount sufficient to permit the exercise in full of the warrants. The warrants are not exercisable without the requisite Stockholder Approvals. We intend to promptly seek stockholder approval for issuances of shares of common stock issuable upon exercise of the warrants but we cannot assure you that such approval will be obtained. The warrants expire on the six (6) year anniversary of the initial exercise date.

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We have agreed to hold a stockholders' meeting in order to seek stockholder approval for an amendment to our restated certificate of incorporation to effect a reverse split of the common stock in an amount sufficient to permit the exercise in full of the warrants in accordance with their terms and to permit the exercise of the warrants in accordance with Nasdaq rules. In the event that we are unable to obtain stockholder approvals to permit the exercise of the warrants and to effect an increase in our authorized shares of common stock or effect a reverse split of our common stock, the warrants will not be exercisable and will have no value.

We do not intend to apply for listing of the warrants on any securities exchange or other trading system. Without an active trading market, the liquidity of the warrants will be limited.

Description of Capital 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 and 127 of which are designated Series F Convertible Preferred Stock (the "Series F Preferred Stock") as of June 30, 2022. 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 September 15, 2022, we had (i) 10,537,606 outstanding shares of common stock, (ii) 127 outstanding shares of Series F Preferred Stock, which, at the currently applicable conversion price, would convert into 50,800 shares of common stock, subject to future adjustment, (iii) outstanding options to acquire 1,200,259 shares of our common stock, and (iv) outstanding warrants to purchase 1,630,627 shares of our common 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).

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 Securities –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;

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- 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 Securities —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 Securities –Choice of Forum;”
- the limitations on director liability and indemnification described below under the heading “Description of Securities –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 designation 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.” See “Prospectus Summary-Recent Developments” in this prospectus for important information about the listing of our common stock on the Nasdaq Capital Market.

Description of Preferred Stock

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

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

Outstanding Series F Convertible Preferred Stock. Our board of directors designated 18,000 shares of preferred stock as Series F convertible preferred stock, \$0.0001 par value. As of September 15, 2022, there were 127 shares of Series F Preferred Stock outstanding with a conversion price of \$2.50.

Liquidation. Upon any dissolution, liquidation or winding up, whether voluntary or involuntary, holders of Series F Preferred Stock will be entitled to receive distributions out of our assets, whether capital or surplus, of an amount equal to \$0.0001 per share of Series F Preferred Stock before any distributions shall be made on the common stock or any series of preferred stock ranked junior to the Series F Preferred Stock.

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Dividends. Holders of the Series F Preferred Stock are entitled to receive dividends equal (on an “as converted to common stock” basis) to and in the same form as dividends actually paid on shares of our common stock when, as and if such dividends are paid on shares of our common stock. No other dividends will be paid on shares of Series F Preferred Stock.

Conversion. Each share of Series F Preferred Stock is convertible, at any time and from time to time at the option of the holder thereof, into that number of shares of common stock determined by dividing \$1,000 by the conversion price of \$2.50 (subject to adjustment described below). This right to convert is limited by the beneficial ownership limitation described below.

Forced Conversion. Subject to certain ownership limitations as described below and certain equity conditions being met, until such time that during any 20 of 30 consecutive trading days, the volume weighted average price of our common stock exceeds 300% of the conversion price and the daily dollar trading volume during such period exceeds \$200,000 per trading day, we have the right to force the conversion of the Series F Preferred Stock into common stock.

Beneficial Ownership Limitation. A holder shall have no right to convert any portion of Series F Preferred Stock, to the extent that, after giving effect to such conversion, such holder, together with such holder’s affiliates, and any persons acting as a group together with such holder or any such affiliate, would beneficially own in excess of 4.99% of the number of shares of common stock outstanding immediately after giving effect to the issuance of shares of common stock upon such conversion (subject to the right of the holder to increase such beneficial ownership limitation upon not less than 61 days prior notice provided that such limitation can never exceed 9.99% and such 61 day period cannot be waived). Beneficial ownership of the holder and its affiliates will be determined in accordance with Section 13(d) of the Exchange Act. Holders of Series F Preferred Stock who are subject to such beneficial ownership limitation are and will remain responsible for ensuring their own compliance with Regulation 13D-G promulgated under the Exchange Act, consistent with their individual facts and circumstances. In addition, pursuant to Rule 13d-3(d)(1)(i) promulgated under the Exchange Act, any person who acquires Series F Preferred Stock with the purpose or effect of changing or influencing the control of our company, or in connection with or as a participant in any transaction having such purpose or effect, immediately upon such acquisition will be deemed to be the beneficial owner of the underlying common stock.

Optional Redemption. Subject to the terms of the certificate of designation, the Company holds an option to redeem some or all the Series F Preferred Stock six months after its issuance date at a 200% premium to the stated value of the Series F Preferred Stock subject to the redemption, upon 30 days prior written notice to the holder of the Series F Preferred Stock. The Series F Preferred Stock would be redeemed by the Company for cash.

Conversion Price Adjustment

Subsequent Equity Sales. The Series F Preferred Stock has full ratchet price based anti-dilution protection, subject to customary carve outs, in the event of a down-round financing at a price per share below the conversion price of the Series F Preferred Stock, including in this offering. If during any 20 of 30 consecutive trading days the volume weighted average price of our common stock exceeds 300% of the then-effective conversion price of the Series F Preferred Stock and the daily dollar trading volume for each trading day during such period exceeds \$200,000, the anti-dilution protection in the Series F Preferred Stock will expire and cease to apply.

Stock Dividends and Stock Splits. If we pay a stock dividend or otherwise make a distribution payable in shares of common stock on shares of common stock or any other common stock equivalents, subdivide or combine outstanding common stock, or reclassify common stock, the conversion price will be adjusted by multiplying the then conversion price by a fraction, the numerator of which shall be the number of shares of common stock outstanding immediately before such event, and the denominator of which shall be the number of shares outstanding immediately after such event.

Fundamental Transaction. If we effect a fundamental transaction in which we are the surviving entity, then upon any subsequent conversion of Series F Preferred Stock, the holder thereof shall have the right to receive, for each share of common stock that would have been issuable upon such conversion immediately prior to the occurrence of such fundamental transaction, the number of shares of our common stock and any additional consideration receivable as a result of such fundamental transaction by a holder of the number of shares of

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common stock into which Series F Preferred Stock is convertible immediately prior to such fundamental transaction. If we effect a fundamental transaction in which we are not the surviving entity or a reverse merger in which we are the surviving entity, then the surviving entity shall purchase the outstanding Series F Preferred Stock by paying and issuing, in the event that such consideration given to common stockholders is non-cash consideration, as the case may be, to such holder (or canceling such holder's outstanding Series F Preferred Stock and converting it into the right to receive) an amount equal to the greater of (i) the cash consideration plus the non-cash consideration (in the form issuable to the holders of common stock) per share of the common stock in the fundamental transaction multiplied by the number of conversion shares underlying the shares of Series F Preferred Stock held by the holder on the date of the consummation of the fundamental transaction or (ii) 130% of the stated value of the Series F Preferred Stock then outstanding on the date immediately prior to the consummation of the fundamental transaction. Such amount shall be paid in the same form and mix (be it securities, cash or property, or any combination of the foregoing) as the consideration received by the common stock in such fundamental transaction. A fundamental transaction means: (i) our merger or consolidation with or into another entity, (ii) any sale or other disposition of all or substantially all of our assets in one transaction or a series of related transactions, (iii) any tender offer or exchange offer allowing holders of our common stock to tender or exchange their shares for cash, property or securities, and has been accepted by the holders of 50% or more of the outstanding common stock, (iv) any reclassification of our common stock or any compulsory share exchange by which common stock is effectively converted into or exchanged for other securities, cash or property, or (v) consummation of a stock or share purchase agreement or other business combination with another person whereby such other person acquires more than 50% of the outstanding shares of common stock.

Voting Rights, etc. Except as otherwise provided in the Series F Preferred Stock certificate of designation or required by law, the Series F Preferred Stock has no voting rights. However, as long as any shares of Series F Preferred Stock are outstanding, we may not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series F Preferred Stock, alter or change adversely the powers, preferences or rights given to the Series F Preferred Stock, amend its certificate of designation, amend our certificate of incorporation or other charter documents in any manner that adversely affects any rights of the holders, increase the number of authorized shares of Series F Preferred Stock, or enter into any agreement with respect to any of the foregoing. The Series F Preferred Stock certificate of designation provides that if any party commences an action or proceeding to enforce any provisions of the certificate of designation, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its attorneys' fees and other costs and expenses incurred in the investigation, preparation and prosecution of such action or proceeding. This provision may, under certain circumstances, be inconsistent with federal securities laws and DGCL.

Fractional Shares. No fractional shares of common stock will be issued upon conversion of Series F Preferred Stock. Rather, we shall, at our election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the conversion price or round up to the next whole share.

The Series F Preferred Stock was issued in book-entry form under a preferred stock agent agreement between American Stock Transfer & Trust as preferred stock agent, and us, and shall initially be represented by one or more book-entry certificates deposited with The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC. There is no established public trading market for the Series F Preferred Stock, and the Series F Preferred Stock is not listed on the Nasdaq Capital Market, any other national securities exchange or any other nationally recognized trading system.

Series I Convertible Preferred Stock Being Offered Pursuant to this Prospectus. Our board of directors has designated 23,157,124 shares of preferred stock as Series I convertible preferred stock, \$0.0001 par value ("Series I Preferred Stock"), none of which are issued and outstanding prior to this offering. Although there is no current intent to do so, our board of directors may, without stockholder approval, issue shares of an additional class or series of preferred stock with voting and conversion rights which could adversely affect the voting power of the holders of the common stock or the convertible preferred stock, except as prohibited by the certificate of designation of preferences, rights and limitations of Series I Preferred Stock.

The following is a summary of the material terms of our Series I Preferred Stock. For more information, please refer to the certificate of designation of preferences, rights and limitations of Series I Preferred Stock to be filed as an exhibit to the registration statement of which this prospectus is a part.

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Liquidation. Upon any dissolution, liquidation or winding up, whether voluntary or involuntary, the holders of Series I Preferred Stock are entitled to receive, *pari passu* with the holders of common stock (on an as-converted basis), out of the assets available for distribution to stockholders, an amount equal to such amount per share as would have been payable had all shares of Series I Preferred Stock been converted into common stock immediately before such liquidation, dissolution or winding up, without giving effect to any limitation on conversion as a result of the Beneficial Ownership Limitation, as described below.

Dividends. Holders of the Series I Preferred Stock will be entitled to receive dividends equal (on an “as converted to common stock” basis) to and in the same form as dividends actually paid on shares of our common stock when, as and if such dividends are paid on shares of our common stock. No other dividends will be paid on shares of Series I Preferred Stock.

Conversion. Each share of Series I Preferred Stock is convertible, at any time and from time to time at the option of the holder thereof, into one share of common stock (subject to adjustment described below). This right to convert is limited by the beneficial ownership limitation described below.

Forced Conversion. Subject to certain ownership limitations as described below and certain equity conditions being met, until such time that during any 20 of 30 consecutive trading days, the volume weighted average price of our common stock exceeds 300% of the conversion price and the daily dollar trading volume during such period exceeds \$200,000 per trading day, we shall have the right to force the conversion of the Series I Preferred Stock into common stock.

Beneficial Ownership Limitation. A holder shall have no right to convert any portion of Series I Preferred Stock, to the extent that, after giving effect to such conversion, such holder, together with such holder’s affiliates, and any persons acting as a group together with such holder or any such affiliate, would beneficially own in excess of 4.99% (or, upon the election by a holder prior to the issuance of any shares of Series I Preferred Stock, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to the issuance of shares of common stock upon such conversion (subject to the right of the holder to increase such beneficial ownership limitation upon not less than 61 days prior notice provided that such limitation can never exceed 9.99% and such 61 day period cannot be waived). Beneficial ownership of the holder and its affiliates will be determined in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder. Holders of Series I Preferred Stock who are subject to such beneficial ownership limitation are and will remain responsible for ensuring their own compliance with Regulation 13D-G promulgated under the Securities Exchange Act of 1934, as amended, consistent with their individual facts and circumstances. In addition, pursuant to Rule 13d-3(d)(1)(i) promulgated under the Securities Exchange Act of 1934, as amended, any person who acquires Series I Preferred Stock with the purpose or effect of changing or influencing the control of our company, or in connection with or as a participant in any transaction having such purpose or effect, immediately upon such acquisition will be deemed to be the beneficial owner of the underlying common stock.

Conversion Price Adjustment

Stock Dividends and Stock Splits. If we pay a stock dividend or otherwise make a distribution payable in shares of common stock on shares of common stock or any other common stock equivalents, subdivide or combine outstanding common stock, or reclassify common stock, the conversion price will be adjusted by multiplying the then conversion price by a fraction, the numerator of which shall be the number of shares of common stock outstanding immediately before such event, and the denominator of which shall be the number of shares outstanding immediately after such event.

Fundamental Transaction. If we effect a fundamental transaction in which we are the surviving entity, then upon any subsequent conversion of Series I Preferred Stock, the holder thereof shall have the right to receive, for each share of common stock that would have been issuable upon such conversion immediately prior to the occurrence of such fundamental transaction, the number of shares of our common stock and any additional consideration receivable as a result of such fundamental transaction by a holder of the number of shares of common stock into which Series I Preferred Stock is convertible immediately prior to such fundamental transaction. A fundamental transaction means: (i) our merger or consolidation with or into another entity, (ii) any sale or other disposition of all or substantially all of our assets in one transaction or a series of related transactions, (iii) any tender offer or exchange offer allowing holders of our common stock to tender or exchange their shares for cash, property or securities, and has been accepted by the holders of 50% or more of the

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outstanding common stock (iv) any reclassification of our common stock or any compulsory share exchange by which common stock is effectively converted into or exchanged for other securities, cash or property, or (v) consummation of a stock or share purchase agreement or other business combination with another person whereby such other person acquires more than 50% of the outstanding shares of common stock.

Voting Rights, etc. Except as otherwise provided in the Series I Preferred Stock certificate of designation or required by law, the Series I Preferred Stock has no voting rights. However, as long as any shares of Series I Preferred Stock are outstanding, we may not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series I Preferred Stock, alter or change adversely the powers, preferences or rights given to the Series I Preferred Stock, amend its certificate of designation, amend our certificate of incorporation or other charter documents in any manner that adversely affects any rights of the holders, increase the number of authorized shares of Series I Preferred Stock, or enter into any agreement with respect to any of the foregoing. The Series I Preferred Stock certificate of designation provides that if any party commences an action or proceeding to enforce any provisions of the certificate of designation, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its attorneys' fees and other costs and expenses incurred in the investigation, preparation and prosecution of such action or proceeding. This provision may, under certain circumstances, be inconsistent with federal securities laws and Delaware general corporation law.

Fractional Shares. No fractional shares of common stock will be issued upon conversion of Series I Preferred Stock. Rather, we shall, at our election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the conversion price or round up to the next whole share.

The Series I Preferred Stock will be issued in book-entry form under a preferred stock agent agreement between American Stock Transfer & Trust as preferred stock agent, and us, and shall initially be represented by one or more book-entry certificates deposited with The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC. There is no established public trading market for the Series I Preferred Stock and we do not expect a market to develop. We do not plan on applying to list the Series I Preferred Stock on The Nasdaq Capital Market, any other national securities exchange or any other nationally recognized trading system.

Description of Outstanding Warrants

As of September 15, 2022, there were warrants outstanding to purchase a total of 1,630,627 shares of our common stock, which expire between 2022 and 2025. Each of these warrants entitles the holder to purchase one share of common stock at prices ranging from \$2.50 to \$890.40 per share, with a weighted average exercise price of \$25.47 per share. Certain of these warrants have a net exercise provision under which its holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of our common stock at the time of exercise of the warrant after deduction of the aggregate exercise price. Each of these warrants also contains provisions for the adjustment of the exercise price and the aggregate number of shares issuable upon the exercise of the warrant in the event of dividends, share splits, reorganizations and reclassifications and consolidations. Certain of these warrants provide that, subject to limited exceptions, a holder will not have the right to exercise any portion of its warrants if the holder, together with its affiliates, would beneficially own over 4.99% of our then outstanding common stock following such exercise; provided, however, that upon prior notice to us, the warrant holder may increase its ownership, provided that in no event will the ownership exceed 9.99%.

Anti-Takeover Effects of Certain Provisions of Our Certificate of Incorporation and Bylaws and Delaware Law Certificate of Incorporation and Bylaws

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;

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

Delaware Law

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

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

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.

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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.

UNDERWRITING

We are offering the securities described in this prospectus through the underwriters named below. Ladenburg Thalmann & Co. Inc. is acting as representative of the underwriters and book-running manager of the offering. We entered into an underwriting agreement with the underwriters on October 14, 2022 (the “Underwriting Agreement”). Subject to the terms and conditions of the Underwriting Agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase from us on a firm commitment basis, at the public offering price less the underwriting discount set forth on the cover page of this prospectus, the number of Units listed next to its name in the following table:

Underwriters	Class A Units	Class B Units
Ladenburg Thalmann & Co. Inc.	15,235,196	23,157,124
Total	15,235,196	23,157,124

A copy of the underwriting agreement has been filed as an exhibit to the registration statement of which this prospectus is part.

We have been advised by the underwriters that they propose to offer the Units directly to the public at the public offering price set forth on the cover page of this prospectus. The underwriters may sell Class A Units or Class B Units separately to purchasers or may sell a combination of Class A Units and Class B Units to purchasers in any proportion. Any securities sold by the underwriters to securities dealers will be sold at the public offering price less a selling concession not in excess of \$0.0119952 per share (or per share of common stock underlying the Series I Preferred Stock) and \$0.0000048 per 1.5 warrants.

The Underwriting Agreement provides that the underwriters’ obligation to purchase the securities is subject to conditions contained in the Underwriting Agreement. The underwriters are obligated to purchase and pay for all of the securities offered by this prospectus, if any are purchased.

No action has been taken by us or the underwriters that would permit a public offering of the Units, or the shares of common stock, shares of preferred stock and warrants included in the Units in any jurisdiction outside the United States where action for that purpose is required. None of our securities included in this offering may be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sales of any of the securities offering hereby be distributed or published in any jurisdiction except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons who receive this prospectus are advised to inform themselves about and to observe any restrictions relating to this offering of securities and the distribution of this prospectus. This prospectus is neither an offer to sell nor a solicitation of any offer to buy the securities in any jurisdiction where that would not be permitted or legal.

The underwriters have advised us that they do not intend to confirm sales to any accounts over which they exercise discretionary authority.

Underwriting Discount and Expenses

The following table summarizes the underwriting discount and commission to be paid to the underwriters by us.

	Per Class A Unit⁽¹⁾	Per Class B Unit⁽¹⁾	Total without Exercise of Overallotment	Total with Full Exercise of Overallotment
Public offering price	\$0.25	\$0.25	\$9,598,080.00	\$12,909,417.60
Underwriting discount to be paid to the underwriters by us (8.0%) (2)(3)	\$0.02	\$0.02	\$ 767,846.40	\$ 3,311,337.60
Proceeds to us (before expenses)	\$0.23	\$0.23	\$8,465,727.60	\$12,141,571.20

(1) The public offering price and underwriting discount corresponds to (x) in respect of the Class A Units (i) a public offering price per share of common stock of \$0.2499 and (ii) a public offering price per 1.5 warrants of \$0.0001 and (y) in respect of the Class B Units (i) a public offering price per share of Series I Preferred Stock of \$0.2499 and (ii) a public offering price per 1.5 warrants of \$0.0001.

(2) We have also agreed to reimburse the accountable expenses of the representative, including legal fees, in this offering, up to a maximum of \$85,000.

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- (3) We have granted a 45 day option to the representative to purchase up to 5,758,848 additional shares of common stock and/or additional warrants exercisable for up to an additional 8,638,272 shares of common stock at the public offering price per share of common stock and the public offering price per 1.5 warrants set forth above less the underwriting discounts and commissions solely to cover over-allotments, if any.

We expect the total expenses payable by us in this offering, excluding underwriting discounts and commissions, to be approximately \$364,506.

The securities we are offering are being offered by the underwriters subject to certain conditions specified in the Underwriting Agreement.

Over-allotment Option

We have granted to the underwriters an option exercisable not later than 45 days after the date of this prospectus to purchase up to a number of additional shares of common stock and/or warrants equal to 15% of the number of shares of common stock sold in the primary offering (including the number of shares of common stock issuable upon conversion of shares of Series I Preferred Stock but excluding any shares of common stock underlying the warrants issued in this offering and any shares of common stock issued upon any exercise of the underwriters' over-allotment option) and/or 15% of the warrants sold in the primary offering at the public offering price per share of common stock and the public offering price per warrant set forth on the cover page hereto less the underwriting discounts and commissions. The underwriters may exercise the option solely to cover over-allotments, if any, made in connection with this offering. If any additional shares of common stock and/or warrants are purchased, the underwriters will offer these shares of common stock and/or warrants on the same terms as those on which the other securities are being offered.

Determination of Offering Price

Our common stock is currently traded on the Nasdaq Capital Market under the ticker symbol "NUWE."

The public offering price of the Units offered by this prospectus were negotiated between us and the underwriters. Among the factors that were considered in determining the public offering price of the Units:

- our history and our prospects;
- the industry in which we operate;
- our past and present operating results;
- the previous experience of our executive officers; and
- the general condition of the securities markets at the time of this offering.

The public offering price stated on the cover page of this prospectus should not be considered an indication of the actual value of the shares of common stock sold in this offering. That price is subject to change as a result of market conditions and other factors, and we cannot assure you that the shares of common stock sold in this offering can be resold at or above the public offering price.

Lock-up Agreements

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, such persons may not offer for sale, contract to sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate, or otherwise dispose of, directly or indirectly, any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock. Certain limited transfers are permitted during the lock-up period if the transferee agrees to these lock-up restrictions. We have also agreed, in the Underwriting Agreement, to similar lock-up restrictions on the issuance and sale of our securities for the later of (i) 90 days following the effectiveness of the Underwriting Agreement and (ii) 30 days following the later of (x) the effective date of the reverse stock split to permit the exercise in full of the warrants and (y) stockholder approval of the exercisability of the warrants, although we will be permitted to issue stock options or stock awards to directors, officers and employees under our existing plans. The representative may, without notice, waive the terms of any of these lock-up agreements.

Leak-out Agreements

Certain investors in this offering may enter into leak-out agreements wherein each investor who is party thereto (together with certain of its affiliates) will agree not to sell, dispose or otherwise transfer, directly or indirectly (including, without limitation, any sales, short sales, swaps or any derivative transactions that would be equivalent to any sales or short positions), on any trading day, shares of our common stock, including shares of common stock purchased in this offering and the shares of common stock issuable upon exercise of the warrants and conversion of the Series I Preferred Stock, in an amount more than a specified percentage of the trading volume of the common stock on the principal trading market, subject to certain exceptions. This restriction will not apply to sales or transfers of any such shares of common stock in transactions which do not need to be reported on the Nasdaq consolidated tape so long as the purchaser or transferee executes and delivers a leak-out agreement. After such sale or transfer, future sales of the securities covered by the leak-out agreement entered into by the original owner (together with certain of its affiliate) and the purchaser or transferee will be aggregated to determine compliance with the terms of the leak-out agreement.

Fee Tail

We have also agreed to pay the representative a tail fee equal to the cash compensation in this offering, if any investor, who was contacted or introduced by the representative during the term of its engagement, provides us with capital in any public or private offering or other financing or capital raising transaction during the six-month period following expiration or termination of our engagement with the representative.

Other Relationships

Ladenburg Thalmann & Co. Inc. has performed investment banking services for us in the past, for which it has received customary fees and expenses. The underwriters and their respective affiliates may, from time to time, engage in transactions with or perform services for us in the ordinary course of their business. Upon completion of this offering, we have granted the representative a right of first refusal to act as sole bookrunner or exclusive placement agent in connection with any subsequent public or private financing by us, subject to certain exceptions. This right of first refusal extends for twelve months from the closing date of this offering. The terms of any such engagement of the representative will be determined by separate agreement.

Common Stock Listing

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

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company LLC.

Stabilization, Short Positions and Penalty Bids

The underwriters may engage in syndicate covering transactions, stabilizing transactions, and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of our common stock;

- Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. Such a naked short position would be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect investors who purchase in the offering.
- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specific maximum and are engaged in for the purpose of preventing or retarding a decline in the market price of the shares of common stock while this offering is in progress.
- Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These syndicate covering transactions, stabilizing transactions, and penalty bids may have the effect of raising or maintaining the market prices of our securities or preventing or retarding a decline in the market prices

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of our securities. As a result the price of our common stock may be higher than the price that might otherwise exist in the open market. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on the Nasdaq Capital Market, in the over-the-counter market or on any other trading market and, if commenced, may be discontinued at any time.

In connection with this offering, the underwriters also may engage in passive market making transactions in our common stock in accordance with Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of the distribution. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for that security. However, if all independent bids are lowered below the passive market maker's bid that bid must then be lowered when specific purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

Neither we, nor the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the prices of our securities. In addition, neither we nor the underwriters make any representation that the underwriters will engage in these transactions or that any transactions, once commenced will not be discontinued without notice.

Electronic Offer, Sale and Distribution of Shares

This registration statement may be made available in electronic format on websites or through other online services maintained by the underwriters, or their affiliates. Other than this registration statement in electronic format, the information on any underwriter's websites and any information contained in any other websites maintained by such underwriter is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter, and should not be relied upon by investors.

Indemnification

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

LEGAL MATTERS

Honigman LLP, Kalamazoo, Michigan, will issue a legal opinion as to the validity of the securities offered by this prospectus. The representative of the underwriters is being represented by Ellenoff Grossman & Schole LLP, New York, New York.

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, 2021 and 2020 included in our Annual Report on Form 10-K for the year ended December 31, 2021, 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. You may read and copy our reports, proxy statements and other information filed by us at the public reference room of the SEC located at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information about the public reference rooms. 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, 2021, filed with the SEC on [March 3, 2022](#);
- our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2022, filed with the SEC on [May 12, 2022](#) and for the quarter ended June 30, 2022, filed with the SEC on [August 11, 2022](#);
- our Current Reports on Form 8-K filed with the SEC on [April 21, 2022](#), [May 18, 2022](#), [May 26, 2022](#), [June 3, 2022](#), [September 23, 2022](#), [October 3, 2022](#), and [October 5, 2022](#);
- the information specifically incorporated by reference into our Annual Report on Form 10-K for the year ended December 31, 2021 from our definitive proxy statement for the annual meeting of stockholders held on May 17, 2022, filed with the SEC on [April 11, 2022](#), and supplemented on [May 18, 2022](#) and by Form 8-K on [May 26, 2022](#) for the adjournment of the annual meeting of stockholders held on May 25, 2022;
- our definitive proxy statement for the annual meeting of stockholders held on May 17, 2022, filed with the SEC on [April 11, 2022](#), and supplemented on [May 18, 2022](#) and by form 8-K on [May 26, 2022](#) for the adjournment of the annual meeting of stockholders held on May 25, 2022;
- the description of our common stock in our registration statement on Form 10 filed with the SEC on [September 30, 2011](#), including any amendment or report filed for the purpose of updating such description; and
- the description of our Series A Junior Participating Preferred Stock, par value \$0.0001 per share, in our registration statement on Form 8-A filed with the SEC on [June 14, 2013](#).

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 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.nurwellis.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: Nestor Jaramillo, Jr.
President and Chief Executive Officer